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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
TRADEMARK TRIAL AND APPEAL BOARD

HERBACEUTICALS, INC., Petitioner, v. XEL HERBACEUTICALS, INC., Registrant.	Cancellation No. 92/045,172 **MEMORANDUM OPPOSING PETITIONER/COUNTER-REGISTRANT'S MOTION FOR SUMMARY JUDGMENT**
XEL HERBACEUTICALS, INC., Counter Petitioner, v. HERBACEUTICALS, INC., Counter Registrant,	

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MEMORANDUM OPPOSING PETITIONER/COUNTER-REGISTRANT'S MOTION FOR SUMMARY JUDGMENT

Petitioner/Counter-Registrant, Herbaceuticals, Inc. (hereinafter "Herbaceuticals"), filed a Motion for Summary Judgment on or about December 5, 2006 (hereinafter "SJ Motion"). Registrant/Counter-Petitioner, XEL Herbaceuticals, Inc. (hereinafter "XEL"), hereby urges this Board to deny Herbaceuticals' SJ Motion because Herbaceuticals' trademarks are invalid because they are generic, and because XEL did not commit fraud on the PTO in obtaining its trademark registrations.

STATEMENT OF DISPUTED FACTS

The following facts are in dispute in this case:

1. Herbaceuticals does not have standing to petition for cancellation of XEL's trademarks because Herbaceuticals' trademarks are invalid because they are generic.
2. Herbaceuticals does not have standing to petition for cancellation of XEL's trademarks because the products described in Herbaceuticals' trademarks are not related to the products described in XEL's trademarks.
3. The statements made by XEL in its Statements of Use are not false because the "Declaration" portion of the Statements of Use, which is the sworn portion of the statement, asserts that the trademark is used on "the goods/services" as opposed to "all goods and/or services." The separate language implies a separate meaning. Therefore, XEL only swore that the trademarks were being used on the goods, which was an accurate statement. *See*, Declaration of Peter M. de Jonge (hereinafter "de Jonge Declaration"), paragraphs 2-4.
4. XEL did not intend to obtain a trademark registration, or any trademark rights, to which it was not entitled. *See*, de Jonge Declaration, paragraph 5.

5. The Examining Attorney for the PTO had determined that XEL was entitled to a trademark registration that included the complete identification of goods for each respective application and XEL did not commit fraud in obtaining that approval. *See*, de Jonge Declaration, paragraph 6.

6. Any false statements in XEL's Statements of Use are not material to the registration of the trademarks with respect to the goods in use.

7. Herbaceuticals has delayed in asserting its trademark rights, and XEL prejudicially relied on Herbaceuticals' acquiescence in XEL's trademark use. Accordingly, Herbaceuticals is estopped from obtaining a cancellation of XEL's trademarks based on laches.

ARGUMENT

To prevail in its SJ Motion, Herbaceuticals must establish that there is no genuine issue as to any material fact, and that Herbaceuticals is entitled to judgment as a matter of law. *See, Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). A factual dispute is genuine if sufficient evidence is presented such that a reasonable fact finder could decide the question in favor of the non-moving party. *See, Opryland USA Inc. v. The Great American Music Show Inc.*, 23 USPQ2d 1471, 1472 (Fed.Cir. 1992) (requiring just sufficient evidence to show an evidentiary conflict as to the material fact). Furthermore, XEL must be given the benefit of all reasonable doubt as to whether genuine issues of material fact exist, and all inferences from the undisputed facts must be viewed in the light most favorable to XEL. *Id.*

Herbaceuticals has not met its burden of demonstrating an absence of any genuine issue of material fact, nor that it is entitled to judgment as a matter of law. *See, Copelands'*

Enterprises Inc. v. CNV Inc., 20 USPQ2d 1295, 1298-99 (Fed.Cir. 1991) (conclusory statements insufficient).

I. HERBACEUTICALS HAS NO STANDING TO PETITION CANCELLATION OF XEL'S TRADEMARKS BECAUSE HERBACEUTICALS' TRADEMARKS ARE GENERIC

To obtain cancellation of XEL's trademarks, Herbaceuticals must first demonstrate that it has standing to petition for cancellation. *See, Cunningham v. Laser Golf Corp.*, 222 F.3d 943, 945 (Fed.Cir. 2000). While there is a broad requirement that Herbaceuticals believe it would suffer some damage from XEL's trademarks, Herbaceuticals must also meet two judicially-created requirements: a real interest in the proceedings and a reasonable basis for its belief of damage. *See, Ritchie v. Simpson*, 170 F.3d 1092, 1095 (Fed.Cir. 1999).

As the basis for its assertion of standing, Herbaceuticals cites its trademark registrations, U.S. Registration Nos. 2,585,974 and 2,822,094. This makes the validity of Herbaceuticals' trademarks a material issue, because without valid trademarks, Herbaceuticals would not have standing to petition cancellation. A genuine issue as to the material fact of the validity of Herbaceuticals' trademarks, and therefore its standing, currently exists.

In Registrant/Counter Petitioner's Answer and Counter Petition to Cancel, filed with this Board on or about March 16, 2006, and incorporated by this reference, XEL has asserted that Herbaceuticals' trademarks are generic as an affirmative defense, and counterclaimed Herbaceuticals' trademarks are generic and should be canceled. XEL's counterclaim is made pursuant to 15 U.S.C. §1064; a party can petition to cancel a registration at any time if the subject mark "becomes the generic name of the goods or services."

Determining whether a mark is generic involves a two step inquiry: (1) identify the genus of the goods or services at issue; and (2) determine if the registered term is understood

by the relevant public to refer to that genus of goods or services. *See, H. Marvin Ginn Corp. v. International Association of Fire Chiefs, Inc.*, 782 F.2d 987 (Fed.Cir. 1986). Evidence of the relevant public's understanding of a term may come from a variety of sources, including without limitation, consumer surveys, magazines, dictionaries, and other publications. *See, In re Merrill, Lynch, Pierce, Fenner and Smith, Inc.*, 828 F.2d 1567 (Fed.Cir. 1987).

XEL has provided substantial evidence during discovery regarding the fact that the term "herbaceutical" is understood by the public to refer to a genus of products. *See*, de Jonge Declaration, Exhibit A. As an example of disputed facts regarding whether "herbaceutical" is generic, the documents Bates numbered XEL001609 and XEL001613 seems to indicate that a company called Phytopharm originally developed the term "herbaceuticals" to describe Phytopharm's approach of providing natural medicine products. *Id.* However, Herbaceuticals claims its President, Tricia Grose, created the name "herbaceuticals." *See*, de Jonge Declaration, Exhibit B, Response to Interrogatory No. 8.

Herbaceuticals' SJ Motion does not mention or address XEL's assertion or evidence that its trademarks are generic. Therefore, Herbaceuticals' trademarks must be inferred to be generic, and Herbaceuticals' SJ Motion denied.

II. XEL DID NOT COMMIT FRAUD IN OBTAINING ITS TRADEMARKS

To establish that XEL procured its trademarks by fraud, Herbaceuticals must establish that XEL knowingly made false, material representations of fact in connection with its applications. *See, Torres v. Cantine Torresella S.r.l.*, 808 F.2d 46, 47-48 (Fed.Cir. 1986). Herbaceuticals' allegation of fraud must be proven "to the hilt" by clear and convincing evidence. *See, Smith International, Inc. v. Olin Corporation*, 209 USPQ1033, 1043-44 (TTAB 1981).

XEL did not commit fraud because XEL did not make a false statement, did not have the requisite intent for fraud, and any statements if they be deemed false made by XEL were not material to the registration of its trademarks.

A. XEL DID NOT MAKE FALSE STATEMENTS

XEL's trademarks where initially filed as "intent-to-use" trademark applications, and XEL intended to use its trademarks on all those goods. The statements made by XEL in its Statements of Use are not false because the "Declaration" portion of the Statements of Use, which is the sworn portion of the statement, asserts that the trademark is used on "the goods/services" as opposed to "all goods and/or services." The separate language implies a separate meaning. The former was understood to mean within the scope of the goods so identified, but not necessarily each and every one of the goods identified. Therefore, XEL only swore that the trademarks were being used within the scope of those goods, which was an accurate statement. *See*, de Jonge Declaration, paragraphs 2-4.

XEL knew that it was entitled to certain trademark rights, but did not make any statement intending to obtain trademark rights, or a trademark registration, to which it was not entitled. *Id.*, at paragraph 5.

Even if this understanding of the language in the Statements of Use was mistaken, it is not fraud because the declarant believed "on information and belief" that XEL was using its trademark on all the goods identified. The "Declaration" portion of the Statements of Use contains the language "on information and belief," allowing that certain statements can be made "on information and belief" and do not require actual knowledge. Simply put, declarant did not have actual knowledge that the mark was not used on each and every one of the goods identified. As the attorney of record for XEL, the Declaration was signed on information and

belief that the mark was used on each and every one of the goods identified. *Id.*, at paragraphs 7-9.

B. XEL DID NOT INTEND TO OBTAIN REGISTRATION OF A TRADEMARK TO WHICH IT WAS NOT ENTITLED

Generally, the factual question of intent is particularly unsuited to disposition in motions for summary judgment. *See, Copelands'*, 20 USPQ2d at 1298-99. One court determined that facts analogous to those in this case did not warrant a finding of fraudulent intent. "The undisputed evidence thus shows that [Registrant's] statement of use contained statements known to be false by the President of [Registrant], who attested to its truth. Even with this determination, however, this Court cannot conclude that [the President] did so with the necessary fraudulent intent, that he made a 'conscious effort to obtain for his business a registration to which he knew it was not entitled.'" *Horizon Healthcare Servs. v. Allied Nat'l, Inc.*, 2006 U.S. Dist. LEXIS 5440, *26 (D.N.J. Feb. 10, 2006), *citing, Metro Traffic Control v. Shadow Network*, 104 F.3d 336, 340 (Fed.Cir. 1997).

It has already been noted that an allegation of fraud must be proven "to the hilt" by clear and convincing evidence. *See, Smith International*, 209 USPQ at 1043-44. "In contrast, a defendant's intent is not an element of a claim that a mark was not used on certain of the identified goods or services, nor is an enhanced standard of proof required." *See, Grand Canyon West Ranch, LLC v. Hualapai Tribe*, 2006 TTAB LEXIS 82, *3-4, 78 USPQ2d 1696 (TTAB Mar. 17, 2006) (holding "that as long as the mark was used on some of the identified goods or services as of the filing of the application, the application is not void in its entirety").

The Examining Attorney for the PTO had determined that XEL was entitled to a trademark registration that included the complete identification of goods for each respective

application. The fact that XEL obtained and consolidated this approval does not demonstrate the requisite intent to commit fraud.

C. ANY FALSE STATEMENTS IN XEL'S STATEMENTS OF USE ARE NOT MATERIAL TO REGISTRATION OF THE TRADEMARK WITH RESPECT TO THE OTHER GOODS IN USE

A statement in an application or representation to the PTO may be "false" without being "fraudulent." *See, Morehouse Mfg. Corp. v. J. Strickland & Co.*, 407 F.2d 881 (CCPA 1969). In the context of trademark law, the correct standard for materiality is that a material misrepresentation arises only if the registration should not have issued if the truth were known to the examiner. *Pennwalt Corp. v. Sentry Chemical Co.*, 219 USPQ 542 (TTAB 1983) (finding full disclosure would not have resulted in a proper refusal of registration by the Trademark Examiner). Even if a statement made by XEL in its trademark applications was deemed to be false, fraud would not be established because it would not be a material misrepresentation.

Numerous cases exist where an overly broad description of goods, or non-use on some, but not all, of the identified goods and/or services resulted in amendment of the identified goods, or a partial cancellation of the subject trademark with respect to those goods not used. *See, e.g., Rogers Corp. v. Fields Plastics & Chemicals, Inc.*, 176 USPQ 280 (TTAB 1972), *aff'd*, 181 USPQ 169 (CCPA 1974) (finding that the applicant had not committed fraud even though the identification of goods included some proposed, rather than actual, uses of the mark); *see also, Edison Bros. Stores, Inc. v. Cosmair, Inc.*, 2 USPQ2d 1013 (SDNY 1987) (finding claim of use of mark on a variety of clothing items, where use was in fact only on pants, was not fraud justifying cancellation; the erroneous statement was made honestly and was not material to the registration); *see also, Alcan Aluminum Corp. v. Alcar Metals, Inc.*,

200 USPQ 742 (TTAB 1978) (finding no fraud from over-inclusive list of goods); *see also, Space Base, Inc. v. Stadis Corp.*, 17 USPQ2d 1216 (TTAB 1990) (suggesting that fraud claim could be restated as claim for partial cancellation to limit and narrow overly broad identification of services in the registration). Accordingly, XEL's non-use of its trademarks on certain identified goods should not amount to fraud, nor result in cancellation of the entire trademark.

The Board in *Grand Canyon West* states it is not appropriate to treat an applicant's non-use of its mark on some of the identified goods or services in the same manner as an applicant's complete failure to make use of its mark on any of its identified goods or services, noting that "the Board has made a distinction in the remedies for fraud and for nonuse on some, but not all, of the identified goods and/or services." *See, Grand Canyon West Ranch*, 2006 TTAB LEXIS 82, *4-6, *citing, Rogers Corp., supra.* This same case also notes that in *Medinol Ltd. v. Neuro Vasx Inc.*, 67 USPQ2d 1205 (TTAB 2003) the Board found fraud, but also stated if the finding of fraud were overturned, the registration would have to be amended to delete the goods for which the mark was not used, "thus indicating that, in the absence of fraud, the registration would survive." *See, Grand Canyon West Ranch*, 2006 TTAB LEXIS 82, *4-5.

In the present case, the alleged false statement relates to a non-use of some of the identified goods. Whether this false statement was made or not, XEL was still entitled to a registration. Since XEL was still entitled to a registration, the false statement cannot be material to the registration and no fraud can exist.

D. THE PROPER REMEDY IS NOT CANCELLATION, BUT AMENDMENT OR PARTIAL CANCELLATION

The proper remedy in this case is not cancellation of XEL's trademarks in their entirety. The proper remedy would be amendment of the description of goods in XEL's trademarks, or similarly partial cancellation to remove those goods on which XEL's trademark is not used. The Board is especially equipped to accomplish this end.

In *Grand Canyon West*, the Board holds "that as long as the mark was used on some of the identified goods or services as of the filing of the application, the application is not void in its entirety." *See, Grand Canyon West Ranch*, 2006 TTAB LEXIS 82, *3. The reasons discussed in *Grand Canyon West* that provide the basis for this holding include: the distinction in remedies for fraud as compared to non-use, where fraud is characterized by no use of the subject mark on any of the goods or services, as compared to non-use characterized by use of the subject mark on some, but not all of the goods or services; and the recognition of the policy justification for amending the goods provided in part by the Trademark Law Treaty Implementation Act of 1998, Pub.L.No. 105-330, 112 Stat. 3064. *Id.*, at *4-7. Specifically, *Grand Canyon West* notes that the policy justification provides support for its position that "an application should not be treated as void as long as the mark was used on some of the identified goods or services." *Id.*, at *7.

The Board is in a favorable position to amend or modify descriptions of goods based on market realities. The Board can make appropriate modifications, or not, accounting for the balance sought between the strict requirement that a mark be used on "all goods and/or services," and the market reality that descriptions of goods run from vague and broad to more narrow, and are also intended to apply to related goods. *See, e.g., Procter & Gamble v. Economics Laboratory, Inc.*, 175 USPQ 505 (TTAB 1972), *modified, without op.*, 181 USPQ

722 (CCPA 1974) (finding no fraud where registration for a mark identified products as "sudsing cleanser, cleanser and detergent," and the mark was only used on a detergent).

In the case currently before the Board, it does not seem equitable that Herbaceuticals can assert a claim of fraud when its own registrations include a description of goods as vague and overly broad as "distributorship" of "wellness products." Herbaceuticals' trademark Reg. No. 2,822,094 describes: "retail and wholesale distributorship services in the field of homeopathic preparations, cosmetics, dietary supplements and wellness products." *See*, Rubinstein Dec., Exhibit 17.

Based on the standard for determining fraud asserted by Herbaceuticals, XEL could allege that Herbaceuticals obtained its trademark Reg. No. 2,822,094 by fraud. Certainly Herbaceuticals is not using its trademarks on "all goods and/or services" related to "wellness products."[1] Therefore, it is just as reasonable for XEL to argue that Herbaceuticals has committed fraud by making a knowingly false, material statement of fact with regards to its trademark application.

Application of the standard for determining fraud asserted by Herbaceuticals would open the floodgates of litigation for claims of fraud in trademark cases. Claims of fraud in trademark cases would become as prevalent as claims of inequitable conduct in patent cases. *See, e.g., Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed.Cir. 1988) (stating that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague").

[1] The Board has addressed a similar issue with respect to the description of goods, "computer programs." This description was determined to be so broad as to be devoid of any information regarding what computer programs were actually marketed. *See, In re SunGuard Development Corporation*, 1999 TTAB LEXIS 735, *9-10 (TTAB June 9, 1999).

E. CASE LAW CITED BY HERBACEUTICALS IS LEGALLY AND FACTUALLY DISTINGUISHABLE

Herbaceuticals relies heavily on *Medinol Ltd. v. Neuro Vasx Inc., supra*, for the proposition that XEL committed fraud in procuring its trademarks and that that fraud should result in cancellation of each trademark in its entirety.[2] It has already been established that the Board in *Grand Canyon West* has moved away from treating fraud, described as no use of a mark with respect to identified goods, in the same manner as non-use, described as use of a mark on some, but not all of the identified goods. *See, Grand Canyon West Ranch*, 2006 TTAB LEXIS 82, *4-6, and similar cases, *supra*.

Medinol is also factually distinguishable from the present cancellation. Respondent in *Medinol* did not support any claims with affidavits or other evidence. See, *Medinol*, 67 USPQ2d at fn10. XEL has provided evidence supporting XEL's assertion that Herbaceuticals' trademarks are generic, as well as evidence that statements made by XEL in its trademark applications were not false.

III. HERBACEUTICALS IS ESTOPPED FROM OBTAINING CANCELLATION OF XEL'S TRADEMARKS BASED ON LACHES

When used as a defense to cancellation, laches must be based on a product of Herbaceuticals' delay and the resulting prejudice to XEL. The Federal Circuit has established that mere delay in asserting trademark related rights does not necessarily result in the changed conditions that support a finding of laches. There must also be some detriment due to the delay. *See, Bridgestone/Firestone Research, Inc. v. Automobile Club De L'Ouest De La France*, 245 F.3d 1359 (Fed.Cir. 2001). A five-year delay coupled with prejudicial reliance has been found to constitute laches. *See, Turner v. Hops Grill & Bar, Inc.*, 52 USPQ2d 1310

[2] Herbaceuticals also relies on *J.E.M. International, Inc. v. Happy Rompers Creations Corp.*, 2005 WL 548069, Cancellation No. 92043073 (TTAB Feb. 10, 2005), however, the disposition in this cancellation is not citable as precedent of the TTAB.

(TTAB 1999) (finding prejudicial reliance based on a substantial expansion of restaurant outlets over the five-year period).

Herbaceuticals first contacted XEL regarding XEL's use of its trademarks on or about December 18, 2000. *See*, de Jonge Declaration, Exhibit C. Herbaceuticals filed its Petition for Cancellation on or about November 8, 2005. While Herbaceuticals did contact XEL sporadically between the initial contact and filing its Petition for Cancellation, the prejudicial reliance is established by the acquiescence of Herbaceuticals to XEL's trademarks being published for opposition and registered without Herbaceuticals objection, and by the growth in XEL business, and product line, during the delay period.

For example, XEL trademark Reg. No. 2,948,359 was published for opposition on April 23, 2002, and did not register until May 10, 2005. *See*, Rubinstein Dec., Exhibit 1. Similarly, XEL trademark Reg. No. 2,948,354 was published for opposition on January 1, 2002, and did not register until May 10, 2005. *See*, Rubinstein Dec., Exhibit 2. Herbaceuticals did not file any opposition proceedings. Similar acquiescence is demonstrated by Herbaceuticals with regards to XEL trademark Reg. Nos. 2,860,543 and 2,845,260 and 2,970,979 and 2,970,981. *See*, Rubinstein Dec., Exhibits 6, 7, 10 and 11, respectively, showing analogous dates for publication of opposition and registration, which Herbaceuticals did not oppose.

Moreover, XEL was continuing to expand its product line and grow its business while Herbaceuticals was essentially silent. The prejudice to XEL would have been greatly diminished if Herbaceuticals would have asserted its trademark rights earlier. The period of delay, coupled with the detriment to XEL based on Herbaceuticals' acquiescence, constitutes laches and precludes Herbaceuticals from canceling XEL's trademarks.

CONCLUSION

Herbaceuticals' SJ Motion should be denied because Herbaceuticals has failed to establish standing to petition cancellation of XEL's trademarks, and because Herbaceuticals has failed to establish any of the necessary elements of its fraud claim.

DATED this 19th day of January, 2007.

Respectfully submitted,

Peter M. de Jonge
Gordon K. Hill
Attorneys for Registrant/ Counter Petitioner

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing Memorandum Opposing Petitioner/Counter-Registrant's Motion for Summary Judgment was served upon the Petitioner/Counter-Registrant at the following by the methods indicated below:

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Attorneys for XEL Herbaceuticals, Inc.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
TRADEMARK TRIAL AND APPEAL BOARD

HERBACEUTICALS, INC., Petitioner, v. XEL HERBACEUTICALS, INC., Registrant.	Cancellation No. 92/045,172 **DECLARATION OF PETER M. DE JONGE**
XEL HERBACEUTICALS, INC., Counter Petitioner, v. HERBACEUTICALS, INC., Counter Registrant,	

DECLARATION OF PETER M. DE JONGE
PURSUANT TO 37 C.F.R. §2.20

I, Peter M. de Jonge, declare:

1. I am a partner associated with the firm of Thorpe North & Western, representing Registrant/Counter-Petitioner, XEL Herbaceuticals, Inc. (hereinafter "XEL") in connection with Cancellation No. 92,045,172. I have personal knowledge of the material facts stated herein and I make and submit this Declaration in support of XEL's Memorandum Opposing Petitioner/Counter-Registrant's Motion for Summary Judgment.

2. XEL's trademarks where initially filed as "intent-to-use" trademark applications, and XEL intended to use its trademarks on all those goods.

3. The statements made by XEL in its Statements of Use are not false because the "Declaration" portion of the Statements of Use, which is the sworn portion of the statement, asserts that the trademark is used on "the goods/services" as opposed to "all goods and/or services."

4. The separate language implies a separate meaning. The former was understood to mean within the scope of the goods so identified, but not necessarily each and every one of the goods identified. Therefore, XEL only swore that the trademarks were being used within the scope of those goods, which was an accurate statement.

5. XEL knew that it was entitled to certain trademark rights, but did not make any statement intending to obtain trademark rights, or a trademark registration, to which it was not entitled.

6. The Examining Attorney for the PTO had determined that XEL was entitled to a trademark registration that included the complete identification of goods for each respective application and XEL did not commit fraud in obtaining that approval.

7. Even if my understanding of the language in the Declaration was mistaken, it is not fraud because I believed "on information and belief" that XEL was using its trademark on all the goods identified.

8. The "Declaration" portion of the Statements of Use contains the language "on information and belief," allowing that certain statements can be made "on information and belief" and do not require my actual knowledge.

9. Simply put, I did not have actual knowledge that the mark was not used on each and every one of the goods identified. As the attorney of record for XEL, the Declaration was signed on information and belief that the mark was used on each and every one of the goods identified.

10. Attached hereto as Exhibit A is a true and correct copy of documents produced by XEL to Petitioner/Counter-Registrant, Herbaceuticals, Inc. (hereinafter "Herbaceuticals") in response to at least one request for production from Herbaceuticals.

11. Attached hereto as Exhibit B is a true and correct copy of Petitioner/Counter Registrant's Response to Registrant/Counter Petitioner's Revised First Set of Interrogatories received by XEL on or about July 21, 2006 from Herbaceuticals.

12. Attached hereto as Exhibit C is a true and correct copy of a document received by XEL from Herbaceuticals in response to at least one request for production from XEL.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

DATED this 19th day of January, 2007.

Signed,

Peter M. de Jonge

THORPE NORTH & WESTERN, LLP

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing Declaration of Peter M. de Jonge was served upon the Petitioner/Counter Registrant at the following by the methods indicated below:

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__X__ United States Mail
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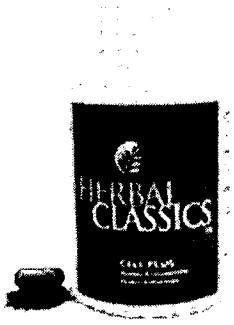

Herbal Classics Inc.

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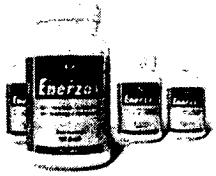
XEL 000453

Herbaceuticals: an overview for counselors.(Practice & Theory)

Journal of Counseling and Development; 9/22/2005; Ingersoll, R. Elliott

Magazines

While more information on psychotropic medications is becoming available to counselors (Ingersoll, 2000; Ingersoll, Bauer, & Bums, in press), there is little published information on herbaceuticals. In this article, I use the word" herbaceuticals" because it is more accurate than "herbal medicines" or "herbal drugs?' The compounds discussed in this article, under U.S. federal law, cannot be advertised as medicines or drugs, so it would be confusing to refer to them as such. It must be noted, however, that many herbaceutical compounds contain pharmacologically active elements as ...



OUR SERVICE

From the desk of Elizabeth Halen™

We sincerely thank you for visiting our company's website.

Elizabeth Halen Cosmetics and Laboratories are the names behind many prestigious brands of skin & body cares as well as prescription dermatological formulations in the market. You may choose among our successful Stock Formulas or we can make Custom Formulas to suit your specifications.
If we do not have a stock product that will satisfy your needs, we are fully equipped to develop a custom formula to meet your requirements. A custom product is suitable for those customers who require a private label product to certain specifications and wish to make an exclusive product. Let our experienced team help you develop winning, profitable products under your own label.

Most of our Herbaceutical and Cosmeceutical products are **FDA** or **CTFA** proven in ingredients and moneymaking products, which, we stongly believe, can bring your company excellent profits and credibility with your clients. Strict Quality Control is taken throughout the production process to assure extreme cleanliness, product purity and efficacy.

We sell to customers everywhere by way of direct retail and wholesale sales to dealers. We welcome inquiries from interested brokers, retailers, wholesalers and independent sales representatives.

The market in 2003 for Herbaceutical and Cosmeceutical is estimated to be huge. Call us today and let us help you design your custom formulations and business to best suit your needs.

Sincerely,

Halen Bach, *C.E.O.*
Elizabeth Halen Corp.

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XEL 000457

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XEL 000458

Avon mavens: real girlfriends tell us how they look fabulous with Avon! Redbook readers were the first to try Anew Alternative, Avon's herbaceutical breakthrough in skincare. Learn about the difference it made for them.(Brief Article)

REDBOOK Redbook; 11/1/2005

"Lori and I noticed that Anew Alternative made our skin feel softer, tighter and helped reduce fine lines around the eyes and mouth. Anew Alternative also has a refreshing feeling. We could tell a difference by the end of the first week.

Lori said it made me look years younger (which I love!) and I think it reduced Lori's laugh lines and gave her skin a youthful glow (which she loved)! We would recommend Anew Alternative to others and will continue using it ourselves."

--Cathy Thornton

"I liked using Anew Alternative prior to going to bed because it hydrated my skin ...

598 of 1392 Characters

Source: Advanced Communications Technologies, Inc.

Advanced Communications and Pacific Magtron International Jointly Announce Court Approval of Pacific Magtron International's Reorganization Disclosure Statement and Confirmation of Pacific Magtron, Inc.'s and Pacific Magtron (GA), Inc.'s Plans Of Liquidation

Pacific Magtron International Plan of Reorganization Includes Merger with Operating Bio-Herbaceutical Company and Distribution of New Shares to all PMIC and Advanced Communications Share Holders

NEW YORK, Jan. 31, 2006 (PRIMEZONE) -- Advanced Communications Technologies, Inc. (OTCBB:ADVC), a New York-based holding company that specializes in the technology after-market service and supply chain known as reverse logistics, and its majority owned subsidiary Pacific Magtron International Corporation, Inc. (OTCBB:PMICQ), jointly announced today that at a January 24, 2006 bankruptcy court hearing, Pacific Magtron International Corporation, Inc.'s (PMIC) Disclosure Statement to accompany it's Plan of Reorganization filed with the U.S. Bankruptcy Court in the southern district of Nevada has been approved. At the same hearing, the court confirmed Pacific Magtron, Inc.'s (PMI) and Pacific Magtron (GA), Inc.'s (PMIGA), wholly-owned subsidiaries of PMIC, Plans of Liquidation.

PMI and PMIGA Plans of Liquidation

The PMI and PMIGA Plans of Liquidation which were overwhelmingly approved by a majority of each company's creditors, provides for the complete liquidation of PMIC's former operating entities, the sale of PMI's building in Milpitas, California, an estimated payout of approximately 50 percent before preference payment recoveries, if any, to each PMI creditor holding a valid claim and the establishment of a Creditor Trust to prosecute preference litigation against certain creditors for the recovery of payments received from PMI within the 90 day period prior to the commencement of the bankruptcy case. It is estimated that creditors of PMIGA that hold allowed claims will receive a dividend on their claims of approximately 20-25 percent before the collection of any preference recoveries. A separate Creditor Trust will also be established for the PMIGA creditors for the purpose of prosecuting preference litigation. Under the Plans of Liquidation, Tim S. Cory has been appointed Trustee for both the PMI and PMIGA Creditors Trust.

The PMI building sale was completed in November and netted

Recent Quote for **ADVC**	
Last Trade:	**$ 0.0041**
Trade Time:	11:58 ET
Change:	+0.0004 (+10.81%)
Prev Close:	+0.0004
52-Wk Range:	0.0003 - 0.0090

Other News Releases from Advanced Communications Technologies, Inc.

Advanced Communications Remains Focused on Business Expansion Path - Jan 27, 2006

Advanced Communications' Subsidiary Cyber-Test Expands Tech Space by Over 1,500 Square Feet - Nov 16, 2005

Demand for High-Tech Product Repairs Increases Service Offering for Advanced Communications' Subsidiary Cyber-Test - Nov 8, 2005

Delay in Form 10-KSB Filing for Advanced Communications - Oct 20, 2004

Advanced Communications Technologies, Inc. Reports Fiscal 2004 Financial Results - Sep 8, 2004

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approximately $1.6 million after payment of closing costs and the first and second mortgages to Wells Fargo Bank and the SBA, respectively.

Related Industry:
Biotech News

Under the PMI and PMIGA Plans of Liquidation, Advanced Communications has been irrevocably appointed the estate representative to prosecute any and all causes of action that may be brought by the bankruptcy estates or PMIC against former officers Ted Li and Cynthia Lee, the former board of directors and any other party or parties acting in concert with the above. In this regard, Advanced Communications shall, as estate representative prosecute such claims and claim objections for the benefit of the estates of PMI and PMIGA or the PMI or PMIGA Creditor Trusts, and PMI and PMIGA shall retain the right to receive an allocated portion of the proceeds of any such litigation to the extent that there is an affirmative recovery.

The effective date of the PMI and PMIGA Plans of Liquidation will be February 10, 2006 at which time an initial cash distribution will be made to creditors.

PMIC Plan of Reorganization

The court's approval of PMIC's Disclosure Statement paves the way for PMIC to distribute the proposed Plan of Reorganization and Disclosure Statement to all creditors and shareholders for voting purposes. PMIC's proposed Plan of Reorganization provides for an estimated payout of approximately 50 percent to creditors holding valid claims and the merger of Herborium, Inc. into PMIC. The Livewarehouse (LW), a wholly-owned subsidiary of PMIC, plan provides for up to a 100 percent payment to those creditors of LW holding valid claims. Herborium, a privately-held New Jersey-based bio-herbaceutical company, distributes proprietary natural and complimentary healthcare solutions to consumers and healthcare professionals seeking alternative answers to disease treatment, management and prevention. Its products address healthcare problems that are not met satisfactorily by conventional ethical pharmaceuticals. Herborium's reported revenue for fiscal 2005 was in excess of $800,000. After the merger, PMIC is expected to change its name to Herborium.

For more information on Herborium, visit www.herborium.com.

The proposed Plan of Reorganization also provides for the cancellation of all the previously outstanding common and preferred shares of PMIC and the distribution of unrestricted newly issued PMIC/Herborium stock to former PMIC shareholders of record other than Advanced Communications on a one for one basis. Advanced Communications' 62 percent majority interest in PMIC will be cancelled and newly issued unrestricted shares of Herborium will be issued to all shareholders of Advanced Communications directly as a special dividend. In connection with the merger, the former shareholders of Herborium would receive newly issued shares of PMIC/Herborium common stock representing 85 percent of the outstanding common stock. The shares owned by PMIC's current common shareholders, other than Advanced Communications, would represent 3.71 percent of the post merger shares, Advanced Communications' shareholders would hold 10.55 percent, and common shares representing less than 1 percent of the outstanding stock would be issued to former PMIC preferred shareholders.

The Plan of Reorganization Disclosure Statement and voting ballots was mailed to all creditors of PMIC and LW and all PMIC shareholders on January 30, 2006. The court has set March 3, 2006 as the date for the plan confirmation hearing. All ballots need to be submitted to PMIC's bankruptcy counsel on or before 5:00 p.m. PST, February 24, 2006.

The cash to fund the PMIC proposed Plan of Reorganization will be from:

XEL 000463

i) estimated proceeds from LW's allowed claim against PMI, estimated to be in the amount of $180,000; (ii) an IRS tax refund in the amount of approximately $74,000; (iii) existing cash and allocable share of proceeds, if any, from the Theodore Li and Cynthia Lee litigation and iv) a contribution of up to $50,000 of new value from Advanced Communications.

The merger of Herborium into PMIC is subject to confirmation of the Plan by PMIC's creditors and shareholders, execution of a merger agreement and the closing of financing.

Martin Nielson, chairman and CEO of Pacific Magtron International Corporation stated, "These reorganization plans provide significant relief for creditors and an opportunity for PMIC and Advanced Communications' shareholders to retain and gain additional value." Nielson continued, "I am confident that we have taken a sensible step towards securing the approval from creditors and shareholders."

Wayne Danson, president and CEO of Advanced Communications said, "We have been working very closely with PMIC's management and our legal counsel in designing a reasonable strategy for all parties and are confident that once the plan is confirmed, we will have repositioned our investment into a value-added opportunity for our shareholders through the distribution of the Herborium shares."

Advanced Communications will also be appointed the estate's representative to prosecute any and all causes of action that may be brought by PMIC against former officers Ted Li and Cynthia Lee, the former board of directors and any other party or parties acting in concert with the above.

Details of PMIC's and LW's Plan of Reorganization Disclosure Statement may be accessed as public records among the court filings of the United States Bankruptcy Court in the southern district of Nevada and through the SEC's website (www.sec.gov).

About Advanced Communications Technologies, Inc.

Advanced Communications Technologies is a New York-based public holding company specializing in the technology after-market service and supply chain, known as reverse logistics. Its wholly owned subsidiary and principal operating unit, Encompass Group Affiliates, Inc. acquires and operates businesses that provide computer and electronics repair and end-of-lifecycle services. Encompass owns Cyber-Test, Inc., an electronic equipment repair company based in Florida that provides board-level repair of technical products to third-party warranty companies, OEMs, national retailers and national office equipment dealers. Service options include advance exchange, depot repair, call center support, parts and warranty management for office equipment, fax machines, printers, scanners, laptop computers, monitors and multi-function units, including high-end consumer electronics such as PDAs and digital cameras. For more information, visit http://www.advancedcomtech.net.

This release and oral statements made from time to time by the company's representatives concerning the same subject matter may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements can be identified by introductory words such as "expects," "plans," "intends," "should," "believes," "will," "estimates," "forecasts," "projects" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Many factors may cause actual results to differ from forward-looking statements, including inaccurate assumptions and a broad variety of risks and uncertainties, some of which are known and

others of which are not. Known risks and uncertainties include those identified from time to time in the reports filed by the company with the Securities and Exchange Commission, which should be considered together with any forward-looking statement. No forward-looking statement is a guarantee of future results or events, and one should avoid placing undue reliance on such statements.

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(646) 227-1600

Keywords: ELECTRONICS, MERGERS

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Welcome to our Acne Guide Center

Here our Herbaceutical experts share with you the latest information on Herbal Medicinal Solutions and provide helpful advise on how to improve and mange different types of Acne and Rosacea skin related problems. Thanks to our resident Herbalist we also provide you with many helpful recipes for "do it at home" masks, cleansers, and skin treatments to make your skin the best it can be.

Peruse the articles below to find out more. If you need a specialized advise e-mail us at : Herbaceuticals@Herborium.com

Alice Lyon
Certified Medical Herbalist
Diplomat Phytotherapy
MNIMH, MRCHM
About Alice

Ask Alice
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Special Skin Care Tips

"Easy Home made herbal fixes for oily and dry skin"
"Winter & Acne and Rosacea"

Skin Care and Diet

"You Are What You Eat: Diet, Acne and Rosacea"
"At Last - Fat that Your and Your Skin Can Love"
"Before You Indulge at the Holiday Table"

Controlling Different Acne and Rosacea Problems

"Traditional Chinese Medicine and Acne and Rosacea"
"How to Control Rosacea"
"The Main Cause of Body Acne "
"Prevent Acne Scars"

Skin Care and Stress (psychological and environmental)

"Your Skin & Stress"

Men and Acne

"Men's Skin Care and Acne Treatment"

Spring and Summer Skin Care and Acne Management

"Healing Spring Herbs And Foods For Acne Skin Care"
"Special Summer Skin Tip : Skin Juice Tonics"
"Skin Rejuvenation Program"
"Managing Acne in the Summer
- Vegetable and fruit masks for your skin"

XEL 000466

Apptec PharmaChem Inc

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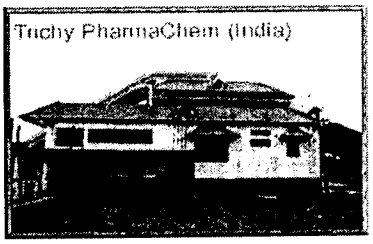
Apptec PharmaChem Inc. is an FDA registered small business located in Cranbury, New Jersey. It is a technology driven Company with a mission to develop, manufacture and sell safe and efficacious Pharmaceutical, Herbaceutical, Cosmeceutical, and Chemical Products and Intermediates.

The founder, Mr. Anil Torgalkar, has over 30 years of work experience in Consumer Products and Medical Products Companies including Johnson and Johnson, Convatec, Bristol Meyers Squibb and Becton Dickinson.

Business areas of focus include:

- Alternative Treatment for Psoriasis
- Natural Extracts for use in PetCare and HealthCare Industry
- Anti-Diabetic Products
- Products for Alcohol De-Addiction
- Eczema Products
- Chemical Product Intermediates.
- Medicinal Product Intermediates.



Apptec PharmaChem Inc. is a member of a group of eight companies with manufacturing and marketing operations in USA and India.

XEL 000468

Clinical Resolution Laboratory
welcome >to new innovations

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INTRODUCTION
Welcome
About Clinical Resolution
Our Business
Private Label
Formulation
Manufacturing
New Innovations
Glossary of Ingredients
MAIN DEVELOPMENTS
Microneedle Therapy
MTS Treatments
Peptide Development
Anti-Aging Solutions
MAJOR BRANDS
COSMECEUTICAL
DermaCept
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From the Desk of President

Dear Friends,

Clinical Resolution Laboratory is the name behind many prestigious brands of skin & body cares as well as prescription dermatological formulations in the market. You may choose among our successful stock formulas or we can make custom formulas to suit your specificat ions.

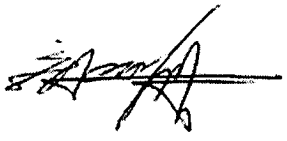
If we do not have a stock product that will satisfy your needs, we are fully equipped to develop a custom formula to meet your requirements. A custom product is suitable for those customers who require a private label product to certain specifications and wish to make an exclusive product. Let our experienced team help you develop winning, profitable products under your own label.

Most of our Herbaceutical and Cosmeceutical products are FDA or CTFA proven in ingredients and moneymaking products, which, we stongly believe, can bring your company excellent profits and credibility with your clients. Strict Quality Control is taken throughout the production process to assure extreme cleanliness, product pu rity and efficacy.

We sell to customers everywhere by way of private label and wholesale to dealers.
We welcome inquiries from interested companies, wholesalers and independent sales representatives.

Call us today and let us help you design your custom formulations and business to best suit your needs.

Sincerely,



Halen Bach, C.E.O.
Clinical Resolution Lab.

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See larger image

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Avon ANEW ALTERNATIVE Intensive Age Treatment

Other products by Avon

(13 customer reviews)

More about this product

Price: $32.00

Availability: Usually ships in 1-2 business days. Ships from and sold by AVON.

Special Offer: Get free shipping from Avon on Avon ANEW CLINICAL Eye Lift during the month of March.

Quantity: 1

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Avon ANEW CLINICAL Line and Wrinkle Corrector 1.7 fl. oz.

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Avon ANEW ALTERNATIVE Intensive Age Treatment SPF 25 Day

Avon ANEW CLINICAL 2-Step Facial Peel

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Product Features

- A Radical New Fusion in Anti-Aging

Product Description

Product Description

Undo damage. Turn back time. Let the healing age begin. ANEW combines Eastern plant therapies with advanced Western technology to create a breakthrough in herbaceutical science. This powerful fusion stimulates the skin's reparative healing ability to fight and even undo the signs of aging. Lines and wrinkles visibly diminish. Youthful contours are restored. Firmness and elasticity are renewed. Dark spots fade away. 1.7 fl. oz. HOW TO USE Use nightly after cleansing and before moisturizing. OVERNIGHT Diminishes the appearance of fine lines and wrinkles. AFTER 2 WEEKS - 80%* of women saw their natural facial contours restored. - 91%* of women saw more-resilient skin. WITH CONTINUED USE - 76%* of women saw the overall symmetry of their face restored. - 90%* of women saw skin that looked and felt firmer. - 100%^ of women showed more-even skin tone. FEATURES Eastern healing herbs and our exclusive pharmaceutical-inspired Glycation-Reversing Technology unite to create a powerful fusion that's formulated to stimulate the skin's natural restorative processes....

XEL 000460

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ASIN: B000BCXY32

Average Customer Review: ☆☆☆☆☆ based on 13 reviews. (Write a review.)

Amazon.com Sales Rank: #790 in Beauty (See Top Sellers in Beauty)
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Customers who bought this also bought

Avon ANEW CLINICAL Deep Crease Concentrate with Bo-Hylurox™

Avon ANEW Perfect Eye Care Cream SPF 15

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Avon ANEW ULTIMATE Transforming Lift Eye Cream

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Last tag: young

young (1)

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8 of 13 people found the following review helpful:

☆☆☆☆☆ **Good, but Not Comprehensively Effective**, November 4, 2005
Reviewer: **J. Reynolds** (Houston, TX United States) - See all my reviews
TOP 1000 REVIEWER

This compound works well on smooth surfaces, such as one's upper cheekbones, but it fails completely for areas such as elbows that have permanent wrinkles. This is a long-term treatment -- it's not a quick fix like Preparation H, which can remove (via shrinking the tissues) eye wrinkles quickly but just for a short time. Anew Alternative requires a full commitment for the long haul, if you are to achieve the results you want.

Was this review helpful to you? Yes No (Report this)

3 of 3 people found the following review helpful:

☆☆☆☆☆ **Some Skin Irritation but no more wrinkles**, March 3, 2006

XEL 000470

Reviewer: **Zana E. Holley** (Gainesville, FL United States) - See all my reviews
REAL NAME™

It did irriate my skin at first, but I have sensitive skin, so everything does. I ignored it and kept using it anyway. Now my skin has quit reacting to it, and all of my crow's feet, laugh lines, and other wrinkles are gone. I use it once a day. When my skin was getting burned, then I would just skip a day or two between applications.

Was this review helpful to you? Yes No (Report this)

Customer Reviews

Average Customer Review: ☆☆☆☆☆
Write an online review and share your thoughts with other customers.

1 of 1 people found the following review helpful:

☆☆☆☆☆ **New Tecnology works great!**, March 13, 2006
Reviewer: **C. Farley "seafaire"** (Bakersfield, CA USA) - See all my reviews
REAL NAME™

As a 50+ gal w/very sensitive skin I'm always on the lookout for products using new technology that really work. This product does a great job making skin brighter and glowing.
Use a little, warm it up on your fingertips and apply. Because the new technology breaks down some of the cellular debris, make sure you wash your face w/water afterwards and don't let your skin go out w/some coverage. Enjoy your blooming skin this spring.

Was this review helpful to you? Yes No (Report this)

3 of 3 people found the following review helpful:

☆☆☆☆☆ **LOVE IT!**, March 2, 2006
Reviewer: **Elizabeth** (New York, NY) - See all my reviews
I've had painful cystic acne for 20 years and this is THE FIRST cream that I've used that doesn't cause me to break out further.(I've tried the expensive department store brands, the cheapo drug store brands and the very expensive creams from my dermatologist.) My skin loves it. It even reduced the irritation and peeling caused by the Retin-A Gel that I have to use. It smells nice, it's a great moisturizer, my skin looks great and I am one happy woman!!!

Was this review helpful to you? Yes No (Report this)

1 of 2 people found the following review helpful:

☆☆☆☆☆ **DON't purchase product**, February 27, 2006
Reviewer: **laura m** (fl) - See all my reviews
Followed directions, started with clean face. Applied ANEW ALTERNATIVE to face and neck area. The following morning I woke up SWOLLEN AND RASHED. My skin is not sensative but whatever is in this product is detrimental to skin.

Was this review helpful to you? Yes No (Report this)

XEL 000471

5 of 5 people found the following review helpful:

★★★★★ **Wouldn't Be Without This Product!**, January 19, 2006
Reviewer: **L. A. Vitale** (Carpinteria, CA USA) - See all my reviews
REAL NAME™

I use this product as directed on my face and neck at night. It feels wonderful on the skin! I've been using this product since it was introduced last year (2005) and feel it has helped improve the quality and appearance of my skin. I even love how it smells~~ herbal/natural!

I have very sensitive skin, however I have not had a negative experience with the Anew Alternative. I'm sorry to hear that others have had a reaction to this product.

Was this review helpful to you? Yes | No (Report this)

See all 13 customer reviews...

Customer Discussions Beta (what's this?)

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This product's forum

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Products > Skincare > ANEW > Moisturizers
Products > Skincare > ANEW > Specialty Treatment
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XEL 000472

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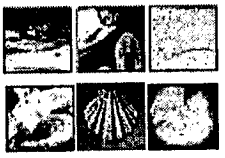
GMP (Good Manufacturing Practice)



visit Cawthron's other labs

Contact
Paul Parker
Toll free: 0800 50 25 25

Good Manufacturing Practice (GMP) Certification

The Cawthron analytical, physical and microbiological laboratories are certified by Medsafe to the New Zealand Code of Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Part 1.

Test Methodology

Cawthron offers testing to USP, BP, EP, FCC and other protocols. A wide range of analytical techniques are available in our laboratories: FTIR, HPLC, GC, TLC, ICP-OES, AAS (Flame and Furnace), LCMS.

Range of Tests

A growing range of full monograph testing is available:

- Ascorbic Acid
- Ethyl Alcohol
- Alanine
- L-Aparagine
- Guar Gums
- Microcrystaline cellulose
- Chromium Picolinate
- Fructose
- Glucose
- Vitamin B3
- Peppermint oil
- Povidine

XEL 000475

- Stearic Acid
- Talc

Capabilities include detection of Heavy Metals, Chloride, refractive index, various assays, ID testing, sulphated ash, LOI, pH etc.

Microbiological testing includes:

Product Testing	**Reference**
Aerobic Plate Count	BP 2003
Yeasts and Moulds	BP 2003
Bacillus cereus	BP 2003
Clostridium perfringens	BP 2003
Staph aureus	BP 2003
Enterobacteriaceae	BP 2003
Coliform/E.coli (Present/Absent)	BP 2003
Coliform/E.coli (MPN Count)	BP 2003
Listeria (culture)	FDA BAM 8th Ed 1995
Salmonella	BP 2003
Pseudomonas	BP 2003
Environmental swabs	
APC	
Y&M	
Enterobacteriaceae/E.coli	
Listeria (Clearview)	AOAC R Cert. No. 960701
Salmonella	
Settle Plates	

Products and Materials

Our certification covers raw materials, in-process testing and final product for Micro-biological testing, and raw materials for chemical and physical testing, with final product testing to be added in the near future.

Typical final products tested in our microbiology laboratory include:

- Ganapoly Capsules
- Echinacea Capsules
- Spirulina Capsules
- Deer testicle powder
- Colostrum Capsules
- Shark Cartilage capsules
- Deer blood capsules

XEL 000476

- Bee pollen and propolis capsules

Please contact us if you do not see your raw material or product listed, as our laboratories can cope with a wide range of other materials.

Customers

Cawthron can test to GMP standard for a range of customers:

- Nutraceutical
- Natural products
- Contract Manufacturers
- Herbal products

Why GMP Testing

In July 2005, the newly established joint agency between Australia and New Zealand for the regulation of therapeutic products will commence operation. At this time, a new regulatory scheme for therapeutic goods will come into effect.

Under this scheme, the distributor (sponsor) of a product will be required to hold a product licence in order to manufacture, supply, import, export or promote the product. The joint agency will set requirements for product licensing with regard to labelling and GMP. Laboratory testing is part of the GMP requirements.

For more info, see **http://www.jtaproject.com**

Testing of your raw materials and final product will support the application for licensing of your product for the New Zealand and Australian market.

Cawthron is committed to:

- increasing the scope of monographs for testing of raw materials
- bringing final product/active ingredient testing under its scope
- liaising closely with customers to facilitate troubleshooting related to the manufacturing process
- developing new analytical methods for final product testing in the herbaceutical and nutraceutical industry.

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XEL 000477

Sarati international inc.

Company History

Corporate Mission
To distribute safe and effective: sodium-lauryl-sulfate-free hair, bath & beauty products; all natural toothpaste; hair removal products; anagen hair inhibitors; natural herbaceutical formulations; liposomal delivery systems for anti-aging facial creams, gels and skin-healing systems. Our goal is to manufacture high quality products that work. Our company creates an excellent wholesale or retail business opportunity for healthcare professionals, health-food stores, drug stores, and entrepreneurs.

Founders:
Sarati International was founded in 1993 by Barbara Creighton, Doug Cox, and Tom Flynn. Since that time, Barbara has become the CEO. Daughter Allison Musser, son-in-law Hamilton Musser, and Gary and Fran Gordon are her new partners. This team works closely together in product selection, formulation, and implementing the philosophy, "Products that work."


CEO: Barbara Creighton

CORPORATE MISSION:

We at Sarati International are committed to service through the distribution of safe, effective and the highest quality cosmetic and health care products for the entire family. Our goal is to ensure the success of your personal healthcare by providing a superior product that we stand behind. We help make dreams come true.

Foundations:

Since our founding in 1993 the Sarati team works closely together in product selection, formulation, and implementing the philosophy, "Products that work."

Sarati – what's in a name?

Not wanting to use synthetic products for cosmetic purposes, Barbara Creighton, founder and owner of Sarati International, Inc. began researching the marketplace looking for safe products with as many natural ingredients as possible. She was looking for a topical cream that would allow the ingredients to flow naturally into the body, nourishing and replacing nature's own nutrients. The search revealed the potential for a natural product, which she decided to manufacture herself. Barbara decided not only to provide other women with safe creams as close to their natural form as possible, but to give women and men an opportunity to distribute the products and share in the profits.

Now Barbara needed a name for her new company. When she mentioned to her sister Jeanie Bockelman, thinker and photographer, the concept of flowing naturally, her sister said, "Why don't you name your company 'sarati,' the Sanskrit word for 'it flows'?" Barbara loved her sister's idea, and created Sarati International, Inc.

Design by Webefx

XEL 000478

Business Preview play Movie

Be a Marketing Professional

Business Launch Australia!

PRODUCTS & SERVICES

"The Important Thing Is Quality; The Great Thing Is Price!"

Our Exceptional-Quality, Environmentally Safe Products provide a safe alternative to highly toxic, hazardous products and is certainly the solid foundation on which we build our businesses. There are hundreds of thousands of customers who have never worked the business but who simply buy these great products each and every month through our convenient **DIRECT MARKETING SYSTEM & SAVE MONEY. . .**

Frequently Asked Questions GO

SAFE PERSONAL CARE PRODUCTS FOR MEN, WOMEN & CHILDREN: French Milled Glycerin Bars, Bath & Body Cremes, Hand Lotions, Problem Skin Lotion, Bubble Bath, Natural Antibacterial Soap, Shower Gels, 4-Step Acne Solution, Dental Hygiene including Tooth Paste, Whiteners, Mouth Wash, Gum, Shampoos & Conditioners for all types of hair, Alcohol Free Setting Gels and Sprays, Volumizing Foam and Non-Aerosol Hair Spray, Aluminum Free Deodorant, Perfumes, Colognes, Sun Screens, and more.

SKIN CARE AND COSMETICS TO TURN BACK THE CLOCK: Cleansers, Toners, and Moisturizers with sunscreen, antioxidants, botanicals and European sea salts, Cellular Delivery Hydrating Mask, Revitalizing Hydroxy Cremes, Intensive Recovery Serum, Daily Multi-Vitamin Complex, and Eye Repair Cremes, Liquid and Crème Foundations, Bronzers, Eye Liners with Vitamin A & E, Lip Liners, Lipsticks, Lip Gloss, etc. Products are rich in Antioxidants, Botanicals, European Sea Salts, and Amino Acids to safely moisturize, improve elasticity, fade fine lines, help support collagen replacement and more.

OVER-THE-COUNTER-PHARMACEUTICALS: Nature's Best Solution/Tea Tree Oil, Natural Pain Relievers including Acetaminophen and Ibuprofen, Antacid Herbaceutical Complex, Cough Syrups without alcohol or codeine, Pain Relievers for Arthritis, Antibiotic Ointments and Gels, Sleep Aid without the drowsy feeling, Quick relief from fungal infections, athlete's foot, and more.

ENVIRONMENTALLY SAFE HOME HYGIENE PRODUCTS: Laundry System and cleaning products with stain-targeting enzymes, multiple whitening agents and without Chlorine, Phosphates, Formaldehyde, Dioxin and other highly toxic, harmful chemicals, Dishwasher Gel with Sheeting Action, Dishwashing Liquid with long-lasting suds and fresh lemon scent, Organic All-Purpose Cleaners that will clean your kitchen, pool or garage floor with ease and yet be safe enough to use as a vegetable wash, Shower and Tile cleaner with scour power and no toxic fumes, No ammonia, Streak-Free Glass Cleaners, Furniture Polish and more.

ORGANIC NUTRITIONAL SUPPLEMENTS: Multivitamin/mineral formula with 55 important vitamins, minerals and other nutrients using an exclusive patented processing. This process binds each mineral with a fructose molecule, so your cells and body can more readily accept it.

Superior Antioxidants that include the highest quality of grapes, the most potent source of proanthocyanidins, bioflavonoids and an exclusive enzyme blend.

XEL 000479

Pure Glucosamine HCI for Bone and Joint mobility and the promotion of cartilage regeneration.

Cardiovascular Heart Protection - A unique blend of proven antioxidants containing the highest quality grape seed extract. A 190 pound man would have to eat approximately 2000 grapes (9300 calories) every day to get the same cardiovascular protection found in just 6 capsules. **It is the only heart protecting product on the market that's proven to be effective in human studies... THE ONLY ONE!**

Eye Health by promoting optimal function of the macula containing Lutein, Vitamin C & more.

Prostate Health including Saw Palmetto, Berry, Pumpkin Seed, Zinc and lycopene.

Natural Plant Estrogens from soy, black cohosh and dong quai helping reduce hot flashes and other symptoms related to Menopause.

Pre-Natal Vitamins and **Children's chewables** you can trust.

St. John's Wort blend for mood support.

Immune Complex - A natural blend of Echinacea, astragalus and other natural ingredients to support a strong immune system. An important natural aid, when needed, to help the family stay well.

Great Tasting Diet Shakes, Fat-Conversion Activity Bars... and much more.

BUYING FACTORY-DIRECT/ WHOLESALE: Would you like to save 30%, 40%, 50% and more on products and services you already purchase by just simply switching stores and buying through our factory-direct catalog shopping system? Your purchases do not go through an advertiser, distributor, wholesaler, retailer or any other middlemen, and with our system you don't need to buy in case lots.

Products are conveniently shipped directly to you from the manufacturer **VIA THE INTERNET OR AN 800#.**

NO RISK GUARANTEE: Our product satisfaction is validated by our documented high re-order rate... however if you are not completely satisfied for any reason, you will receive a **Full Refund** on empty bottles anytime within sixty days and anytime within ninety days on our vitamins/minerals.

DISCOUNTED SERVICES INCLUDE: TRAVEL, INTERNET, LONG DISTANCE, AND CREDIT CARDS.

If you like saving money, don't book an airline ticket without checking with us first! Our **Travel Service** can save you hundreds and even thousands of dollars on airline tickets, hotel and car rentals.

Our **Long Distance Service** is available at rates as low as $4.9 cents per minute and **Internet Access** as low as $13.95 per month... and if you're working the business you can earn some of these services **FREE**. We offer major **Credit Card benefits** and more.

All of our containers and packaging materials are biodegradable and recyclable.

We are a company committed to bringing you something better!

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- DHEA Plus Gel
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- Educational Information
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Sarati International

Essential Extras is an independant distributor of Sarati International products. Sarati International provides and distributes safe, readily available over-the-counter transdermal natural progesterone and phytoestrogen creams and herbaceutical formulations that work to heal, accompanied by informative educational materials for their use. Sarati Internaitoanl's mission is to produce and provide only the highest-quality products at easily affordable prices.

www.sarati.com

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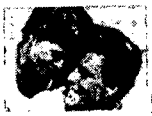
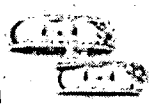
Dr. John Lee's website is:

www.johnleemd.com



Far below retail... Guaranteed.

Click here for top quality jewelry at extremely affordable prices!



HEALTHLINKS select site

Healing Well.com

XEL 000482

About Us

HerboriumSH is a division of Herborium Inc. and was established to foster Sexual Health, and to improve sexual performance in view that sexual activities are an important part of healthy living. HerboriumSH provides safe, healthy and efficacious alternatives to sexual performance enhancers. HerboriumSH also supports its products with content that assist its clients to better understand and realize their sexuality and to increase their satisfaction, and their overall quality of life.

HERBORIUM is an industry innovator offering what constitutes a Complete Alternative Medicine Solution. Our goal is to attract, coach and maintain high involvement and high enduring clients in both organizational and consumer markets. We provide proprietary and superior products, and employ interactive and customized strategies with targeted content and delivery.

Business Opportunity
Herborium is a provider of trade secret and patent protected, all natural medicinal products to both consumers and healthcare professionals seeking alternative answers to disease treatment, management, and prevention. Each product is supported by customized content. The Company uses clinical validation and a proactive approach to its regulatory strategy to establish and maintain a differential advantage. To realize these goals Herborium has developed collaborative relationships with proactive medical institutions in the US, UK, Japan, Hong Kong, and the PRC. The company utilizes Health Care Information Technology to empower its customer and consumer base to make informed medical and self-medication decisions.

HERBORIUM defines several of its products as "Bridge Products," which are bioherbaceutical medicines that have a record of clinical efficacy and safety and can be marketed in the US and Europe as dietary supplements thereby allowing for immediate market entry.

The Company is located in New Jersey, an important center for pharmaceutical discovery and manufacturing. Herborium maintains offices in London, UK and Beijing, PRC.

The Company's Management Team possess the highest quality, versatile business, medical and herbaceutical expertise and involves professional consultant groups in the US and abroad.

Herborium pursues a multi-channel marketing and distribution strategy by developing partnerships with selected traditional and non-traditional health care providers, nutraceutical and supplement sales channels as well as high quality consumer products and service providers.

XEL 000483

Natural Health and Beauty 4 Her

Selected natural products for a healthy lifestyle, formulated with Her in mind.

Index

PMS / Menopause (Severe Symptoms)
Natural Progesterone Cream formulated for women of all ages who experience symptoms relating to PMS, Menopause and osteoporosis. Safe and very effective.
Click here for relief.

Slim Beauty
Rapidly burns fat, suppresses your cravings and controls your appetite. Truly a break-through in weight loss formulation. Zero side effects and guaranteed to work
Click here for a slimmer you.

Menopausal Relief (Mild Symptoms)
Estro-All cream, designed for relief from the discomforts related to Pre and Menopausal Symptoms by restoring hormone balance naturally and without any side effects.
Click here for relief

Elicina Cream - A miracle of nature
Heals and regenerates damaged tissue, drastically reduces scars, removes damaged cells and imperfections. Leaves your skin feeling baby smooth and soft, retaining natural moisture.
Click here for the miracle of natur

On-Line Pharmacy
For those who need synthetic drugs, we offer US based Medical Consultation and Prescriptions with low medication prices and no doctor fees.
Click here for low prices.

Urinary Tract Infection
A safe and effective way to eliminate urinary tract infections without enduring any side effects. Symptoms start disappearing within 48 hours! No prescription needed!
Click for fast urinary track infection reli

~ Tell a Friend About Natural Health and Beauty 4 Her ~

Feminine Moisturizer Cream
A new and unique herbaceutical solution to vaginal dryness, irritation and itching. Safe, all natural ingredients developed by Sarati International, Inc.
Click here for more info.

Osteporosis Treatment Formula
An effective formula that combines the most essential and proven ingredients for bone health. Designed specifically for the woman by Wellness for Woman
Click here for strong bones.

Health Fit Counter
Monitor your food intake to control your weight and maintain peak overall health scientifically, at the touch of a button. Also a great aid for diabetes.
Click here for a slimmer you.

Unwanted Hair Remover
Now you can do away with unwanted hair naturally, just spray. Made from plant enzymes, a completely safe and effective product. Guaranteed to work for you.
Click here to do away with unwanted h

~~Bladder Control~~
A synergistic blend of herbs and amino acid formulated to support healthy urinary control.
An all natural product that effectively works without side effects. Guaranteed!
~~Click here for natural urinary control.~~

~~Soy Isoflavones~~
Soy supplement to support bone and estrogen functions. Can reduce menopausal symptoms and increases bone density in women.
Suggested alternative to estrogen replacement.
Click here for the natural solution.

ZHEN Acne Pills
Chinese secret formula.....
An herbal approach for the fight against acne.

Ovulation Home Test
A saliva-based ovulation predictor offering unlimited tests. Designed to assist a woman

XEL 000485

For a smooth and more youthful appearance.
Results become noticeable in as little as 5 days!
Click here to end acne

in identifying her fertile days of the month.
High quality at a low cost!
Click here to better your chances

Fertility Blend
A Scientifically validated herbal/nutritional blend for women to improve fertility health by optimizing hormonal & menstrual cycle balance. Clinically validated by Stanford University.
Click here for more info

Yeast Infection Control Formula
A powerful yeast infection treatment that uses friendly bacteria, natural antibiotics, vitamins, and nutrients to help stop yeast infections. For vaginal, oral, and other forms of yeast overgrowth.
Click here for fast relief

Super Multi-Vitamin
For today's active woman, a top of the line product to get all of your daily vitamins and minerals in one convenient capsule. You will feel the difference with this one.
Click here for your daily power source.

Female Endocrine Formula
Supports the system that maintains hormonal balance to relieve menopause, hot flashes, nervous exhaustion, frigidity, fatigue, and lack of libido. Aids the efficient metabolism of fat.
Click here for natural recovery.

~ Bookmark this site for future reference! ~

Gloves In A Bottle *New!*
Revive your dry skin in ways conventional lotions can't. These "invisible gloves" keep moisture-robbing irritants out while helping to retain your skin's natural moisture.
Click here for softer hands to feet.

JojobaGentle Facial Scrub
This exclusive formula gently removes dead skin cells and debris that blocks pores. Unlike soap, it cleans without drying or tightening the skin. Leaving your skin soft and smooth.
Click here for clearer pores & smooth skin.

~ We Offer Safe and Secure Ordering ~

We Guarantee Your Full Satisfaction!

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XEL 000486

Transdermal Cream Products

Natural Progesterone Cream

FemPower Natural Sexual Enhancer

AndroPower Natural Testosterone

Natural progesterone and natural tri-phyto-estrogens

Androstenedione Transdermal Cream

Vaginal Moisturizing Cream

Hormone Test Kit Using the salivary collection

Natural Hormone Balance Research

Summary On Natural Progesterone and Estro-All

Frequently Asked Questions About Natural Progesterone

JOHN R. LEE, M.D - FAQ

Hormone Balance Research Data

Return Home

info@sunrisewd.com

Physician Recommended Transdermal Creams

Natural Progesterone

Are you experiencing...

- Hot Flashes?
- Not sleeping well?
- Night sweats?
- Weight gain?

Read about Menopause and weight gain

Read all the articles on menopause and hormone replacement therapy here

You could benefit from Natural Progesterone Cream. **Get rebalanced today.**

Learn about progesterone here: Progesterone 101

Natural Progesterone Cream is a topical dietary supplement designed for women of all ages who experience symptoms relating to PMS, Menopause and Osteoporosis.

Over 50 million American women are now making major health decisions on the best method to cope with the physical and mental effects of menopause. Many women are becoming discouraged and switching from synthetic hormones to natural hormone replacement therapy.

These courageous women are deciding on how to deal with hot flashes, memory loss, fatigue, depression and a host of unpleasant symptoms which signal the approach of nature's changing time for females. Many are turning to natural hormone replacement therapy by choosing hormones made that are bioidentical to the hormones that are made naturally in the body.

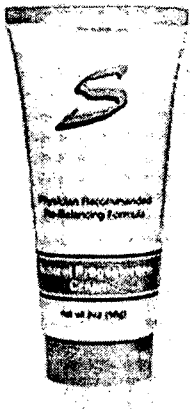
Define Progesterone

Progesterone is the primary hormone responsible for both fertility and pregnancy. Progesterone's biosynthesis pathway starts with cholesterol then to prednisone and finally to progesterone. Progesterone is manufactured primarily in the corpus lustrum

Not sure which product is best for you?Compare.

XEL 000487

Natural Progesterone



Description: Elegant white cream with natural progesterone. Formulated for quick absorption into the skin with superior bioavailability of natural progesterone.

New and Improved Formulation
Ingredients: 960 mg USP Natural Progesterone extracted from Wild Yam in a 2 Ounce Base of: Deionized Water, Caprylic/Capric Triglycerides, Polyacrylamide/C13-14, Isoparaffin/Laureth 7, Aloe Vera Gel, SD Alcohol, Grapefruit Seed Extract, Vitamin E Acetate.

Packaging: 2 fl. Ounces in two color tube, in a 5 color paper box, packaged in a 12 unit display carton.

1 Retail $24.95 BUY	6 Wholesale $90.00 BUY	12 Wholesale $120.00 BUY
+Free Shipping and Handling*		

Checkout

Progesterone with Phyto-Estrogens

Progesterone with Phyto-Estrogens (80-10-10) is a transdermal cream with natural progesterone and natural tri-phyto-estrogens formulated for quick absorption into the skin with superior bioavailability. Product designed for relief from Peri and Menopausal symptoms. In a ¼ teaspoon this product delivers about 1 mg of the three natural estrogens, and 20 mg of natural progesterone.

Phyto-Estrogens are found in many plant sources, primarily soy, wild yam, licorice, black cohosh, and chamomile. Our formulation attempts to copy the same molecular structure as in female human production of natural estrogens. We feel by adding progesterone to our phyto-estrogen cream helps in protecting women against osteoporosis, which is one of the many benefits of natural progesterone

Estro-All

Description: Elegant white cream with natural progesterone and natural tri-phyto-estrogens formulated for quick absorption into the skin with superior bioavailability. Product designed for relief from Peri and Menopausal symptoms.

Ingredients: 960 mg of USP natural progesterone extracted from wild yam and soybean, with natural phyto-estrogens extracted from black cohosh, licorice, wild yam, red clover blossom, dong quai, in a 2 ounce base of: deionized water, aloe vera gel, caprylic/capric triglycerides, polyacrylamide/c13-14, isoparaffin/laureth 7, vitamin E acetate, ethyl alcohol, phenoxyethanol, methyparaben (food grade).

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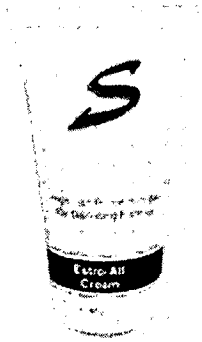


Packaging: 2 fl. Ounces in two color tube, in a 5 color paper box, packaged in a 12 unit display carton.

1 tube $29.95 BUY	6 tubes $90.00 BUY	12 tubes $144.00 BUY

Checkout

DHEA

DHEA - Plus is special formulation of DHEA, Pregnenolone, and Androstenedione DHEA Plus contains the "Mother" steroid pregnenolone, which has many benefits such as memory enhancement and anti-depressant effects. It enhances the DHEA levels by fueling the biosynthetic pathway with its primary precursor. An increasing number of scientific studies show that pregnenolone may increase resistance to stress through its impact on adrenal function.

DHEA - Plus has been formulated to provide a superior synergistic effect in men. The amount of DHEA Pregnenolone and Androstenedione declines dramatically with age and are associated with many of the diseases of aging. However, when these precursors are restored to youthful levels, the result is a broad spectrum of benefits. Over 4,000 articles in the scientific literature point to the benefits.

DHEA Plus

Description: Designed to replace oral supplementation with a superior transdermal delivery system. Each ¼ tsp. contains 15mg of DHEA, 3mg Pregnenolone, and 2 mg of Androstenedione.

Suggested Use: Massage into soft areas of the skin, such as upper chest, inner arms, abdomen, inner thighs or behind the knees. Rotate sites to avoid saturation. Apply ¼ tsp. once or twice daily as needed.

Ingredients: Deionized Water, Caprylic/Capric Triglycerides, Polyacrylamide/C13-14, Isoparaffin/Laureth 7, Aloe Vera Gel, Ethyl Alcohol, DHEA, Pregnenolone, Androstenedione, Phenoxyethanol, Methylparaben (Food Grade), Peppermint Oil.

1 tube $25.95 BUY	6 tubes $90.00 BUY	12 tubes $150.00 BUY

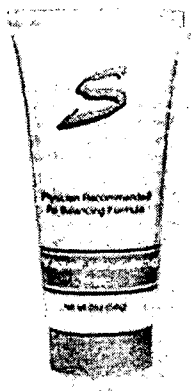
XEL 000489

Checkout

As many as half of the 40 million postmenopausal women in the United States suffer from vaginal dryness.

Sarati International Inc. has researched and developed a new and unique Herbaceutical solution which is an effective answer to this condition.

Vaginal Moisturizing Cream



$24.95 per tube
$120.00 wholesale per case (12 tubes)

Description: Our cream, applied locally to vaginal tissues, is inserted into the vagina with an applicator, add or can be used in the vulva area without the applicator. Use a l/4 tsp. daily for first week and 3-5 times weekly as needed.

Ingredients: Deionized water, caprylic/capric triglycerides, (food grade coconut oil) Simulgel 600 (plant based thickener) aloe vera gel, vitamin E, proprietary herbal blend of chamomile, comfrey, goldenseal, grapefruit seed extract. This product is not intended to be used as a sexual lubricant. Also, avoid mixing therapies with natural products.

1 tube $24.95 BUY	6 tubes $90.00 BUY	12 tubes $120.00 BUY

Checkout

Who Needs it?

Our vaginal cream is intended for women whose chief complaint is vaginal irritation, dryness, itching, and painful intercourse.

What are the advantages of our formulation?

The advantage of our formulation is that it is all natural ingredients and poses no risk for women trying to limit their estrogen exposure. Can this cream help with other menopausal conditions? This cream is not appropriate for other menopausal symptoms, such as hot flashes, or for the prevention of osteoporosis or heart disease.

What is atrophic vaginitis?

Atrophic vaginitis is a skin condition of the vulva and vagina. It occurs when a hormone called estrogen is lacking in the body. Atrophic vaginitis can occur at any age, but it most commonly occurs in menopausal women.

What are the signs and symptoms of atrophic vaginitis?

XEL 000490

Common signs and symptoms include:

- Problems with urination
- Painful intercourse
- Bleeding/Spotting
- Vulvar itching and/or burning

What is a safe treatment for vaginitis? Topical Vaginal Moisturizing Cream by Sarati International Inc.

Can this cream help with other menopausal conditions? This cream is not appropriate for other menopausal symptoms, such as hot flashes, or for the prevention of osteoporosis or heart disease.

What is the latest conventional prescription options? Another medical option for this condition is a vaginal estrogen ring The estradiol vaginal ring (Estring) is a soft, flexible ring for insertion into the vagina. The ring releases a slow, continuous dose of estradiol, an estrogen produced by the ovaries, that lasts for 90 days. Until the availability of Estring, treatment options included estrogen tablets, transdermal patches and vaginal creams.

E! online

SEARCH

03.30.2006

LATEST NEWS

TODAY'S NEWS

FIRST LOOK: The News in Brief

"Idol" Says So Long to Little Lisa

Paris, Three 6 Mafia Hit the Studio

Paula Is Forever Your Judge

"Survivor" Sean Tossed, Returns for New TV Gig

by Mark Armstrong
Aug 17, 2000, 1:20 PM PT

Survivor's nipple-pierced alphabet man is gone. Only the rats remain.

Yes, Wednesday night spelled A-B-See ya for the neurological (and densely diabolical) Dr. Sean Kenniff, the 30-year-old, um, brain surgeon from Long Island who irked fellow castaways with his diplomatic alphabet system, and became the last person to figure out his days were numbered (not lettered).

A record 28.7 million viewers watched as the island's mythological wind snuffed out Dr. Sean's torch (or was that just a breeze from his head?), while Kelly enjoyed immunity and a well-endorsed Bud Light (yes that's Bud Light, for all your island refreshment, *Bud Light*), and the remaining contestants nervously waited for someone to insert a knife in their own backs.

All told, it's getting dark and dirty on Pulau Tiga.

That's just the way we like it, apparently. With one week to go and four castaways left before *Survivor*'s mega-finale, the show once again pulled in record ratings: A 17.9 household rating and 32 share (up from last week's previous high of 17.4/31), and a 12.7 rating and 38 share among adults 18-49 (up from last week's 12.1/39). Observers are already predicting that next week's finale could become the highest rated post-season show since the 1996 Summer Olympics.

Meanwhile, Dr. Sean is hoping his new career in TV looks just as promising. In addition to an upcoming guest spot on CBS' soap *Guiding Light* and a novel he's shopping around, the neurologist has just scored a full-time job as a New York-based medical correspondent for the syndicated news mag *Extra*.

"We are delighted to offer Dr. Kenniff a more permanent residence than his *Survivor* surroundings," Executive Producer Lisa Gregorisch-Dempsey said in a statement. "If 'Dr. Sean' can survive on the remote island, he'll have no trouble working in the daily

XEL 000492

news grind."

In all fairness to the clean-shaven castoff, he does have the credentials. Kenniff spent four years with the Long Island Jewish Medical Center and was chief neurology resident there before starting his own private practice (he quit shortly before applying for *Survivor*). And he's flexed his medical muscle with articles like this one, touting the benefits of Ginkgo Biloba Extract:

"While a growing body of medical evidence has confirmed the potency of this 'herbaceutical' in the treatment of memory disorders," Dr. Sean writes, "the future therapeutic applications of GBE will probably include Intermittent Claudication, Stroke, brain and spinal cord injury, Macular Degeneration, Myocardial Infraction, Tinnitus, Raynaud's Phenomenon, and Congestive Heart Failure."

Gripping stuff.

Corporate conniver Richard Hatch also has taken his shtick elsewhere. During the week of August 28, Hatch will host his own radio talk show on WPRO-AM in Rhode Island, sitting in for a vacationing host. No word on whether he'll be offered a permanent gig.

But while *Survivor*'s castaways are rushing off to the world of TV "news," newscasters have whisked themselves off to the fantasy world of castaways. CBS today announced that *Early Show* newsman Bryant Gumbel will host *Survivor*'s live, one-hour town hall powwow following the season finale next Wednesday.

The show will feature the first-ever reunion of all 16 castaways (cleaned up, well-fed and only battered by their nonstop media coverage), while host Jeff Probst will file a special report from Australia, where he's prepping for *Survivor II: The Australian Outback*.

Despite the recent fallout from newsgal Julie Chen's ill-fated jump to hosting *Big Brother*, CBS suits stood by their decision to put another journalist at the helm of their reality series.

"The idea is, he's doing everything he's done on our show since the first week of [*Survivor*]," *Early Show* senior executive producer Steve Friedman tells *Daily Variety*, adding that it's no different than when NBC's Matt Lauer and Katie Couric host the Macy's Thanksgiving Day parade. "They're up there saying, 'Oh, here comes Snoopy!" and reading their scripted [comments]."

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FRESH FEATURES

Awful Truth: Are the *Friends* getting ready to reunite, or is there a holdout?

Fashion Police: Mischa Barton knows how to beat the blues

Guilty Pleasures: The newest must-haves in movies, music and videogames

Megaplex: Buffy goes from vampire slayer to porn star

FAIRFAX COUNTY
ECONOMIC DEVELOPMENT AUTHORITY

Press Room

Press Releases

XEL 000494

FOR IMMEDIATE RELEASE

Alan Fogg, Director of Communications
afogg@fceda.org, 703-790-0600 (o) or 571-213-5065 (m)

Fairfax County EDA competition yields four Virginia companies to vie for space in U.K. tech incubators

Five U.K. bioscience companies to vie for space in new Fairfax County incubator

Fairfax County, Virginia, July 24, 2002 — Four Virginia technology companies have entered a competition organized by the Fairfax County Economic Development Authority to win space in a British incubator. At the same time, five biotechnology companies from the United Kingdom are vying for space and free business services at the BioAccelerator, the bioscience incubator that the FCEDA will open this summer.

On Thursday, July 25, judging panels composed of U.S. and British business executives will begin ranking the companies. Winners will be announced in the fall.

This is the second year the FCEDA has organized a competition for a U.K. start-up to expand to the U.S., but it is the first time that the FCEDA is helping a U.S. company expand into Britain.

The Virginia companies that will be judged for acceptance into a U.K. incubator are:

- **Biotraces Inc.**, Herndon: Provides supersensitive detection techniques for proteomics, HIV-1 detection and prionics.
- **Enlightened Technologies Associates Inc.**, Fairfax: Specializes in medical devices and technologies to treat sleep disorders, seasonal depression and jet lag without drugs.
- **Leading Edge Consortium**, Reston: Provides consultancy, research and outsourced management services. The consortium is composed of executives from Persona Inc., MQI Inc., Oakland Consulting, Staub Leadership Consultants, AJR Consulting and Worldwide Services Consultants.
- **Outsource Inc.**, Front Royal: Performs high-end computer-aided design services.

The U.K. companies that will be judged for the BioAccelerator are:

- **Aneda Ltd**, Roslin, Scotland: Develops software for the pharmaceutical industry.
- **Mirada Solutions**, Oxford: Creates software to help physicians analyze medical images.
- **Riley Fletcher Organisation Ltd**, Warwick: Specializes in herbaceutical remedies.
- **Smartbead Technologies Ltd**, Cambridge: Provides bead array technology for testing new pharmaceutical products.
- **Synthese a Grande Vitesse**, Manchester: Manufactures micron-scale biochemical synthesis apparatus.

"There has been an excellent response to this competition from both sides of the Atlantic," said Gerald L. Gordon, president and CEO of the FCEDA. "Ultimately, these relationships will benefit the entrepreneurs, their employees and communities on both sides of the Atlantic, and provide new opportunities for marketing and growth."

Incubators in the British counties of Berkshire, Hampshire, the Isle of Wight, Surrey and Yorkshire are participating in the competition to receive a U.S. company.

In addition to the FCEDA, other competition organizers and sponsors are the UK Science Park Association, UK Business Incubation, British Trade International, the Confederation of British Industry, British-American Business Association, BritishAmerican Business Inc., Penningtons, South East England Development Agency, Cyril Leonard & Co., and Taylor Joynson Garrett.

About the FCEDA
The Fairfax County Economic Development Authority (www.FairfaxCountyEDA.org) promotes Fairfax County, Virginia, as a business and technology center. The FCEDA assists businesses by identifying possible sites and facilities, and is a source for up-to-date demographic and economic statistics. Its programs help small and minority-owned businesses grow, and help entrepreneurs find sources of capital. The FCEDA has marketing representatives in London, Frankfurt and Tokyo.

###

A Personal Touch Gifts, Inc.

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Company Profile

Anew Alternative Skin Care Products

Anew Alternative Skin Care Products
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odel No.: 002-041

Detailed Product Description

Specifications:
ANEW ALTERNATIVE Intensive Age Treatment

A Radical New Fusion in Anti-Aging.
ANEW THE #1 BRAND IN ANTI-AGING brings you a new anti-aging skin care line combining exclusively harvested Eastern healing herbs with Western pharmaceutical-inspired technology an herbaceutical breakthrough. This powerful fusion is formulated to help undo all signs of aging. Let the healing age begin.

Reverse wrinkles. Restore contours. Repair damage.

Contact Information

Company Name: A Personal Touch Gifts, Inc.
Contact Person: Ms Jennifer Conte
Leave me a message Contact Now
Address: Haverhill St, N Reading Ma, Massachusetts, United States
Telephone: 1 978 6044348
Fax: 1 978 N/A
Website: http://www.aptgifts.biz

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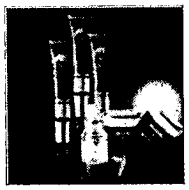
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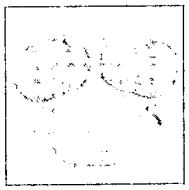
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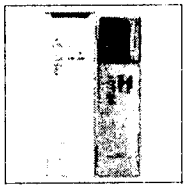
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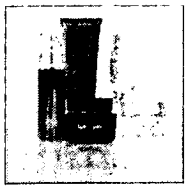
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Serenity by Natasha Nicole

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Guest Book
Special Offers
Body Lotions
Body Washes
Body Butters
Natural Soy Candles
About Us
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Terms And Policies
How To Order

Welcome!

Serenity by Natasha Nicole

is happy to help you learn more about our products!

We Offer:

Aromatherapy

Neutraceutical

Herbaceutical

*Products that are made with **100%** natural ingredients.*

XEL 000498

Attention Retailers!

For free samples and a wholesale catalog please send an email to:

inquiry4serenitybynatashanicole@yahoo.com

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We respect your privacy and will not share your information with any unrelated third party.

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Testimonials

- "Without the right skills, the pharmaceutical industry is a difficult sector to enter. Through my hard work and determination,

Yelena Pastanowitch

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- "I would like to express my sincere thanks and appreciation for the excellent training program that AIPT offers. "

Hema Rana

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About AIPT ▸ Mission Statement

OUR MISSION

AMERICA 'S INVESTMENT FOR THE BRIGHT FUTURE

IT'S YOUR LIFE, LET'S GROW AND PROSPER

It is the mission of AIPT to provide a quality education for our students. We specialize in Pharmaceutical technology training for the chemical industry such as Pharmaceutical, Healthcare, Cosmeceutical, Nutraceutical, Herbaceutical and environmental. We offer high quality training on state-of the art equipments and modern classroom training facility. We are committed to offering our students the best training available in the market. We also encourage good business practices, the development of critical thinking skills, effective communication skills, and leadership training.

It is our mission to keep people healthy and happy throughout their life by providing quality education and training to the people. We expect from our trained graduates that can prosper the healthcare industry through research and development of new innovative drugs.

We believe in our quality of training can bring an global drug research new shines and hope for new diseases.

XEL 000500

better by nature

Patented Natural Synergistic Herbal Remedies

Essential Health Information

How you become ill
Testimonials
Your Health Questionnaire
Synergistic Herbaceuticals
Why Ongoing Nutrition
Stress Management
Formula Ingredients
»Aloe Vera
»Probiotics
»Essential Fatty Acids
»Vitamins, Minerals & Anti-oxidants
»Essential Oils
»Chinese & Western Herbs
»Spices
Patents and Trials
Our Contributors
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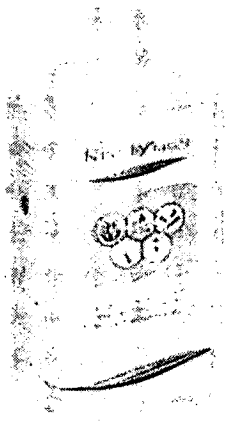
Products

Core Herbal Formulations
Ongoing Nutritional Formulas
Aloe Vera Products-> [142]
PDF Product Catalog

Our Core Herbal Formulation



Our Ongoing Nutritional Formula

Welcome to Better by Nature

Better by Nature.

We

How you Become Ill
Discover how you become ill...

Why Synergistic Herbaceuticals
Nature's way to a healthy life...

Your Personal Health Questionnaire
Even if you are healthy, it's important to understand how you become ill and what preventative nutrition you should be taking...

invite you to complete your Confidential Health Questionnaire.

Having studied it we will then agree a convenient time to have a consultation to discuss, without any obligation, how Better by Nature synergistic herbal remedies may be able to help you.

Click here to begin your questionnaire now

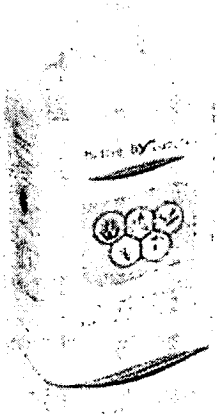
Patented Natural Synergistic Herbal Remedies

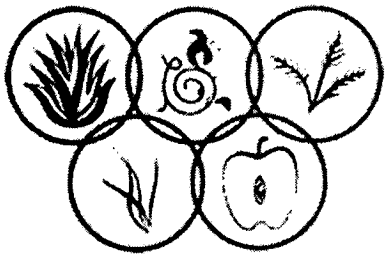
The Riley Fletcher Foundation has been pioneering the synergistic effect of the natural medical cultures of essential oils, Chinese and Western herbs, spices and aloe vera since 1995, which have never been combined before. Based on its findings and success of its formulas the Foundation has been granted patents in the E U and U S A with additional patents pending worldwide. The underlying range of 40 internal, external and emotional remedies based on natural plant products, have been further synergised into 7 integrated 'holistic' formulas each covering a broad spectrum of related ailments. The success of the Foundation is based on patient referrals.

Click here to see our testimonials

"Optimum Nutrition is the"

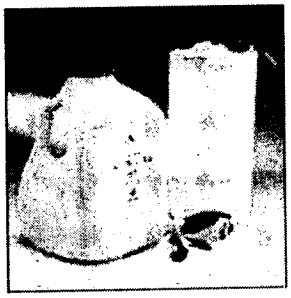
XEL 000502



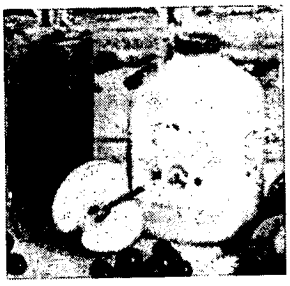


Synergistic blends of Aloe Vera, Essential Oils, Chinese and Western herbs, spices and Organic Nutrition

Essential Nutrition



Aloe Vera Gel (1 Litre)



Aloe Berry Nectar - Aloe with fruit juice (1 Litre)

Medicine of the future

Dr Linus Pauling
Twice (Unshared) Nobel Prize Winner
Voted second most important scientist of the 20th Century
48 PhDs

Your Safety

'Better by Nature' is the brand name of these synergistic herbaceutical remedies which are only created from plants and natural substances, which are non-toxic and which strengthen the body's natural mechanisms, rather than overriding or disrupting the body's systems as pharmaceutical drugs often do with side effects. Synergised plant-based medicines such as traditional Chinese medicine, have been helping people for millennia.

Your Confidential History Questionnaire

In order to have a comprehensive and efficient consultation it is essential you complete your questionnaire. This questionnaire relates to the information addressed by the Riley Fletcher Foundation within this site and is designed to collect a comprehensive level of specific, background and historic information in order to quantify both the 'cause and effect' of your condition/ailment. There are three sections:

- Medical history
- Emotional background
- Home and work environment

We recommend you read our questionnaire first to avoid duplicating answers.

Regulatory Issues

In order to comply with current legislation the Better by Nature products, classed as herbal remedies, are mixed in the Foundation clinic and supplied as a consequence of a consultation between the Foundation and their patients, following the completion of their confidential health questionnaire. Being classed as herbal remedies the Foundation cannot make claims such as curing arthritis/asthma, helping candida/chronic fatigue, alleviating depression/stress, balancing hormonal problems etc. The Foundation is not allowed to set out or advertise any medical claims even using basic words such as repairs, combats, alleviates, removes, avoids, stops, heals etc, particularly with or in the context of, a disease, illness or specific adverse condition. The Foundation has made its best effort and intention throughout www.betterbynature.com to comply with these constraints. In order for the Foundation to do its best to assist you it is essential you begin the consultation process by completing the confidential history questionnaire - *click here*

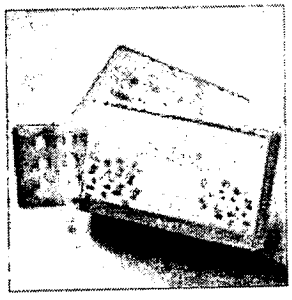
Better by Nature formulas also have a complementary roll to play in the management of various conditions. It is very important however that people should always seek the advice of their doctor when the diagnosis is in doubt or when a condition does not improve. Self diagnosis can be extremely dangerous as many serious conditions can minic more simple ones.

XEL 000503

Forever Freedom (1 Litre)

Bits n Peaches - Peach flavoured Aloe Vera Juice (1 Litre)

Forever Pomesteen Power



Forever Pro-Biotic

Affiliates

Associate Practitioners
Affiliate Information
Affiliate Program FAQ
Affiliate Log In

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Despite the success of the cultures throughout history, it is illegal to state the products/formulas mentioned are intended to diagnose, treat, cure or prevent any disease.

XEL 000505

Airplus for her(R) Launches Spa-la-la(TM) Luxury Footcare Line

Spa quality Herbaceutical footcare products now available in the Drug, Grocery and Discount Store Channels

Website

RESEARCH TRIANGLE PARK, N.C., Nov. 15 /PRNewswire/ -- Airplus for her Footcare, a leader in innovative footcare solutions announced the launch of its newest product line Spa-la-la. Airplus for her taps into the growing "masstige" trend bringing specialty prestige spa quality products to the mass market.

"We wanted to offer footcare consumers in the mass market channel the types of products they would expect from their favorite spa or specialty goods retailer," said John Andrews, Airplus for her Vice President of Marketing. "Our new line features many natural ingredients such as Mango Butter, Raw Sugar and Oat Kernel to offer a luxurious foot beauty experience."

The innovative new brand includes five new items for a complete foot beauty regimen:

- Pedistone(TM) a double sided pumice stone - made with 100% pure Indonesian volcanic pumice with medium and heavy coarseness sides
- Scrub(TM) sugar scrub - exfoliant sugar scrub with a special emulsifier to maintain granularity
- Repair(TM) cracked heel creme - restorative heavy creme with mango butter
- Heal(TM) - super-hydrating heel creme made with paraffin for extra moisture retention
- Spa Therapy Sock(TM) - ultra-comfortable therapy sock with Heal(TM) sample included

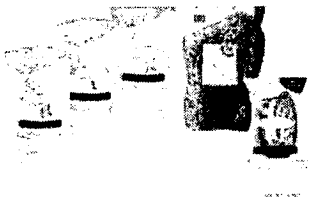
"We had lots of help from our Celebrity Pedicurist, Carla Kay," said Andrews. "Her vast experience with luxury footcare products brought a new level of expertise to our product development team." Ms. Kay's celebrity clients include Gwen Stefani, Debra Messing and Ashley Judd.

The Spa-la-la line is an extension of the popular Airplus for her footcare line featuring insoles and devices specially designed for women's shoes. Distinctively positioned in the brand's clear and lavender packaging Spa-la-la will be available in Drug, Grocery and Discount stores nationwide March 2006, and will retail for $5 - $8.

About Airplus for her Airplus for her is a brand of North Carolina based Implus Footcare, LLC, a leading "below the ankle" footcare accessory company. Implus brands include Sof Sole, Airplus, Sof Comfort and apara. Implus products are sold in over 30,000 outlets nationwide and over 55 countries worldwide. For more information, please visit http://www.implusfootcare.com/ or call 800-446-7587.

For additional information or product samples, please contact John Andrews, Implus Footcare, LLC at jfla@4implus.com or Mike Dixon, ADSTREET, Inc. at mike@adstreet.com.

Website: http://www.implusfootcare.com/



XEL 000507

HERBORIUM™ .inc

Power of Botanical Therapeutics ®

Herborium Team

The Company's Management Team possess the highest quality, versatile business, medical and herbaceutical expertise and also includes professional consultant groups in the US and abroad.

Agnes P. Olszewski, Ph.D. MBA; Co-President, Business Development
Dr. Olszewski, Co-Founder of HERBORIUM, has over 20 years experience in business strategy, strategic marketing management and international business as well as content delivery and distant learning strategies. She has conducted international negotiations and managed diverse teams of professionals and has recently concluded the establishment of a multi-million dollar pharmaceutical JV in the PRC.

James P. Gilligan, Ph.D. MSIB; Co-President, Product Development
Dr. Gilligan, Co-founder of HERBORIUM, has over 20 years experience in the pharmaceutical and biotechnology industry. Dr. Gilligan has extensive experience in pharmaceutical product development including pre-clinical and clinical research, toxicology, manufacturing and regulatory affairs as well as design and management of clinical studies.

Alice Lyon, Diplomat Phytotherapy, MNIMH, MRCHM
Ms. Lyon has extensive expertise in Western and Chinese Herbal Medicine with over 18 years of practical experience. Ms. Lyon is a member of the National Institute of Medical Herbalists and the Register of Traditional Chinese Medicine (TCM), and holds a Diploma in Phytotherapy.

Ms. Iris Nagel, Managing Director Herborium UK LLC.
Former managing director of State of Play Ltd. Ms Nagel has worked with US, UK, Germany and Hong Kong based clients including Channel V (Asia's equivalent of MTV), PC World Hong Kong, UndBitte TV, the Council of Mortgage Lenders in the UK and WorldCom. Her special area of expertise is designing multi-channel promotional strategies and operation management.

Mr. Baocheng Liu MBA/MSIB: General Manager , Beijing Office, PRC.
Mr. Liu has extensive experience with MOFTEC and International Trade procedures including managing foreign operations in China.

XEL 000508

Health - Dr. Sean Kenniff, M.D.

Ginkgo Biloba - An Ancient remedy for the failing mind

The scientific community has finally recognized the therapeutic potential of Ginkgo Biloba Extract (GBE) for the treatment of a variety of medical conditions. Most notably, a considerable performance and memory function of patients suffering form Alzheimer's disease. While a growing body of medical evidence has confirmed the potency of this "herbaceutical" in the treatment of memory disorders, the future therapeutic applications of GBE will probably include Intermittent Claudication, Stroke, brain and spinal cord injury, Macular Degeneration, Myocardial Infraction, Tinnitus, Raynaud's Phenomenon, and Congestive Heart Failure.

According to the fossil record, the Ginkgo trees, also known as the maideuhair tree, first appeared approximately 200 million years ago. Indigenous to China and the Southeastern United States, it is considered by some authorities to be the world's longest living species of tree. Individual trees have been reported to live as long as one thousand years, and its medical use in China for respiratory and neurological ailments have been well documented for over five thousand. It is a resilient and tenacious plant, capable of hearty growth in a variety of environmental conditions.

The medical benefits of GBE are derived from its two primary constituents – The bioflavinoids and terpene lactones. Bioflavinoids serve as potent antioxidants and free-radical scavengers in the brain and many other tissues of the body. The bioflavinoids are also responsible for GBE's ability to inhibit platelet aggregation, thus preventing atherosierosis. The terpene lactone component of GBE, also inhibants platelet aggregation, but additionally they exert a neuroprotecttive effect on the neurons of the central nervous system. This constituent has also been shown to increase blood flow to the brain and other organs.

The medical evidence for the treatment of Alzheimer's disease and Vascular dementia is impressive and well established. A 1998 study, published in the Archives of Neurology, reviewed the available published material and compiled the data. Their analysis showed a small but significant improvement in the cognitive functioning of patients with Alzheimer's disease who were administered 120mg to 240mg of GBE daily. Several well-controlled follow-up studies have reproduced this promising result, or have shown a significant slowing of mental decline. In fact, for statistically similar to the best currently available pharmacological therapy.

Some recent studies with GBE have demonstrated a significant Improvement on working memory of healthy volunteers. After the administration of two daily doses of GBE, a clear improvement on memory testing was noted, particularly in the 50-59 year-old range group. Recent animal data has suggested that there may be a significant neuroprotective effect in spinal cord injury, brain injury, stroke, and degenerative disorders of the brain.

Recommended doses range from 10mg to 240mg daily. Higher doses are under

investigation. There have been a few reports of spontaneous bleeding, even inside the brain, but these side effects are considered rare events. There are some potentially hazardous medical interactions one should be aware of before starting Ginkgo Biloba. Particularly if you are taking aspirin (or aspirin containing products), warfarin (aka, Coumadin), Ticlopidine (aka, Ticlid), or any other anticoagulant, GBE therapy should be avoided. Of course check with your pharmacist, physician, or healthcare provider before starting any nutritional supplement or medication.

Sean Kenniff, MD

.

One there's just me

WHAT IT IS WHAT IT IS WHAT IT IS....
APR.28.2004

damn i love that song. turn yo' speakers up!!! it's on the radio.blog. "let's call this song exactly what it is...(what it is what it is what it is....) Rock Steady, baby!!" damn i love that song. miss aretha can put anyone in a good mood. listen to Goapele, too. I saw her a few months ago with Musiq. She was off the hook. They only play her at 1 AM on BET, though... she won't get no love anywhere else.

i've been lacking with my blogging, i'm a lazy bastard. so sorry.

i got this new freelance job through a friend of a friend. they sell natural herbaceutical remedies for everyday problems (genital warts, herpes, cirrhosis of the liver... what have you. lol). the guy that hired me sent me their detox kit. i can't wait to start it, but i definitely want to wait until after paris, 'cause Lord knows everything that's going in my body there is gonna be toxic. it's very interesting to read the herbalist's writings. It sorta grosses you out. Let's just say I can't eat yogurt or drink milk after reading it, and meat is gettin' kinda shaky. He talks about how we should be putting whole, raw foods in our bodies, and not dead animal carcuses and cow mucus (see what i mean? lol). Very enlightening.

People probably get sick of me when I learn new stuff, because it's all I can talk about. I'm big on research. If I want to know about something, I'll google it to death, find out everything I can about it and tell you and ya momma until you get sick of hearing about it, or until I'm bored with the subject and have moved on to bigger and better things. this month's obsession is the raw foods diet and detoxing. Last month it was all about calories, how many you have to burn to lose 1 lb (3500, btw). Or you can be -500 calories a day and burn 1lb a week. I can give you more info, just hit me up . I've done researched that one to hell and back. Just because I know all about it don't mean I follow it, tho. lol

sigh

20 Days until Paris

man oh man. baguettes and butter, make way. Jonathan said they don't even give you butter with the free bread on the table - they give you moutarde (mustard, y'all)! mon Dieu! (see jonathan, i'm practicing). then they look at you like a stupid american when you ask for butter. that's okay.
Je suis une Américaine stupide! Et vous, vous êtes un canard gigantique!

Is everything conjugated correctly, Jonathan? I aint' gon' lie... i had to look up the cojugation for "être", but at least I knew which conjugation to look for, right? right! Four years of french and all I can say is that I'm a stupid american and you, you are a gigantic duck.. sigh... how

Home

WHO DAT IS?

it's Holly, bitch! twenty-something. "niggapino". web designer by day, knitter by night. (i make hats n' scarves n' shit). i can cook up a mean plate of cheese eggs, fat back and grits. i can eat the hell out of some sushi. never been in love . i'm a fruit fly. holly at itsholly dot com if i forgot anything. thanks.

SOME OF MY FAVORITE PEOPLE

Tina (the sista) | Heavyminds
Jonathan (the BFF) | Generically Different
Justin (best thing ever) | Disconnected
Lisa (the co-worker) | Sunkissed
Tomoko | Hassii
Huny | That Bitch
Shunda | Sugar Water
Etc... | Her Realm
Antoine | M3CCA
Joanna | BoJo
Dominique | Domibaby
Mark | Everything,But
Mike & Hechung | Michael Paul
Population: 25675

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The Sneeze
Gallery of the Absurd
cityrag
Yeeeah!
Perez Hilton
Brittle Bones

FAVORITES

...ooh girl, i love me some...
Holly's Policy
The New Sweater.
Hot Chocolate Time
Beautiful Weekend
Hurricaine Season
Busted Pipes
It's DEEP FRIED, bitch!
On My Own
Cramps

SHOWS

little brother & chaundon
Those Dang Robinsons
John Legend

sad for me. Ah hell, they're used to tourists by now. Why not add me to the bunch.

holly @ 09:37 AM PST [link] 4 Comments

THE BIGGEST CHICKEN EVER
APR.20.2004

on sundays, my mom likes to cook one big ass meal so she won't have to cook the rest of the week. so all week, we eat the same meal for lunch and dinner...all..week...long. it's not bad, i mean, the woman can cook. so this past sunday she had just gotten back from the store and i asked her what she was making. she said chicken. i peeked in the bag and the label says "Young Turkey". I said "Mom, that's a turkey." And she says "Well, it was the biggest chicken I could find..." ::sigh:: only mom mom could get away with something like that. it was good turkey though.

my new addiction: RICE CAKES! oh man... these things are good. They have ranch flavored, too? It's like eating potato chips man!!! Rice cakes and carnitas street tacos (carnitas, baby!) from Rubios. I got a couple tacos for me and moms, and all night she tried to convince me that "carnitas" meant "tongue". I'm thinking to myself, ohhell, all this time i thought it was just pork!!! she had me going there for a minute. it's braised pork. i swear, it's not tongue. right? right!

The new countdown: **28 Days Until I'm up in PARIS** ...baguettes and butter, baby!

holly @ 01:29 PM PST [link] 2 Comments

IT'S FRUIT N' YOGURT, Y'ALL!
APR.16.2004

i go through these phases when I'm addicted to a certain food. Last month is was tuna... and we ALL remember the fruit cup phase. but man oh man... i can tear UP a fruit and yogurt parfait from mcdonalds, man. that granola is somethin 'else. i could prolly eat 'em all day long, if i wasn't so lactose intolerant. one serving i'm good, but two? it can get a little gassy up in thurr. so i went on the website to check the nutritional information and I get all excited. Only 160 calories and 2 grams of fat? Hot damn! I could eat this all day for real! But you know those bastards at WacDonalds, always tryin' to fool a sistah with happy radio jingles ("I'm lovin' it!") and big smiles. Turns out that was for the "Snack" size. I only found that out because I went to nutritiondata.com and got the lowdown. There, they tell you there are TWO sizes - snack and regular. You know th WacDonalds site didn't say whether it was regular or snack size. lying bastids... Regular ain't no damn 160 calories. Try 380. Which is still okay, for what it is... but dang. I was all excited when i thought they were 160! hmph.

our microwave is broken at home, and for me, you might as well shout out "Armageddon!" 'cause that shit is like the end of the world for me. i'm hungry as all get out last night, tryin' to heat up some leftovers in

the microwave so i can eat it with some hot fresh rice my moms made (mmm, mmm!!!). The only button that was working was "Clear/Stop". Oh hell. I'm punching in times, hittin the "Popcorn" and "Thaw" buttons...I hit the little Reset/Test buttons on the outlet...just going crazy. How is we gon' eat without the microwave? What you want me to do? Use the stove? Please...! But that's what a sista had to do :(So I asked my mom about the microwave and she was like "Why you think I made fresh rice? I had leftover I wanted to heat up but the microwave wasn't working." Man oh man, you don't know what you got 'til it's gone. You may think I'm crazy, but you unplug your microwave for a day and try to do without. I was like "I'll be right back, I'm goingn to work to use the microwave..." lol It's no joke. Appreciate your microwave!... and everything else you take advantage of on the daily basis.

holly @ 09:10 AM PST [link] 1 Comment

FRIDAY FIVING
APR.09.2004

1. What do you do for a living?
I'm a web designer... or so I like to think

2. What do you like most about your job?
It's really laid back. Not like my last job (full of stress and crazy germans... not that all germans are crazy, just these particular ones). All my co-workers are really cool people to work with and I get a fast ass Mac G5. That's all I really need :)

3. What do you like least about your job?
... I can only use the same 3 colors for everything. it can be "confining", but you learn to get creative with those 3 colors, I tell ya.

4. When you have a bad day at work it's usually because _...
I ate some dairy based product and i don't want the bathroom to explode. Yogurt, café mocha... apples do the same thing to me. Or I'll eat a big lunch and be in a FOMA (food coma) for the rest of the day.

5. What other career(s) are you interested in?
I know I don't really want to be in front of a 'puter for the rest of my life. I want to do something where I can talk to different people (who aren't complaining... customer service is a no-no!). I would love to be involved in music, but not be famous. Just rich and behind the scenes :)

holly @ 01:49 PM PST [link] No Comments

I JUST LOVE HIM!
APR.08.2004

call me a fan, call me obsessive, but i'm going to see prince again. this time, this one is tagging along. since she rarely gets out anyway (except to shoot targets and buy books on PHP), I decided that it would be a nice birthday present to take my big sis. She's not *technically paying for the ticket (she's just subtracting the amount

from my "Bank of Big Sister Who Makes More Than Little Sister" debt), so it *can count as a present, right? right! hopefully i won't be looking at the back of prince's head the whole time (which was actually still quite alright with me!), but I know we have floor seats so it's always that possibility.

i've got 40 more days until I'm off to Paris for two weeks to visit jonathan. I am too excited. I've got a little Paris Trip countdown on my whiteboard at work n' everything. :)

I finally organized a whole bunch of my baby pictures. i'm thinking of using them for a new layout. we'll see if i feel inspired.

that's about it.

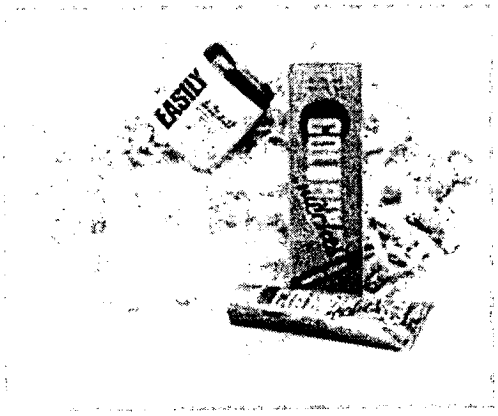
holly @ 04:36 PM PST [link] 1 Comment

AUTOPLAY
APR.05.2004

Yeah... i went ahead and turned off that autoplay feature on the radioblog. i knew if it was annoying me it was annoying the *hell outta you. so ya welcome.

holly @ 08:22 AM PST [link] 1 Comment

Hair Color



Colorly Hair Color & Treatment

- A. I. I. USA
- Adore USA
- Bigen Japan
- Clairol USA
- Colorful USA
- Divelop Plus USA
- Elgon Italy
- Fudge Great Britain
- Henna USA
- Herbaceutical Italy
- Jerome Russel USA
- Just for Man
- Loreal France
- Paon Japan
- Satin Italy
- Schwarzkopf Germany
- Wella Germany

Haircare@GlenPro.Beauty

XEL 000515

Orals dosage noni formulations

Brief Patent Description- **Full Patent Description** - Patent Application Claims

THE FIELD OF THE INVENTION

[0001] The present invention relates generally to a composition and method for administering Noni plant extracts. More particularly, it concerns a Noni plant extract formulation which eliminates unpleasant Noni taste and enhances Noni metabolism and absorption.

BACKGROUND OF THE INVENTION

[0002] Morinda citrifolia, a small evergreen tree commonly referred to as "Indian Mulberry," is indigenous to various south pacific costal regions and islands, and has been used for centuries in traditional folk medicine to treat a variety of ailments. Today, known best as the "Noni plant," many people believe that Morinda citrifolia extract is useful in treating diabetes, cancer, ulcers, heart trouble, high blood pressure, kidney and bladder disorders, as well as a myriad of other physical conditions.

[0003] Noni plant extract is most often prepared for oral dosage delivery as a liquid infusion or tincture of the Noni plant fruit. Unfortunately, fresh Noni fruit and liquid preparations thereof generally have a strong disagreeable taste and odor. Additionally, because liquid oral formulations are often bulky, may require refrigeration, and are messy if spilled, they are inconvenient for multiple daily dose regimens. This is especially true for individuals who lead an active lifestyle and may travel throughout the day.

[0004] In order to alleviate the problems associated with liquid oral dosages of Noni plant extract, a variety of powdered forms have become available which may be delivered as an oral dosage tablet or capsule. Such formulations are thought to eliminate the strong disagreeable Noni plant taste and smell. However, it has been found that the Noni taste may still be experienced to an unpleasant degree as a residual taste after oral consumption of tablets or capsules.

[0005] Additionally, metabolism and absorption of orally administered Noni extract by body tissues has been found to be less than optimal. Particularly, as with many other substances, cellular metabolism and absorption of Noni is enhanced in the presence of insulin. Unfortunately, Noni's therapeutically active ingredients are very susceptible to degradation by the digestive forces of the upper gastrointestinal tract. Therefore, administration of a Noni dose in close proximity to a nourishment event that is sufficient to significantly raise insulin levels actually reduces Noni dosage efficacy.

[0006] As a result, research and development efforts continue to pursue Noni fruit extract dosage formulations which are easily consumable, portable, and that maximize metabolism and absorption by the body.

SUMMARY OF THE INVENTION

[0007] Accordingly, the present invention provides a Noni extract formulation which includes a caramel or taffy base having an effective amount of a Noni extract dispersed therein. In one aspect, the amount of Noni extract may be from about 1% to about 25% w/w of the formulation. In another aspect, he amount of Noni extract may be from about 5% to about 15% w/w of the formulation.

[0008] A wide variety of Noni plant types may be utilized in connection with the present invention or producing an acceptable Noni extract. In one aspect, the source of the Noni extract may be a member of the group consisting of Tahitian Noni plants, Hawaiian Noni plants, Samoan Noni plants, and mixtures thereof. In another aspect, the Noni extract may be obtained from a Samoan Noni plant.

[0009] Numerous active agents in Noni extract have been indicated as causing the positive health benefits imparted. One such agent is polysaccharide. In one aspect, the Noni extract used in the present invention may include a therapeutically effective amount of a polysaccharide. In another aspect, the amount of polysaccharide may be from about 2% to about 5% w/w of the Noni extract. In yet another aspect, the amount of polysaccharide may be about 3% w/w of the Noni extract.

[0010] An additional active agent which is reputed to play a role in imparting positive health benefits is proxeronine and its activating enzyme proxeroninase. In one aspect, the Noni extract used in the present formulation may include a therapeutically effective amount of proxeronine. In another aspect, the amount of proxeronine may be from about 0.1% to about 50% w/w of the Noni extract. In yet another aspect, the amount of proxeronine may be about 5% w/w of the Noni extract.

[0011] The amount of sugar in the caramel or taffy base of the present invention may be an amount sufficient to mask or reduce the objectionable Noni extract taste, and may also be sufficient to rapidly enhance insulin levels. The total sugar in the caramel base may include an effective amount of an invert sugar. In one aspect, the amount of invert sugar may be from about 1% to about 20% w/w of the formulation. In another aspect the amount of invert sugar may be from about 3% to 15% w/w of the formulation.

[0012] A variety of invert sugar types may be utilized with the present invention to provide a heightened sweetening effect. In one aspect, the invert sugar may be a mixture of dextrose (i.e. D-glucose) and fructose. In another aspect, the dextrose and the fructose may each be present in an amount of about 50% w/w of the invert sugar. In yet another aspect, the invert sugar may be provided by rice syrup and include a mixture of glucose and maltose. In a further aspect, the amount of rice syrup may be from about 15% to about 40% w/w of the formulation.

[0013] The present invention additionally provides a Noni extract formulation which includes a caramel or taffy base having an insulin enhancing amount of sugar and invert sugar, and a therapeutically effective amount of a Noni extract, wherein said invert sugar is present in an amount sufficient to reduce a disagreeable taste imparted by the Noni extract, and the formulation has a total dosage size or amount that is insufficient increase upper gastro intestinal tract digestive activity to a level or degree which substantially inactivates one or more active agents, or a substantial portion thereof, in the Noni extract.

[0014] The present invention also encompasses a method for making a Noni extract. In one aspect, a method of making a Noni extract formulation comprising the steps of: a) preparing a caramel or taffy base containing an effective amount of an invert sugar in a conventional manner in a heated liquid caramel phase form; b) partially cooling said heated liquid caramel phase to a temperature at which Noni extract is stable; c) adding a desired amount of Noni extract to said partially cooled liquid caramel phase; d) agitating said partially cooled liquid caramel phase until the Noni extract is substantially uniformly dispersed therein; and e) further cooling said partially cooled liquid caramel phase to a solid thereby resulting in said Noni extract formulation.

[0015] In one aspect, the temperature of said partially cooled liquid caramel phase may be between about 160.degree. F. to about 220.degree. F. at the time said Noni extract is added. In another aspect, the temperature is from about 180.degree. F. to 200.degree. F.

[0016] In one aspect, the amount of Noni extract added may be from about 0.1% to 24% w/w of the Noni formulation. In another aspect, the amount of Noni extract may be from about 9% to 13% w/w of the Noni formulation.

[0017] In one aspect, the invert sugar is provided by an effective amount of rice syrup. Further, the present method may additional include the step of dividing the Noni extract formulation into individual serving size portions.

[0018] Another method included in the present invention is a method of increasing the efficacy of a Noni extract dose. Such a method may include the steps of: a) distributing an amount of Noni extract into a caramel composition containing an insulin enhancing amount of sugar and an invert sugar; and b) orally administering the composition.

[0019] In one aspect, the amount of invert sugar may be from about 1% to about 20% w/w of the formulation. In another aspect, the amount of invert sugar may be about 3% to 15% w/w of the formulation. In a further aspect, the invert sugar includes a mixture of dextrose and fructose. In yet another aspect, the dextrose and the fructose may each be present in an amount of about 50% w/w of the invert sugar. In an additional aspect, the invert sugar may be provided by rice syrup and includes a mixture of glucose and maltose. In yet another aspect, the amount of rice syrup is from about 15% to about 40% w/w of the formulation.

[0020] The method of enhancing the efficacy of a Noni extract dose may additionally include the step of administering the composition at a time when digestive juices in the upper gastrointestinal tract are at a minimum. Additionally, Noni formulation may be administered in a total amount that is insufficient to increase upper gastro intestinal tract digestive

action to a level which substantially inactivates one or more active agents, or a substantial portion thereof contained in the Noni extract.

[0021] If addition to the above-recited methods, the present invention includes a method of reducing or eliminating an objectionable taste caused by Noni extract. Such a method may include the steps of: a) distributing the Noni extract into a caramel composition containing a sufficient amount of invert sugar to reduce or eliminate any disagreeable taste caused by the Noni extract.

[0022] In one aspect, the amount of invert sugar may be from about 1% to about 20% w/w of the formulation. In another aspect, the amount of invert sugar may be from about 3% to 15% w/w of the formulation. In a further aspect, the invert sugar may include a mixture of dextrose and fructose. In yet. another aspect, the dextrose and the fructose are each present in an amount of about 50% w/w, of the invert sugar. In an additional aspect, the invert sugar may be provided by rice syrup and includes a mixture of glucose and maltose. In another aspect, the amount of rice syrup is from about 15% to about 40% w/w of the formulation.

[0023] There has thus been outlined, rather broadly, the more important features of the invention so that the detailed description thereof that follows may be better understood, and so that the present contribution to the art may be better appreciated. Other features of the present invention will become clearer from the following detailed description of the invention, taken with the accompanying claims, or may be learned by the practice of the invention.

DETAILED DESCRIPTION

[0024] Definitions

[0025] Before the present oral delivery Noni formulations are disclosed and described, it is to be understood that the present invention is not limited to the particular process steps and materials disclosed herein, but is extended to equivalents thereof as would be recognized by those ordinarily skilled in the relevant arts. It should also be understood that terminology employed herein is used for the purpose of describing particular embodiments only and is not intended to be limiting.

[0026] In describing and claiming the present invention, the following terminology will be used.

[0027] The singular forms "a," and, "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to a caramel containing "a Noni component" includes one or more Noni components, reference to "a sugar" includes reference to one or more sugars, and reference to "the flavorant" includes reference to one or more flavorants.

[0028] In describing and claiming the present invention, the following terminology will be used in accordance with the definitions set forth below.

[0029] As used herein, "Noni," "Noni fruit," "Noni plant," "Noni agent," and "Noni extract," refer to an extract made from the fruit of all strains and hybrids of the plant Morinda citrifolia, or of plants significantly related to it, grown anywhere in the world including blends, mixtures, and combinations of such strains and relatives.

[0030] The terms "formulation" and "composition" may be used interchangeably herein.

[0031] As used herein, a "sugar" refers to any type of simple carbohydrate, such as a mono or disaccharide, or a combination thereof, either naturally obtained, refined from a natural source, or artificially produced, which may act as a suitable sweetener in a caramel composition.

[0032] As used herein, "inactivate" refers to a reduction, or substantial reduction in therapeutic action which would be imparted by an active agent when administered to the body.

[0033] As used herein, "invert sugar" refers to a combination of two or more sugars, either naturally obtained, refined from a natural source, or artificially produced, that produces a greater sweetness than a single type of sugar. By way of example without limitation, an invert sugar may include a mixture of fructose and D-glucose in substantially equal parts. One example of a naturally obtained invert sugar is rice syrup. Rice syrup is generally obtained by culturing rice with certain enzymes to break down starches, straining off the liquid, and cooking the remaining portion until a desired consistency is reached. The resultant product contains a mixture of soluble complex carbohydrates, maltose, and glucose. In such a case, the combination of maltose and glucose act much like the more traditional combination of fructose and D-glucose.

[0034] As used herein, "chew" and "chew base" may be used interchangeably and refer to either a caramel or taffy base.

[0035] As used herein, "caramel," and "caramel base," may be used interchangeably, and refer to a smooth, chewy composition made with sugar, butter or other fats, cream or milk or milk solids, and flavoring. Such ingredients may be unaltered natural products, natural products which are processed or refined, or may be fully synthesized products.

[0036] As used herein, "taffy," or "taffy base" refers to a chew candy or confection which is made with various types of sugars, including but not limited to simple sugars, invert sugars, brown sugars, and molasses, which is boiled until very thick and then pulled until it is glossy and holds its shape.

[0037] As used herein, "artificial sweetener" refers to a sweetening agent which does not provide a substantial amount of calories when consumed, as compared to the calories provided by an amount of sugar required to impart an equivalent sweetening effect. A variety of artificial sweeteners are known to those skilled in the art, including without limitation, saccharin, aspartame, sucralose, etc.

[0038] As used herein, an "effective amount," and "sufficient amount" may be used interchangeably and refer to an amount of an ingredient which, when included in a chew composition, is sufficient to achieve an intended compositional or physiological effect. For example, a "sufficient amount" of invert sugar would be the minimum amount needed to reduce or eliminate an off or disagreeable taste caused by an amount of Noni extract. Further, a "therapeutically effective amount" refers to an amount of a Noni extract which is sufficient to achieve a desired physiological effect. The determination of an effective amount is well within the ordinary skill in the art of pharmaceutical, neutraceutical, herbaceutical, cosmetic, and medical sciences. See, for example, Meiner and Tonascia, "Clinical Trials: Design, Conduct, and Analysis," Monographs in Epidemiology and Biostatistics, Vol. 8 (1986), incorporated by reference in its entirety.

[0039] As used herein, "an insulin enhancing amount," or "an insulin level enhancing amount" of a substance refers to an amount of sugar or other nutritional agent that is sufficient to produce or raise the amount of insulin in the blood to a level which increases the metabolism and absorption of Noni fruit extract, or the active agents contained therein, to a rate or amount which is greater than at a lover insulin level. Various methods for measuring and determining various insulin levels and their effect on the metabolism and absorption of various nutritional components are well known to those in the art.

[0040] As used herein, "active agent" refers to an agent contained in a Noni extract which imparts, or is capable of imparting or inducing a measurable physiological effect when administered to the body. Examples of active agents include proxeronine, proxeroninase, polysaccharides, terpenes, alkaloids, vitamins, minerals, etc.

[0041] As used herein, "polysaccharide" refers to a compound containing a combination of nine or more monosaccharides which are linked together by glycosidic bonds.

[0042] Concentrations, amounts, and other numerical data may be expresses or presented herein in a range format. It is to be understood that such a range format is used merely for convenience and brevity and thus should be interpreted flexibly to include not only the numerical values explicitly recited as the limits of the range, but also to include all the individual numerical values or sub-ranges encompassed within that range as if each numerical value and sub-range is explicitly recited.

[0043] As an illustration, a concentration range of "about 0.1% w/w to about 25% w/w" should be interpreted to include not only the explicitly recited concentration of about 0.1% to about 25% w/w, but also include individual concentrations and the sub-ranges within the indicated range. Thus, included in this numerical range are individual concentrations such as 2% w/w, 5% w/w, and 6% w/w, and sub-ranges such as from 1% w/w to 3% w/w, from 2% w/w to 6% w/w, from 8% w/w to 18% w/w, from 5% w/w to 20% w/w, etc. The same principle applies to ranges reciting only one numerical value.

[0044] Similarly, a range recited as "less than about 5.8% w/w" should be interpreted to include all of the values and ranges as elaborated above for the range of "from about 0.1% w/w to about 25% w/w." Furthermore, such an interpretation should apply regardless of the breadth of the range or the characteristics being described.

[0045] Invention

[0046] The present invention is drawn to an oral dosage Noni extract formulation which includes a therapeutically effective amount of Noni extract contained in a chewy confection type vehicle such as a caramel or taffy. Such a formulation provides significantly improved taste, convenience, and efficiency aspects over conventional liquid, tablet, or capsule formulations.

[0047] Single Noni formulation dosage sizes typically range from about 4 to about 12 grams total weight and are individually wrapped for convenient transport and administration. The amount of Noni extract contained in a chew of this size may be from about 0.5 to 1.5 mg. In one aspect, the total weight for a single dosage may be about 8.6 grams, and the amount of Noni extract contained therein may be about 500 mg.

[0048] The Noni component of the present invention is generally included as a powder, and may be obtained by any process of active ingredient extraction known to those skilled in the art. By way of example, without limitation, extraction techniques, such as infusion, tincture, etc. followed by removal of the liquid portion and concentration of the extract may be used. One such method for producing a powdered Noni extract is described in U.S. Pat. No. 5,288,491 which is incorporated herein by reference in its entirety.

[0049] The amount of Noni component contained in the formulation may be varied according the knowledge of one

skilled in the art in order to achieve a particularly desired result. However, the Noni content will be generally from about 1% w/w to about 25% w/w of the formulation. In one aspect, the amount may be from about 5% w/w to about 15% w/w of the formulation. In another aspect, the amount may be about 6% w/w of the formulation.

[0050] A variety of beneficial active ingredients are contained within Noni extract. By way of example, without limitation, beneficial ingredients include vitamins, minerals, enzymes, terpenes, proteins, polysaccharides, and alkaloids. Of these ingredients, significant health effects such as anti-cancer and blood pressure lowering effects have been generally attributed to the alkaloids and polysaccharides.

[0051] The beneficial alkaloid ingredients have been identified as proxeronine and an enzyme known as proxeroninase. The action of proxeronine and proxeroninase, also known as proxeronase, in forming an alkaloid known as xeronine are more fully disclosed and described in U.S. Pat. Nos. 4,409,144, and 4,543,212, each of which are incorporated herein by reference in their entirety. Further, the positive health imparting properties of xeronine, as well as information on the formation thereof is described by Dr. Neil Soloman in his book entitled The Noni Phenomenon: Discover the Powerful Tropical Healer that Fights Cancer, Lowers High Blood Pressure, and Relieves Chronic Pain (1999), which is incorporated herein by reference.

[0052] In one aspect, the Noni extract contained in the present formulation may have a proxeronine content of from about 0.01% w/w to about 95% w/w of the total Noni extract. In another aspect, the proxeronine content may be from about 5% w/w to about w/w of the total Noni extract. The total amount of proxeronine contained in a specific amount of the present Noni formulation may be readily determined by those ordinarily skilled in the art. Simply, using the concentration of proxeronine in the Noni extract, and the amount of extract in the formulation, the total proxeronine amount in the formulation may be calculated.

[0053] The amount of the proxeroninase in the Noni extract will generally have an activity sufficient to activate at least a portion of the proxeronine contained therein under proper conditions. In one aspect, the activity of proxeroninase may be sufficient to activate at least 50% of the proxeronine. In another aspect, the activity of proxeroninase may be sufficient to activate at least 75% of the proxeronine. In yet another aspect, the activity of the proxeroninase may be sufficient to activate 100% of the proxeronine.

[0054] Various sources attribute many of the positive health benefits of Noni to its polysaccharides content, including water soluble polysaccharides. For example, Hirazumi et al., An immunomodulatory polysaccharide-rich substance from the fruit juice of citrifolia (noni) with anti-tumor activity, Phytother Res. August 1999: 13(5):380-7, which is incorporated herein by reference, reports that the anti-cancer effects of Noni are attributed to the polysaccharide content.

[0055] In one aspect, the Noni extract utilized in the present invention may have a polysaccharide content of from about 0.01% w/w to about 25% w/w of the total Noni extract. In one aspect, the polysaccharide content may be from about 1% w/w to about 10% w/w of the total Noni extract. In yet another aspect, the polysaccharide content may be from about 2% w/w to about 5% w/w of the total Noni extract. The total amount of polysaccharides contained in a specific amount of the present Noni formulation may be readily calculated by one skilled in the art using the amount of polysaccharide in the Noni extract and the amount of Noni extract in the formulation.

[0056] The capability of invert sugar to combat the disagreeable taste of Noni fruit extract is due to its particular nature. Invert sugar is generally a combination of the simple sugars dextrose (D-glucose) and fructose which provides a sweetness exceeding that of a single type of sugar. In one aspect, invert sugar may be a product of the action of the enzyme invertase on sucrose to form a mixture of levulose fructose) and D-glucose (dextrose). However, invert sugar, as defined herein, may be any combination of simple sugars which imparts a heightened sweetness. In one aspect, the invert sugar used may be that containing an equal parts mixture of D-glucose and fructose. In another aspect, the invert sugar used may be a combination of maltose and glucose.

[0057] The timing of the sweetening effect of each of the invert sugar components is complimentary. This time variation in part explains the increased sweetness and reduction of objectionable taste. Particularly, the glucose, and maltose or fructose, as simple sugars, provide an initial burst of sweetness as the invert sugar enters the mouth. This quick sweetening masks the initial distaste of Noni extract. The sucrose and corn syrup solids used in making the chew base, being either a disaccharide or starch hydrolysis product, provide a sustained sweetening power during chewing. Further, the maltose or fructose, while involved in the above two mentioned states, are also believed to provide a lingering sweetness which masks the objectionable Noni extract aftertaste or residual taste.

[0058] Notably, a variety of artificial sweeteners may also be used to mask the objectionable Noni extract taste. In one aspect, one or more artificial sweeteners may be used in addition to the sugars present in the chew formulation. In another aspect, one or more artificial sweeteners may take the place of a portion of the sugars present in the chew formulation.

[0059] In addition to improving the taste and convenience of a Noni fruit dose, the chew vehicle of the present oral delivery formulation also improves the overall dosage efficacy. As noted above, many of the beneficial Noni agents, such as proxeronine and proxeronase are very susceptible to degradation by the digestive forces of the upper gastrointestinal tract. Therefore, it is recommended that Noni be taken on an empty stomach. However, when taken on an empty stomach, a portion of a Noni fruit dose may escape metabolism and absorption by the body tissues due to low

blood insulin levels.

[0060] As such, the chew vehicle of the present invention is a particularly well suited vehicle for administering Noni on an empty stomach because of the total amount of combined sugars which are present. Particularly, the total amount of combined sugars in the chew is sufficient to raise insulin levels to a point which enhances Noni agent metabolism and absorption by the cells. Further, the total dosage size of the Noni chew formulation is relatively small and does not by itself facilitate significant production of digestive substances in the upper gastrointestinal tract.

[0061] Thus, because of its small size, the present Noni formulation prevents loss of Noni extract due to digestion in the upper gastrointestinal tract. Further, because of its high sugars content, the present Noni formulation enhances Noni extract metabolism and absorption in the tissues and organs. As such, the combination of high sugar content and small total administration volume allow the Noni formulation of the present invention to maximizes the efficacy of a Noni dose.

[0062] The caramel or taffy composition of the present invention may be a preparation of any combination of ingredients which is known to those ordinarily skilled in the art of making caramel, taffy, or other confections, and is not limited except by a requirement to contain an effective amount of Noni extract.

[0063] While no limitation on the form of Noni extract used in the present invention is made, in one aspect, the Noni extract may be a powder. In another aspect, the Noni extract may be a liquid. Further, in one aspect, the Noni extract may be obtained from the fruit of a Tahitian Noni plant. In another aspect, the Noni extract may be obtained from the fruit of a Hawaiian Noni plant. In yet another aspect, the Noni extract may be obtained from the fruit of an Asian Noni plant. In yet another aspect, the Noni extract may be obtained from the fruit of a Samoan Noni plant. In a further aspect, the Noni extract may be obtained from a mixture of any of the above sources.

[0064] In addition to the Noni extract active ingredient, other active ingredients may be included in the formulation of the present invention which impart a positive health benefit. As will be recognized by those skilled in the art, a wide variety of positive health benefit imparting ingredients may be selected from herbal and botanical extracts, as well as medicinal compounds and be added as desired in order to achieve a specific therapeutic result. Such additions may be made by the skilled artesian without undue experimentation.

[0065] Generally, herbal and botanical extracts are made from all kinds of herb and botanic sources and formulated based on their therapeutic function. For example, anti-flu, bone/joint, brain function, cardiovascular, circulatory, diet, depression, digestion, energy, eye vision, general health, immune system, liver, men's health respiratory, rest, urinary tract, women's health, etc. In one aspect, herbal and botanical extracts for inclusion in the present formulation can be selected from, but not limited to, Ginseng, Ginko Biloba, Dong Quai, Hawthorn berry, St. John's Wort, Saw Palmetto, Kava Kava, Rose Hips, Echinacea, Licorice Root, Grape seed, Chammomile, Sea Buckthorn, Aloe Vera, Cinnamon Bark, Cordyceps, Ho Shou Wu, Dandelion, Gynostemma, mushroom, Notginseng, Dan Shen, and mixtures thereof may be included.

[0066] In one aspect, vitamins either water soluble or oil soluble may be added. Water soluble vitamins specifically contemplated by the present invention include, but are not limited to: vitamin B.sub.1, B.sub.2, B.sub.3, B.sub.5, B.sub.6, B.sub.12, B.sub.13, B.sub.15, B.sub.17, biotin, choline, folic acid, inositol, para-aminobenzoic acid (PABA), vitamin C, and vitamin P. Additionally, oil soluble vitamins include, but are not limited to: vitamin A, vitamin D, vitamin E, and vitamin K.

[0067] Other health imparting substances which may be combined with the desired Noni extract in the formulation of the present invention include amino acids, ionic minerals, and naturally occurring anti-oxidants. The amino acids contemplated include: alanine, arginine, carnitine, gamma-aminobutyric acid (GABA), glutamine, glycine, histidine, lysine, methionine, N-acetyl cysteine, ornithine, phenylalanine, taurine, tyrosine, and valine, but are not limited thereto. Additionally, the ionic minerals contemplated by the present invention for inclusion in an embodiment of the formulation include both anions and cations. Finally, the naturally occurring anti-oxidants contemplated for the formulation of the present invention include: grape seed, beta-carotene, and co-enzyme Q-10, but are not limited thereto.

[0068] In one aspect, the amount of invert sugar contained in the prepared chew composition of the present invention may be from about 1% to about 20% w/w of the chew composition. In another aspect, the amount of invert sugar may be from about 3% w/w to 15% w/w of the chew composition. In yet another aspect, the amount of invert sugar may be from about 5% w/w to about 10% w/w of the chew composition. These amounts of invert sugar are in addition to the amount of table sugar (sucrose) or corn syrup solids required by the particular caramel or taffy recipe employed.

[0069] As defined above, a basic caramel formulation also contains butter or other fats, and either cream, milk, or milk products. Further, a basic taffy formulation may also contain molasses. The exact types and amounts of each of these ingredients may vary depending on the desired characteristics of the final product. Such exact amounts and types may be readily determined by one ordinarily skilled in the art.

[0070] Other ingredients known to the applicant as useful for making a Noni extract containing chew include but are not limited to: water, corn syrup, hydro soy oil, emulsifiers, lecithin, whey solids, sweetened condensed skim milk, flavorants, and vanillin.

[0071] In one aspect, the chew base, which is used as the vehicle for containing the Noni extract of the present invention may be partially or entirely made utilizing natural ingredients. Natural invert sugar sources such as rice syrup and sugar sources such as evaporated cane juice (turbinado sugar) may be used as one or more sweetening ingredients. Sweetened and condensed whole or skim milk and whey may be used as milk product ingredients. Coconut oil and mono and diglycerides from vegetable or other natural sources may be used as oil and fat ingredients. Further ingredients which may be used include without limitation Soya lecithin, and natural flavorings, including chocolate and vanilla.

[0072] Those of ordinary skill in the art will recognize that the amount of each of the above-recited natural ingredients may be varied in order to achieve a particularly desired result. However, in one aspect, the amount of rice syrup may be from about 10% w/w to about 40% w/w of the formulation. In another aspect, the amount of rice syrup may be about 36% w/w of the formulation. Of particular note is that in general, rice syrup is approximately 48% maltose and glucose and 52% complex carbohydrates. As such, the range of effective invert sugar component provided by the rice syrup may be from about 5% w/w to about 20% w/w.

[0073] In one aspect, the amount of turbinado sugar may be from about 15% w/w to about 20% w/w of the formulation. In another aspect, the amount may be about 18% w/w of the formulation.

[0074] In one aspect, the amount of sweetened and condensed milk may be from about 13% w/w to about 18% w/w of the formulation. In another aspect, the amount may be about 14% w/w.

[0075] In one aspect, the amount of whey may be from about 10% w/w to about 17% w/w of the formulation. In another aspect, the amount may be about 13% w/w.

[0076] In one aspect, the amount of coconut oil may be from about 1% w/w to about 5% w/w of the formulation. In another aspect, the amount may be about 2%.

[0077] In one aspect, the amount of mono and diglycerides may be from about 0.25% w/w to about 2% w/w of the formulation. In another aspect, the amount may be about 0.5% w/w.

[0078] In one aspect, the amount of Soya lecithin may be from about 0.05% w/w to about 0.2% w/w of the formulation. In another aspect, the amount may be about 0.1% w/w.

[0079] In one aspect amount of chocolate flavor may be from about 4% w/w to about 8% w/w of the formulation. In another aspect, the amount may be about 6% w/w.

[0080] In one aspect, the amount of vanilla flavor may be from about 0.1% w/w to about 0.4% w/w of the formulation. In another aspect, the amount may be about 0.2% w/w.

[0081] A method for making the Noni formulation of the present invention encompasses all methods for making caramel or taffy which are known to those ordinarily skilled in the art thereof, and is unlimited, other than to the conditions under which the Noni may be added. Particularly, the Noni must not be exposed to conditions which will cause it to become unfit for its intended purpose by changing forms, decomposition of active ingredients, etc. To this end, some restriction may be applied to the time of Noni addition, and the temperature to which it is subjected.

[0082] Therefore, in a one aspect of the invention, the Noni extract is uniformly distributed throughout the chew composition, and is added to a heated chew composition after the composition has been cooled to a temperature at which Noni active ingredients will not degrade. In another aspect, in order to achieve uniform distribution, and ensure Noni extract stability, the temperature will be from about 160.degree. F. to about 220.degree. F., and most preferably, the temperature will be about 180.degree. F. to about 200.degree. F.

[0083] In order to achieve uniform distribution of the Noni extract, the chew composition must be sufficiently agitated after adding the creatine. In one aspect, the chew composition is continuously cooled and agitated after the addition of the Noni extract until the composition is sufficiently solid that agitation is not practical. At this point the chew is ready to be divided into individual pieces for packaging. When a taffy base is used, the composition may be pulled after cooling until the desired consistency is reached, prior to division for individual packaging.

[0084] Because of the heating and stirring process under which most caramel or taffy compositions are prepared, the amount of ingredient added during processing will vary somewhat from the amount retained in the finally prepared chew composition. This is mostly due to the evaporation of water out of the various components which yields a final composition having a greater percentage of some ingredients which are unaffected by the removal of water. Therefore, a desired Noni extract amount in the prepared chew composition as enumerated above, Noni is added during processing in an amount of about 0.1% to about 24% w/w of the chew composition. In one aspect, the Noni extract is added during processing in an amount of about 4% to about 14% of the chew formulation. In another aspect, the Noni extract is added during processing in an amount of about 5% w/w of the chew formulation.

[0085] Additionally, in order to achieve the desired amount or invert sugar enumerated above, invert sugar is added during processing in an amount of about 1% to about 9% w/w of the chew composition. In one aspect, the invert sugar

amnount added during processing is about 5% w/w of the caramel composition.

[0086] The flavors of the final chew composition are unlimited. Any desired flavor may be imparted, as long as attaining the flavor would not render any essential ingredient unfit for its intended purpose. Flavors particularly preferred include but are not limited to: chocolate, strawberry, raspberry, orange, lemon, grape, apple, coffee, and toffee.

[0087] The example provided below is illustrative of only one embodiment of making a Noni extract containing chew of the present invention. While the processing conditions and ingredients may be preferred, no limitation thereto is to be inferred.

EXAMPLE

[0088] To the pot of a standard sized gas fired Savage cooker with agitation, was added a blend of 5.12 lbs. of sugar, 14.85 lbs. of corn syrup (43DE), and 2.51 pounds of water. Agitation was begun at about 100 rpm, and heating of the mixture was commenced. During the heating and agitation, 3.65 lbs. of hyrdo soy oil(98 F), 0.08 lbs. of lecithin, and 0.34 lbs. of an emulsifier were weighed into the pot. The temperature was increased during the addition of the ingredients until the temperature of the mixture was approximately 230.degree. F.

[0089] Approximately 2.81 lbs. of whey solids were dissolved in about 8 lbs. water, and then 2.25 lbs. of invert sugar levulose and D-glucose), and 6.16 lbs. of sweetened condensed skim milk were added to the whey and water to form a milk mixture. The milk mixture was added to the pot and heating continued until the combined mixture reached a temperature of approximately 235.degree. F.

[0090] The mixture contained in the pot was cooled to 232.degree. F. while stirring continued, and 1.40 lbs. of cocoa liquor, 0.11 lbs. of vanillin, and 0.07 lbs. of butter flavoring were added. Mixing was continued, and the composition temperature was allowed to cool to about 200.degree. F. Upon reaching the temperature of about 200.degree. F., 4.70 lbs. of Noni extract was added to the caramel composition. Mixing was continued, and the composition allowed to cool to a temperature of about 180.degree. F.

[0091] Once a temperature of about 180.degree. F. was reached, the caramel composition was removed from the pot and transferred to a cooling table. The composition was allowed to rest upon the cooling table until it reached a temperature of about 91.degree. F., at which time the composition was cut and wrapped into individual pieces.

[0092] The above described process yielded a Noni extract containing caramel composition having the following components in the amounts specified:

1 % Amount of % Amount of Ingredient Composition Ingredient Composition Water 10 Whey Solids 6.93 Sucrose 12.76 Sweetened 10.78 Cond. Milk Corn Syrup 29.76 Chocolate 3.42 Flavor Hydro Soy Oil 10.78 Vanillin 0.27 Emulsifier 0.20 Butter Flavor 0.16 Lecithin 0.20 Noni Extract 11.72 Invert Sugar 4.04

[0093] The Noni extract formulation having the components enumerated above showed excellent flavor, texture, and dissolution qualities in the mouth.

[0094] It is to be understood that the above-described arrangements are only illustrative of the application of the principles of the present invention. Numerous modifications and alternative arrangements may be devised by those skilled in the art without departing from the spirit and scope of the present invention and the appended claims are intended to cover such modifications and arrangements. Thus, while the present invention has been described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred embodiments of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications, including, but not limited to, variations in size, materials, shape, form, function and manner of operation, assembly and use may be made without departing from the principles and concepts set forth herein.

Brief Patent Description - **Full Patent Description** - Patent Application Claims
Click on the above for other options relating to this Orals dosage noni formulations patent application.

Related - 20060062859 - Abstract) - Composition and method to optimize and customize nutritional supplement formulations by measuring genetic and metabolomic contributing factors to disease diagnosis, stratification, prognosis, metabolism, and therapeutic outcomes
Related - 424725000 - Abstract) - Use of anemonin for treating aseptic inflammations
Related - 424725000 - Abstract) - Use of pothomorphe umbellata extract, composition on basis of pothomorphe umbellata extract and method of application of the pothomorphe umbellata extract

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Natural immunostimulant compositions, methods for obtaining the same and phamaceutical formulations thereof
Next Patent Application:
Use of one or more shogaol(s) as an aphrodisiac
Industry Class:
Drug, bio-affecting and body treating compositions

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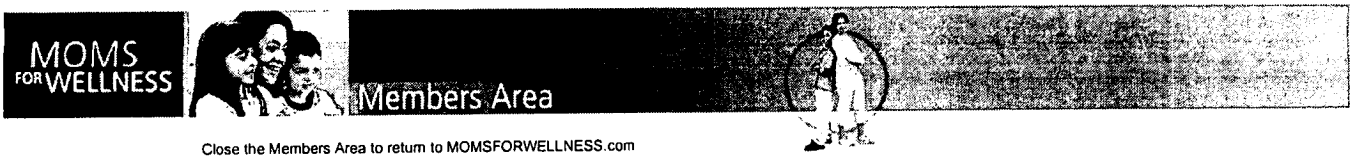

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INTRODUCTION TO MOMS FOR WELLNESS

Who We Are
Moms For Wellness is a group of fellow Moms who, like you, were looking for a better way to help provide for our families. We have gotten together from all over the US, Canada and Australia to work side by side in building a business that we can be proud of. Most of our "MOMS" work from home. We enjoy being able to work with our children in the same room or even, for some of us, on our laps. We are able to play with, teach and learn from our kids. But most importantly we are able to be there to kiss their boo-boos, dry their tears and see that their every need is taken care of without having to rely on strangers or impose on our families. We are very excited to teach you about our program and look forward to helping you succeed in working from home. By learning about our opportunity, we hope to help you understand our system and how it can benefit your family. Please take the time to look this over, check out the links, write down questions, and feel free to keep in contact with the person who enrolled you in this wonderful opportunity. You can also attain a list of support Moms who are always there to help you succeed in every way possible. We are always willing to match your efforts.

Why work from home?
More and more families are choosing to work from home. There are a variety of reasons. The rising cost of daycare is just one reason why Moms are deciding to start a career at home. Some just want more freedom, some want more time to be with their families or a little more financial security. With the rising cost of living, most families need two incomes just to get by, and some families just need to relieve some of the financial burden off of their partner.

Site Updated 11/11/02

All of us want to provide a better life for our families. This is why we have decided to work from home. A great way to remember this is by writing down what you are doing a home business for, and what your short and long term GOALS are. This is something you will want to print off and post close to your work area so you can read it everyday and remember WHY you have choosen to stay home and have a successful home business.

Did you know?
* 1 in 5 American parents are working 2 or more jobs
* Only 1 out of every 6 mother's in America stay at home with her children
* Someone other than their parents cares for 74% of American children
We are finding that for most of these families, staying at home is just a dream! Your dream can become a reality and you have taken the first step! Making the decision.

Moms For Wellness is the solution!
We are confident that with The Moms For Wellness system you can achieve the goals you want for your family. Choosing a home business can be scary, and with so many scams on the market, we all need to be careful. Finding the right company at the right time is essential for your success. And that success will ultimately be dependent upon the following five key areas:
1. Products
2. Company track record and Management
3. Compensation Plan
4. Support and Training systems
5. Timing Don't settle for any less! You will need all five areas to make your business
successful. Moms For Wellness has researched and developed a duplicatable system that utilizes all of these key components. This information will help you completely understand why Moms For Wellness can help you work from home.

Why Moms For Wellness?
Many of the Moms on the team have tried a variety of opportunities. We have been involved in Mary Kay, Herbalife, Tupperware, Nuskin, Rexall, Amway, Shakley, and a wide variety of other companies. Working with Moms For Wellness is so different than all of these, both on-line and off. Moms For Wellness is different because we are in our own home business but we work as a team, can you imagine 10 Moms each working 10 hours a week, that is like working 100 hours in a week. That is the concept behind our system.

Coming Soon
Special Information
Watch This Space
For Details

The timing is now!
With the trend moving towards home business, and with the tax deductions available to a family working from home, you have made the perfect timing decision to start working. Follow us through this training process and become a leader! Work for yourself and help train others to do the same!

The System
The Moms For Wellness system is what will make the difference in your success. The system is designed to be duplicated by every member of the team who wants to build a business. You will too by simply following The Moms For Wellness steps and learning how to use the Internet to find interested customers and business builders.

What could be simpler? I worked smarter, not harder! This part is what makes Moms For Wellness so awesome. We know that people are smart enough to check out our opportunity without us putting on presentations

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and driving hours to do a party. We can simply let technology do most of our work for us. The Moms For Wellness web site and the program is given to each member to use, so even while we sleep, play with our kids, we are working and finally the odds are stacked in your favor. Moms come to you when they are ready to join, there is zero rejection. You just give out The Moms For Wellness web site for others to check out.

Moms For Wellness also has a member's only section of our web site. It is here you will learn how to effectively advertise both online and off and how to build a business to make the income you need from the comfort of your own home.

This is what our system can do for you...it is simple to understand, amazingly fast, and automated. You can work at your own pace. You will receive all your free training once you are enrolled and ready to get your business started.

The Company
Something we have not discussed yet is the company we have chosen to align ourselves with. This is a 17-year-old company with an A1 financial rating. It is one of only 33 companies to appear five times on Inc.500 magazines yearly indexing of America's fastest growing, privately held companies, received the U.S. chamber of commerce blue chip award and listed with the Better Business Bureau. This company is Melaleuca. Whether you wish to physically benefit from it's exceptional products or build a profitable home based business, This Company is for you. Minimal Investment, No Selling, No Inventory, No Collections, No Quotas, No Employer, No Experience, No Ordering Product for Others, No Product Delivery, No Overhead, No Headaches, No RISK!!! This is Not a Pyramid or MLM (Multi-Level Marketing) Not a Get Rich Quick scheme but direct-to-customer marketing plan where Preferred Customers buy Only for personal and family use. You earn money with the company when you help others succeed. Check out this link for a background and marketing plan.

http://www.teamideals.com/melreview/

Melaleuca
Melaleuca has invented the concept called Consumer Direct Marketing. This allows every customer the opportunity to share in revenues through word of mouth referrals. Every month Preferred Customers order products that they used to purchase in a drugstore or grocery store. In return for their commitment, Preferred Customers are entitled to 30-40% off the suggested retail price on exceptional products. Dealing with the customer directly eliminates the hassle. Active Marketing Executives receive residual income month after month. Additional Preferred Customer benefits include travel discounts, a long distance savings program, low priced Internet service, a no-annual-fee credit card program and more. There are NO Distributors - we are all customers helping other customers. Once you enroll someone as a Preferred Customer, the company services him or her from that point on. Every preferred customer has the same opportunity and there are NO penalties for low "sales".

Melaleuca products
By choosing Melaleuca products, you have made a simple shopping decision that will impact the environment and your health in a very positive way! Switching stores and purchasing Melaleuca's full line of consumer necessity products that contain no cancer causing chemicals or environmental toxins is a decision that JUST MAKES SENSE! We are so glad that you have joined us in making this commitment to our planet as well as your overall health. Shop Wholesale vs. Retail, Non- Toxic vs. Toxic, and take 5 minutes to order each month and have the products delivered to your doorstep!! Melaleuca has over 500 thousand families who have made the same decision!

Why? - The Products are guaranteed to work better, contain no cancer causing chemicals- Products cost less per use than paying retail in the stores...Melaleuca offers over 300 necessary products that you and your family uses on a daily basis. Products like Shampoo, Deodorant, Hand soap, Face and Body Lotion, Laundry detergent, Cleaning Supplies, Vitamins, Weight loss Products, Cosmetics..Etc.. You Are Already Someone Else's Customer, Why Not Get Paid For It? Melaleuca offers you SAFE and ECONOMICAL alternatives.

Did you know?
Women who work from HOME have a 54% greater death rate of cancer? An EPA study confirmed that indoor air can be 3-70X more chemically polluted than outdoor air? Scientists are linking cancer to long-term chemical exposure? Cancer used to rarely exist in children and today it is the #1 cause of death in children with the 2nd cause being accidental poisonings -usually by dish soap...-62% of Americans take vitamin supplements...But According to Dr. Julian Whitaker, Over 250 thousand pounds of undigested vitamins are removed from the sewers of Tacoma, WA every 6 weeks. MELALEUCA OFFERS ABSORPTION!!!! Melaleuca offers the only patented vitamin supplements in North America!!! They come with a patented process that guarantees incredible absorption!! The Vitality Pack: Mel-Vita for energy and stress, Mela-Cal to address osteoporosis (your best health insurance) and Provex-CV (a patented product that has been proven in human double blind testing to reduce the risk of heart disease) should be a part of everyone's daily routine! The Vitamins come with a 90 DAY $ BACK GUARANTEE - Feel more vitality in 90 days or get all of your $ back. Your health is your only real asset and your body deserves the best!!! Home is where the heart is . . . it doesn't have to be where the toxins are. In our daily lives we use home cleaners, personal care items, cosmetics and other items that can unquestionably have a negative affect to our physical well being as well as to our family. Each year 42% of death in the U.S. and Canada are caused by cardiovascular disease? The U.S spends more money on the treatment of emotional well-being than cancer,AIDS,or Coranary heart disease? Research suggests that using acetaminophen may reduce the risk of ovarian cancer and heart disease? Melaleuca takes 80,000 orders in a single day through their state-of -the-art call center? There are 97,655 available positions in your 5x7 matrix organization? What qualifies you as a

preferred customer? To become a preferred customer means you are agreeing to switch stores and purchase the minimum 35 Base Points per Month ..... THATS IT!!!!! Each product has a point valued to it. And a minimum order of 35 base points is around $45US.

The average American family spends $80 to $160 on these types of products every month at their local store...We spend under $100. This is money that is already in your budget for your toiletries and household supplies - you are simply getting them in a new place. In addition you will receive a 10% rebate on your base point purchases which can be used to buy your items FREE! Does your grocery store or drug store offer you a 10% rebate on all your purchases?

Generating Extra Income
Did you know by the age of 65, 80% of North Americans live on less than 15K per year!!!!!! Our economy is taking a nosedive and many are looking for a no risk home based business that requires No inventory, no large start up cost, and no large monthly quotas. Tens of thousands of people in Melaleuca are earning thousands of extra dollars every month. We do not sell products in Melaleuca!!! We open up wholesale accounts and show customers the benefits of switching stores. THATS IT...

To become a Preferred Customer, you'll just need to do the following:
* Purchase the $29.00 (Business Starter Kit. Remember this is NO RISK! They will refund your money within 120 days if you choose not to continue!
* Commit to using these exceptional products on a monthly basis.
* Place your first order.You have taken your first step in building a business:
MomsWIN will supply you with a web site, all for FREE. Your personal Marketing Executive will work with you every step of the way. Set your goals and make your action plan. Everything is included when you became a preferred customer. That's it! No hidden costs or fees. Whether you want to build a business or just enjoy our exceptional products, there is no other required investment. Few other business opportunities have the potential for such a good return on such a small investment.

And remember, you are not required to inventory any products.

How Can Your Life be Enhanced?

You want the highest quality products.- These products will outperform anything you buy at the grocery store or department store.

You see the opportunity to enroll Preferred Customers and earn a small monthly income so that you are earning enough to pay for your monthly products. You can see how with a little effort, you can not only purchase these products at the Preferred Customer price but pay for everything you use in your home- for the rest of your life. How? Just share these products with four of your friends and have them each share them with three of their friends. If each of these individuals joins your Melaleuca organization as a Preferred Customer you will receive a commission of 7% as long as they remain Preferred Customers and you remain an active Marketing Executive.

You see the opportunity to supplement your current monthly income with a little extra effort and dedication and earn an additional $300 to $400 from your home based business. This is an excellent opportunity for stay at home and home schooling parents or anyone who wishes to supplement their household income. This level requires ten hours or less per week to achieve.

You see the opportunity to supplement your normal income with an additional $1000 to $2000 per month from your home-based business. How do you do this? By sharing the business with eight Preferred Customers who share it with five Preferred Customers. This can be accomplished on a part-time basis at approximately 10 to 15 hrs per week.

You see a real opportunity for complete financial independence - working for yourself and being your own boss. Your goal is a large business with a large personal income as much as you need, maybe more. You know it will take time and effort, but you are convinced you can do it. Besides, you will be a part of a like-minded organization that you will help to build.
Remember - all categories have a NO RISK, MONEY BACK GUARANTEE. Choose which categorie you want to start at, and let us know when you return our email to order your kit!

The Plan
Marketing Executive (Preferred Customer)
Others can place new customers in your organization, and, you can be paid on your first two generations.
* YOUR Household
* 7% 5 Households 1
* 7% 25 Households 2

Marketing Executive II
With two personally enrolled customers, you can be paid through your 3rd generation.
* Your Household
* 7% 5 Households 1
* 7% 25 Households 2
* 7% 125 Households 3

Marketing Executive III
With four personally enrolled customers, you get paid through your 4th generation.
* Your Household
* 7% 5 Households 1
* 7% 25 Households 2
* 7% 125 Households 3
* 7% 625 Households 4

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Director
With eight personally enrolled customers, you qualify to be paid through all seven generations.
* Your Household
* 7% 5 Households 1
* 7% 25 Households 2
* 7% 125 Households 3
* 7% 625 Households 4
* 7% 3,125 Households 5
* 7% 15,625 Households 6
* 7% 78,125 Households 7

Personally Enrolled Customer commission:
Personal Enrollees: 1-7 8-11 12-15 16+
Your commission: 7% 14% 17% 20%

Senior Director
With 5 personally enrolled Directors, You can qualify for...
* $2,000 cash bonus
* $400 per month for a new car
* 7% commission on all customer orders in your organization
* 20% Commission on personal enrollee's orders
* Share in 1% bonus pool of all company base points per month
* Additional 1st generation positions
* Additional qualified Senior Directors Bonuses

Sites to check out
Corporate Sitehttp://www.melaleuca.com/
NOTE: This site is U.S. Version. Prices for Australia are attached
Independent company reviewhttp://teamideals.com/melreview
Book About The Company
http://www.rmbarry.com/MelaleucaStory/Home.html
Nicole Miller Cosmetics http://www.nicolemillercosmetics.com/
We have done the research for you and have found a company that believes in manufacturing products without toxic side-affects. We are not selling anything to you. We are simply connecting you to the source. Please join us! Moms For Wellness can show you a way to help your family and make an extra income, Get Started Now!

Summary
So now you have read all about Moms For Wellness and Melaleuca, but what does it all mean? These are the steps to success.. When you visited our website and requested more information, a website was created for you! On it, we teach you how to approach Marketing both on the Internet and off. It is through this site that you will find interested people, just like yourself, that want to partner with you in a home-based business. The cost to start this business is a mere $29**. This covers your Membership fee and business kit and also enables you to purchase high quality products through Melaleuca at a 30% to 40% discount. In addition to this, Melaleuca asks you to purchase those products that you use from them instead of from your local store. A 35 Base Point order is all that is necessary per month to qualify you to receive you customer loyalty checks. THAT'S ALL!!!

Questions and Answers:
Q: What is my first step?
A: You will want to read your welcome email and go through the categories to see where you will fit in your home business. Contact your enroller and let her know what category you are in so she can better assist and help you. Make sure you do the required training for your business.

Q: Do I ever have to purchase more than 35bp?
A: Yes, when you reach your Director level you will need to purchase 75bp. Why, You are obviously building a business and will want to convert your home with Melaleuca products. You need to know everything you can and the uses for all the products our company has to offer. You will never have to purchase more than 75bp.

Q: What Do I Need To Do When I Have Reached Director?
A: You will need to fill out a new customer agreement form and at the top, x the preferred customer box and the 75bp box. Fax back to Melaleuca. You will want to also switch your back up order to 75bp.

Q: How Often Do I Contact My Enroller?
A: If you are committed to building your business, it is necessary to keep in contact with your enroller at least once a day so you can go over any questions and she can help and track your progress. It will also give you both a chance to go over what you will be doing daily.

Q: How Do I Build My 5x7 Matrix?
A: On your first level of your Matrix, you have room for only 5 customers. Out of those 5 positions or legs, you will want 1 for customers only. (People who are not building a business) The remaining legs will be for serious business builders. Use your customer leg until you find them. Customers go under Customers, Business Builders go under Business Builders. Never place a personally enrolled customer beneath your 3rd generation.

Q: How Do I Identify A Business Builder?
A: A preferred customer who has started their training right away, attends training calls and listens to live calls to get experience, Is asking questions and keeping in contact on a regular basis. Takes immediate action to become director.

Q: What do I do when I receive a potential customer?
A: First you will want to notify your enroller that you have your first potential customer, than you will want to send out some general info, you would than call your potential customer in 24-48hrs. and see if you can 3way them into a live call. Call your enroller and let her know when you need to do a follow up and make sure she will be available. If not set up a time when it is good for both of you.

Q: When Can I Start My Advertising?
A: As soon as you have gone through the members area, printed off all

information and understand the simple process. Usually within a few days or so.

Q: Why can't we use Melaleuca's name in our advertising?
A: It is a corporate website and represented only through Melaleuca themselves. We are separate from Melaleuca only in the sense, we have our own group and that is who we advertise.

MELALEUCA V.S WALMART COMPARISON
Prices taken on February 3, 2001 at Walmart in suburban Cincinnati)
It's easy to think that Melaleuca products cost more, if you only look at "cost per ounce" But as you will see, if you compare "cost per use", Melaleuca costs less.

PRODUCT COMPARISONS RESULTS - Melaleuca Costs Less!

Tide, 200 oz, 64 loads, $13.98, 22 cents per load
MelaPower, 64 oz, 64 loads, $9.99, 16 cents per load
Tide costs 38% more than Melapower

Downey, 40 oz, 40 loads, $3.68, 9 cents per load
Melasoft, quart, 96 loads, $6.99, 7 cents per load
Downey costs 29% more than Melasoft

Cascade Complete, 45 oz, 8 uses, $3.44, 43 cents/use
Diamond Brite, 38 oz, 25 uses, $6.99, 28 cents/use
Cascade costs 54% more than Diamond Bright

Robitussin Childrens Multi Symptom, 4oz, $4.53
CounterAct Multisymptom, 4oz, 3.99
Robitussin costs 14% more than CounterAct

Tilex, 32 oz, $3.27, 10 cents per ounce
Tub & Tile, 16oz concentrate, $3.99, 4 cents per ounce
Tilex costs 150% more than Tub & Tile

Fantastic, 22 oz, $1.97, 9 cents per ounce
Tough & Tender, quart conc., $4.99, 1 cent per ounce
Fantastic costs 900% more than Tough & Tender

Aquafresh Dental Gum, 16 pack, $1.97, 12 cents/pc
InstaFresh Dental Gum, 20 pack, $1.99, 10 cents/pc
Aquafresh costs 20% more than InstaFresh

Rembrandt Whitening Toothpaste, 3 oz, $6.97
Melaleuca Tooth Polish, 3 oz, $2.99
Rembrandt costs 133% more than Melaleuca

Extra Strength Tylenol, 24 ct, $2.77, 12 cents per pill
Extra Strength Counteract, 50 ct, $3.29, 7 cents per pill
Tylenol costs 71% more than CounterAct

Advil 200, 24 ct, $3.18, 13 cents per pill
CounterAct 200, 50 ct, $3.49, 7 cents per pill
Advil costs 86% more than CounterAct

Childrens Liquid Tylenol, 4 oz, $4.27
CounterAct Childrens Pain Reliever, 4oz, $3.29
Tylenol costs 30% more than CounterAct

Melaleuca products are safer for your home
Melaleuca's Home Hygiene Products contain safe, effective ingredients that have not been tested on animals. Melaleuca uses no ammonia, no phenols, no formaldehyde, no solvent detergents, no abrasives, no phosphates, and no NTA's. Compare the warning labels too. Our Diamond Brite Gel automatic dishwashing detergent is so safe that it does not require a childproof cap! Why should you worry about toxic chemicals?

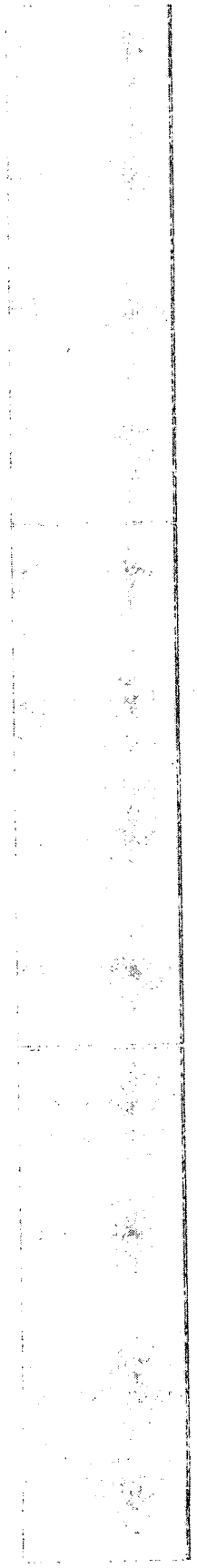
The EPA (Environmental Protection Agency) has reported that toxic chemicals found in the home are three times more likely to cause cancer than outdoor airborne pollutants. The Consumer Safety Commission connects 150 chemicals commonly found in our homes to allergies, birth defects, cancer and psychological disorders. The National Institute of Occupational Safety and Health analyzed 2,983 chemicals used in personal care products of which 884 were found to be toxic. According to the EPA, most homes have airborne concentrations of hazardous chemicals that are two to five times higher indoors than outdoors.

You have a choice: Toxic products that cost more OR Safe products that cost less and are delivered to your door.

Here is a list of some of the products and what they are used for.

TOUGH 'N TENDER*
All-Purpose Cleaner. One quart costs $4.99 and makes 96 quarts = 6 cents/qt. "Anything safe for water is safe for TNT." Spray TNT on plants to kill bugs and shine leaves; cleans hardwood floors; it's a great bubble bath; use it to wash your car, fine washables, fruits and vegetables, children's toys and play areas, kitchen floor, countertops, wallpaper, inside refrigerator, freezer, window blinds, ceiling fan, aluminum, awnings, and window screens, steel and wrought iron furniture (spray with Rustic Touch to help prevent mildew from returning); yet it is tender enough to bathe your infant in it. Used as a bubble bath, it seems to give great relief to patients undergoing chemotherapy. Notice: Ammonia is a poison not found in TNT. Yet, it is in many household cleaners. Besides attacking grease, it attacks skin causing rashes, redness and even chemical burns. It is harmful to the lungs when inhaled. It also causes severe eye damage. Ammonia mixed with bleach (which may be in many other common household cleaners) results in chloramine fumes which can be deadly. Along with bleach, ammonia and formaldehyde, there are many other potentially very dangerous ingredients that we cannot even pronounce. If you know there is a better choice, wouldn't you make the better choice?

Mix TOUGH 'N TENDER® with SPA & BATH OIL® to make insect repellent.



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SOL-U-MEL* and water repels bugs. Use to spray around doors and windows to keep bugs from entering. Spray under sink areas to repel bugs and to kill mold and bacteria. SUN-SHADES* sunblock and AFTER SUN HYDROGEL E* are great bug repellents.

Notice: The biggest myth that is perpetrated on the general public in advertising is that pesticides are safe!! You can watch TV commercials that show "good mothers" spraying deadly pesticides in the same area with their children's Kool-aid that they will lovingly serve to that child . . . as soon as all the roaches drop dead! But, when the manufacturers spend billions to brainwash us with commercials like this one -- it is little wonder that around 91 percent of all American households apply some 300 million pounds of these poisonous substances in and around their homes, most frequently in the kitchen and bedroom.

GOLD BAR* & PLATINUM BAR*.
Get extra-clean & super-soft skin with Melaleuca Precious Metals -- the great clean of a deodorant soap and the softness of a moisturizing soap.

MELALEUCA SHAMPOOS for people and pets are gentle and leave the hair extremely clean and soft. Apply NATURAL SHAMPOO* to dry hair on children to kill head lice. Use it on your pet to kill fleas and lice without having added insecticides. Notice:Keep in mind that when you use a flea and tick treatment on your dog or cat, it is absorbed into their skin and yours, including the powders, sprays, collar, shampoo, dip, etc. When you or your children love your pet, play with and maybe even sleep with them, you absorb exactly the same pesticide.

MELAMAGIC* INDUSTRIAL STRENGTH CLEANER.
One quart costs $4.47 and makes 16 - 32 quarts = 14 - 28 cents/quart. Compared to 8 gallons of Formula 409 = $106.59 & 8 gallons of Easy Off = about $191.36. Use MELAMAGIC* "heavy-duty formula" as a natural solvent for grease and grime. Clean stoves, stove hoods, sidewalks, driveways, tires, walls, crayon marks, magic marker, oven cleaner, garbage disposals, hair spray buildup, outdoor grill, gas spills, outside house siding, machines, greasy hands, garbage cans, power saw blades, whitewall tires, fireplaces, car engines, lawn mowers, bicycles, tractors, concrete floors, outdoor lawn furniture. Great to use with pressure washers. Kills the bacteria that attracts flies in livestock and pet areas.

SOL-U-MEL* Three-in-One Cleaner:
Stain remover, 2) Odor eliminator, 3) Cleaning booster. Deodorizes, disinfects, and dissolves. Makes Melaleuca oil water-soluble. Add a capful to whatever you are cleaning, as a cleaning booster. Dissolve grease and motor oil, crayon marks, road tar, gum, hard-to-clean spots on carpets, upholstery, clothing, bumper sticker removal, gummy & sticky surfaces, ink; neutralizes odors from smoke and cooking; eliminates odor in bathrooms, diaper pails, and pet odors; removes paint from skin; wash and sanitize toys, garbage cans, litter box; spray into air-conditioning and heat system filters to eliminate odors and kill mold growing in the system; add to cold humidifiers to eliminate odors and kill airborne germs; use as a laundry additive for tough stains and odor removal; mix in the pump sprayer of our air-freshening system and spray in your home and hotel rooms to disinfect beds, linens, telephones, door knobs, remote controls, and heat & air system. Notice: Chances are your household disinfectant contains either phenol or cresol. Phenol can temporarily deactivate the sensory nerve endings, which is why contact with it often causes little or no pain. Cresol attacks the liver, kidneys, spleen, pancreas, and central nervous system.

SUN VALLEY Candles & Mists.
Experience the charming warmth, exciting seasonal fragrances, and radiant beauty. You simply won't find a better burning candle. Our fragrances are chosen through a rigid testing process. The wax is so refined that it's classified as food grade. No animal by-products. The wicks are 100% metal- and lead-free. The result? The best, most fragrant candles on the market. Sun Valley Mists add a touch of freshness anytime, anywhere. These seasonal fragrant mists are non-aerosol and 100% recyclable. With a simple touch, these mists give off twice as much fragrance as aerosol cans 3 times their size -- for a burst of freshness that lasts for hours. Notice: Beware of store-brand candles that do not burn clean and that have metal or lead wicks. Most store-brand air-fresheners interfere with your ability to smell offensive odors either by releasing a nerve-deadening agent or by coating your nasal passages with an undetectable oil film. Not so, with Sun Valley.

REVIVE* Wrinkle Relaxer, Quality Control Agent, Stain Fighter.
Spray away wrinkles! A few sprays will make your clothes ready to wear anytime, anywhere! Proprietary formula reduces wrinkles, repels stains, freshens fabrics. Just spray and tug. Use in your laundry room, office, travel, gym bag (refreshens clothes after work-out, pulls out body odor). Use on tablecloths & napkins to protect from spills & stains. Gentle fragrance like a burst of spring.

TUB 'N TILE* Bathroom Cleaner.
Dilute according to your water and what works for you. Cleans bathrooms, tile floors, sinks, tub, shower, door, faucets, drains, removes discoloration and hard-water stains, lime, and mineral buildup with Melaleuca oil. Doubles as a non-abrasive brass, copper and jewelry cleaner. Mix with Diamond Brite* to make a 'soft scrub.' Spray and let it sit to give it time to work. Remember this is a natural solvent. No caustic fumes. Notice: Did you know that Soft Scrub Liquid cleaner is a registered pesticide? Contrast it with the safe active ingredient in TUB 'N TILE being sugar cane. Which would you rather use to clean your house?

NO WORK* The 15-second Daily Shower Cleaner.
Keep your shower sparkling clean with a daily 15-second spray. AquaCharge, a dual-action ingredient, breaks up soap scum and hard-water deposits, leaving behind the freshness of Island Breeze*.

CLEAR POWER* Streak-free Cleaner.
Only $3.23 for an 8 oz. bottle, makes 48 oz. of cleaner, or more! That's less than $0.54/bottle. (It takes 3 times as much of the grocery-store

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brands to clean the same surface area.) Made with natural ingredients, coconut, palm and Melaleuca oils, as well as vinegar. Clean windows, glass doors, mirrors, chrome, jewelry, glasses toaster, oven fronts, microwave, ceramic tile, countertops, anything you want to shine!

RUSTIC TOUCH* Furniture Care.
Not only works great, but it's good for the wood. Surfaces stay dust-free longer with no wax buildup. Use on wood, artificial wood, laminated surfaces, vinyl, leather, shoes, and paneling. Cuts grease marks, stains and fingerprints. Spray inside of shower curtains to help it keep clean and mold free; cleans and shines car dash, leather trim, saddles, and bridles. Non-combustible, non-aerosol container. Protects against drying and cracking. Notice: Phenol, which is suspected of causing cancer in humans, is used in most furniture polish and floor polishes. If phenol touches your skin, it may cause it to swell, peel, burn, and break-out in hives or pimples.

LEMON BRITE* Dishwashing Liquid.
Lemon Brite's triple detergent system and dual grease cutters work on greasy dishes before you do. Long-lasting suds clean 50% more dishes, giving you the cleaning edge when tackling tough food messes. Cuts through grease and dissolves baked-on food; rinses cleaner, helps eliminate hard-water deposits by using powerful surfactants derived from coconut oil and citrus extracts. Contains no phosphates. Use to clean large window areas (wash and squeegee off). Fresh lemon scent.
Notice: Most dishwashing detergents include naphtha, which is a central nervous system depressant. According to the Center for Science in the Public Interest, dishwashing detergents are responsible for more household poisonings than any other household product "Harmful if swallowed" seems to be an understatement.

DIAMOND BRITE* Super-Concentrated Dishwasher Gel.
Without the phosphates or bleach of grocery-store brands. With ingredients like Opti-Shine, Diamond Brite breaks up dried-on foods and leaves dishes spotlessly clean, even in hard water. New, concentrated formula gives you crystal-clear dishes, but you'll use just 1/4 as much as retail brands.

SOL-U-GUARD* Disinfectant. Germ Eliminator.
Hospital-strength disinfectant knocks out virus & bacteria growth in the kitchen or bathroom. Concentrated formula saves you money.

ECOSENSE* Laundry-System.
Biodegradable: When the suds go down the drain, the cleaning agents quickly break down into harmless compounds, and the waste water is safe for disposal because the products are phosphate free.
a.. Naturally Derived: Nature provides Melaleuca's cleaning agents - like softeners made from citrus fruits and enzymes derived from pure resources.
b.. pH-Balanced: None of the EcoSense* products contain caustic or harsh chemicals like bleach. So you can count on a gentle clean that will help your clothes last longer. Because there are no strong acids, EcoSense* laundry products are safer for your skin.
c.. Active Cleaning Agents: Each EcoSense* product is packed with active cleaning agents, not water. Compared to retail laundry products, you'll use a much smaller amount to clean just as much laundry. You can use our laundry products on all washables and in any water temperature.
d.. Special Ingredients: Clothes last longer because of special enzymes and gentle biodegradable surfactants and no bleach (in 1994, the Am. Assoc. of Poison Control Centers reported 19,538 children were involved in exposures or poisonings from household bleach).
e.. Concentrated: You add your own water rather than the company adding the water and asking you to pay for it. The containers are all recyclable.
1.. MelaPower* Laundry Detergent pH-balanced, 128 loads at less than15 cents/load vs. 30 cents or more from other leading brands. Cleans out motor oil, fireplace soot, oil deposits, blood, grape juice, mud, 'farm stuff.' Use our special reusable pump for easy measure of 1/8 cup/load. Just one press of the pump keeps your hands clean, and it saves time. Non-alkaline formula won't fade or weaken clothes. Tide has 8 poisonous chemicals which damage fabric and remove coloring as shown in tests. MelaPower* washes four times as many loads as Tide. The cleaning agents in MelaPower* are surfactants which adhere to dirt particles in the water and on fabric. Then they loosen soil stuck to clothing and pull it into the water. Then a 'bubble' is formed around the dirt and kept afloat in the water until it is rinses away. Completely biodegradable and phosphate free. "We can clean our clothes without contaminating the water."
2.. MelaBrite* Color-safe Whitener & Brightener Twice as concentrated as other 'color-safe' bleaches. You need only 1/8 cup/load, compared to 1/3 or 1/2 cup with leading store brands. Unique ingredients remove broken fibers, and fuzz balls from clothes.
3.. PreSpot Plus* Stain Remover Contains no bleach or harsh chemicals. Uses Melaleuca oil to remove stains, grease smears, food spills, grass stains, and ring-around -the-collar.
4.. MelaSoft* Static-free Fabric Softener Use it in the rinse cycle, or apply to a reusable cloth and toss it in the dryer. One tablespoon per use in rinse cycle; two teaspoons per use in dryer. Eliminates static and reduces wrinkles in fabric. Locks in Mountain Shower fragrance for freshness. T36-C5*

MELALEUCA OIL. A natural antiseptic, soothing, penetrating (carries benefits far below top layers of skin), non-caustic to most skin types, aromatic, natural solvent. Good for minor cuts, wounds, abrasions, scratches and scrapes, minor burns, itching from chicken pox and insect bites, bee stings, poison ivy, and hives. Heals ingrown toenail, foot fungus, mouth ulcers, fever blisters, sore gums and gum disease, blisters, abscesses, acne, thrush, animal hot spots, warts, mashed fingernail allergic reactions, skin irritations, ear aches (dilute 1 drop with 5 to 10 drops of mineral oil or olive oil), diabetic foot ulcerations. Kills bacteria and germs. Effective against E. Coli, staph, strep and pseudomonas. Replaces all first aid and antibiotic ointment. More effective than aloe vera in treating certain skin conditions. (You may request, by fax or email, a page on Melaleuca oil uses entitled: "Common Health Conditions Treated with Melaleuca Oil.")

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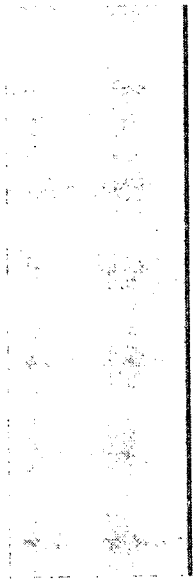
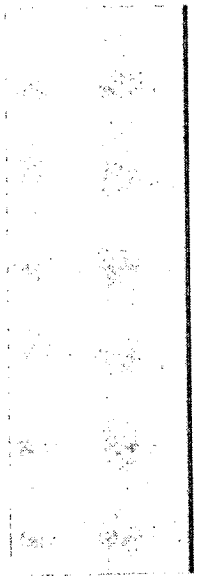
MOISTURSIL*
Problem Skin Lotion and for Extra Dry Skin. Beat the leading brand (more moisturizing, longer-lasting effect, smoother and softer skin, even after washing). Consumer-tested formula makes chronic dry skin feel softer for





XEL 000533

up to 12 hours! Contains allantoin plus Melaleuca oil for moisture that absorbs fast and won't wash off. Relieves itching, scaling, dry skin. Ideal for rashes, poison ivy, and psoriasis. There are 50 documented kinds of dry skin - Moistursil Problem Skin Lotion treats them all!

CORTI CARE Anti-Itch Cream
Perfect for poison ivy and takes the sting out of hives and rashes.
PHARMACY ESSENTIALS for LESS. When you get a headache or catch a cold, you want relief now. So keep your medicine cabinet stocked with the remedies your family needs. Melaleuca Pharmacy has pills, creams, and tablets you trust to relieve pain, colds and indigestion. Plus, these unique formulas work fast, easing symptoms quickly & effectively. They cost 20% to 50% less than retail brands. Don't get caught without relief.

COUNTERACT* Extra-Strength Acetaminophen.
Pain relief you can trust. For whole-body aches. Brings swift relief with unique rapid-dissolve caplets. Doctors recommend acetaminophen for its unbeatable safety rating. You'll trust it, because it works fast without upsetting your stomach. Costs 40% less than retail (1/3 cheaper than Tylenol, yet works 1/3 faster).

COUNTERACT* Kids Pain Reliever.
Relief from fever & aches with safety-proven acetaminophen. Costs 30-50% less than leading brands.

COUNTERACT* Kids Multi-Symptom Cold Plus cough.
One formula does it all: reduces pain & fever, coughing, nasal congestion & sneezing. Costs 30% less than retail.

COUNTERACT* Cough Relief.
Whole-Family Cough Care. No alcohol or codeine means safe, nondrowsy cough relief for the whole family. Affordable price - half the cost of Robitussin.

COUNTERACT* IBUPROFEN.
Fast simple pain relief. One caplet lasts up to 6 hours. Tests have shown Ibuprofen relieves pain faster than acetaminophen. Advanced medicine with rapid-dissolve caplets costs 30-40% less than retail brands.

COUNTERACT* PM.
Get restful sleep. Double-action formula soothes nighttime pain. Helps you sleep but won't leave you groggy in the morning. Half the price of the leading brand.

COUNTERACT* Night-Time Cold, Allergy, Sinus.
Overpower nagging cold, allergy & sinus symptoms. Get much needed rest. This maximum-strength 4-in-1 formula delivers superior cold-fighting relief at a very comforting price.

CALMICID Antacid Plus+.
Quiets heartburn. Natural stomach-calming herbaceutical complex teams up with an effective active ingredient to relieve acid indigestion, heartburn and gas. New Supermint flavor has the same fast-soothing formula with a great minty taste.

TRIPLE ANTIBIOTIC OINTMENT.
The strongest antibiotic ointment you can buy! Kills staph, strep, and pseudomonas bacteria. Helps prevent infection in minor burns, cuts, and scrapes. All purpose infection fighter.

MELA-GEL* Topical Gel.
A 'pocket first-aid kit' with the same qualities and uses as T36-C5* Melaleuca Oil but in a cocoa butter base with wheat germ oil (natural Vitamin E), vitamin A, D3, and beeswax. Won't evaporate on your skin. Can be used on animals, children, and even strangers! Kills bacteria and protects minor wounds from infection. Available by tube or disk (as a topical balm for purse or pocket).

ANTIBACTERIAL LIQUID SOAP*.
A "Moisturizing Disinfectant Soap* . Use only with the correct pump or you will use too much. ($6.99 for 10.5 oz., costs less than 2 cents/ use and has 532 pumps per bottle. For $6.99, Dial has 153 pumps, and Safeguard 139 pumps.) Kills germs and slows regrowth of germs and microbes. Kills bacteria like staph, strep, E. Coli, salmonella, and other viruses. pH balanced. Cuts grease but won't strip moisture from your skin. Use it to wash fruit, vegetables, meats, kitchen cutting boards, wounds and skin irritations, dermatitis, dry skin, eczema, and after exposure to poison ivy. Cleans leather. Spot cleans when you can't wash. Use on babies for diaper rash and then apply Triple Antibiotic Ointment* sparingly and wash baby clothes with MelaPower*.

PAIN-A-TRATE* Pain Relieving Cream.
Penetrates deep, is soothing; eases bone-deep aches with beneficial ingredients: methylsalicylate, menthol, and camphor. Warms muscles before activity to prevent injury. Great for cramped muscles, strains, sprains, bruises, joint discomfort, arthritis, tendentious, back pain, sore muscles, headaches, fatigue, and tightness.

DENTI-CARE SYSTEM*
Is simply the best for clean teeth and healthy gums. Helps prevent serious gum disease. Treats gingivitis and bleeding gums. Three toothpastes as follows:

Classic Tooth Polish*:
Natural, no-fluoride sugar-free combination of T36-C5*, myrrh, and propolis, a natural antibacterial agent found in beeswax. Kills bacteria between teeth and below the gum line.

Extra-Whitening Toothpaste*:
Proprietary mint formula whitens teeth with the natural properties of papain. Calcium, fluoride and zinc help preserve and polish teeth, while Melaleuca oil helps kill odor-causing bacteria.

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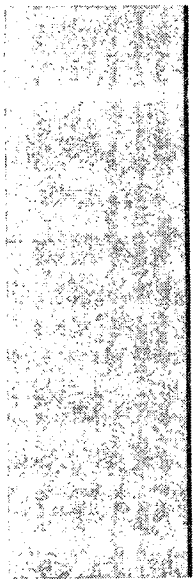


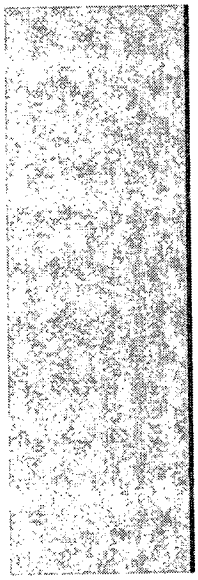
Mint Fluoride Tooth Gel:
Unique combination of baking soda, fluoride and Melaleuca oil protects teeth against plaque and tartar buildup with proper brushing. Preferred over leading retail brand in independent laboratory taste tests!
Other Denti-Care products are:
Dental Floss Waxed with T36-C5* Melaleuca oil to get the antibacterial effects below the gum line.
Breath-away Mouthwash Concentrates
Contains the therapeutic power of T36-C5*. Rinse before brushing to enhance the effectiveness of the toothpaste and rinse after brushing to leave breath fresh.

NICOLE MILLER SKIN CARE.
For beautiful, healthy-looking skin. Clinically-proven formulas contain extracts and proteins to go beyond gentle cleansing & moisturizing to fade the appearance of wrinkles, age spots, and fine lines. More beneficial for your skin as they contain supplement-strength vitamins for true age-defying results.

ADVANCED EXPRESSIONS*.
Get a salon look - without the salon! 13 great products! Hair specific shampoos & conditioners, non-aerosol styling sprays, alcohol-free styling gels and cutting-edge foam. Designed with XPS Complex (exceeds the competition with more nourishing vitamins, essential oils & natural extracts, protects hair color with 4 UV protectors - maximum sun protection, styles your hair with dual heat-activated styling elements - including phytantriol - which turns blow dryer or curling iron heat into a styling ally) each patent-pending formula is engineered to energize your hair with healthy-looking shine, bounce & manageability . . . ultimately giving you the power of statement!

GREAT TASTING NUTRITION.
To really lose weight & keep it off, you need to cut calories and exercise at least 30 minutes a day. Melaleuca helps you with**ATTAIN* shakes and bars:**
Attain* Nutritious Shakes (Rich Chocolate, Creamy Vanilla, Chocolate Raspberry, Chocolate Malt).

The number one protein weight-loss drink! Body-building protein - 13 gm. of protein including 8 gm. of the precious soy protein - potentially beneficial to the cardiovascular system & in preventing breast cancer proven by research (potent soy isoflavones found to have significant health benefits). Add 8 oz. milk (8 gm. protein) for a total of 21 gm. in one glass. (SlimFast only has 5 gm., and none of it is soy protein.) Low fat - only 2 gm. of fat & only 130 calories - won't weigh you down! Richly fortified with minerals & vitamins - beats the other leading brands. (The vitamin-mineral amounts in Attain* are so far above SlimFast that there is no comparison, and yet the cost of Attain* is only 74 cents while SlimFast is $1.00/serving.) Best source of fiber - with cellulose, soy & oat fiber, corn bran, & even psyllium husk - 3 grams fiber helps digestion & contributes to a feeling of fullness. Great taste - shake with water for a quick pick-me-up or shake with milk for a delicious milkshake (add ice cubes & blend for colder thicker taste treat). Convenient - perfect for a fast breakfast, a meal on-the-go, or a nutritious & tasty snack. And now,**Attain*** comes in delicious protein bars.
Attain* Nutritious Bars (Chocolate Raspberry, Cookies & Cream)
Great-tasting protein bars.
Access* Fat-Conversion Activity Bars(Black Cherry, Mint Chocolate, espresso Praline, Peanut Butter)
Helps the burning of one's stored fat. Energy enhancement for physical activity.
This is Fiber?!* Bars (Apricot Apple, Apple Cinnamon, Cherry Almond, Banana Nut).
Enjoy the snack that gives you over 25% of your daily fiber requirement with delicious fruit & fiber bars.
Sustain* Energizing Smoothies (Classic Orange Creme, Luscious Peach, Lively Pina Colada, and Fresh Strawberry). Delicious Fruit Beverage helps keep you going all day with carbohydrates, 100% vitamin C & only 2.5 grams of fat giving you a healthy boost of energy that won't ruin your figure. Also makes the smoothest home-made ice-cream.
Melaleuca Herbal Tea & Herbal Tea Variety (Tangy Lemon, Ginseng, Apple-Berry, Herbal Evening).



Natural herbs like ginseng & chamomile soothe your body and clear your mind.

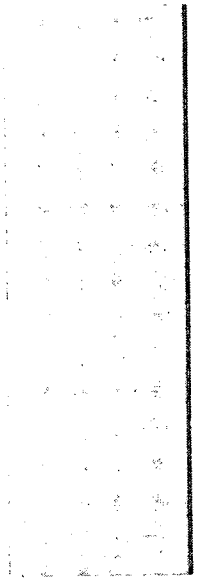
DAILY 4 LIFE* Basic Nutrition.
Make your remaining years healthier years. This exclusive health pack consists of vitamins & minerals (with patented Fructose Compounding for easy assimilation), proven antioxidants, and natural heart protection. A patented absorption process, cutting-edge research, and unprecedented human studies make this combination a wise investment in your most important asset . . your health.
1&2. THE VITALITY PAK*: 1) Mel-vita* (55 important vitamins, minerals and other nutrients) 2) Mela-Cal* (Calcium & vitamin D for strong bones) Patented Fructose compounding. Nutrition you can feel as it is assimilated.

PROVEX CV*
Maintain a healthy heart with the only supplement based on university human studies. Premium ingredients including specific varieties & highest quality of grape skin & grape seed, gingko biloba and more. Leader in cardiovascular heart protection. Exclusive enzyme blend. Superior antioxidant extracts. This patent-pending revolution is the only flavonoid product proven in human studies to help support normal platelet activity.

CELL-WISE* NATURAL E.
Protection at the cellular level. Exclusive combination of powerful proven antioxidants. Exclusive Blend of Antioxidant Vitamins C & E, Beta Carotene, Zinc & Selenium.

NATURAL SOLUTIONS for joint mobility, prostate health, menopause, or mood support. Complete, science-based formula includes natural extracts, vitamins and minerals blended specifically to address your particular health concern. Based on years of research and consistent quality testing.

XEL 000535



REPLENEX* Joint Replenishing Complex*.
"I was surprised to find my knees didn't bother me." With 500 mg. of the purest glucosamine available, helps the body preserve the health of joints, promoting ease of movement.

PROSTAVAN* Promotes Prostate Health*.
Support prostate health. Maintain normal urinary function with this unique blend of saw palmetto berry, pumpkin seed, zinc & high-quality lycopene*.

ACTIVATE IMMUNE COMPLEX*. Unique combination of echinacea (900 mg./serving - the amount used in clinical research), astragalus, vitamins and other natural ingredients. Increases your resistance. Helps you stay well.

ESTRAVAL* Natural Support for Menopause.
Replaces lost estrogen with natural plant estrogens from soy, black cohosh and dong quai. Helps reduce the occurrence of hot flashes.
LUMINEX* Mood Regulation.
Patented formula contains the exclusive dual-action of St. John's wort and griffonia seed for consistent mood-maintenance. With folic acid and vitamin B-12.

NUTRAVIEW*. Powerful Vision Protection*,
helps maintain healthy eyes. The eye is the only part of the body where blood vessels, nervous tissue, and highly specialized cells are exposed to light which can have negative effects. Exclusive formula helps keep your eyes healthy and seeing clearly by promoting optimal function of the macula and lens. With purified lutein crystals, vitamin C, blueberry and billberry.

PROVEX*.
Protection for Healthy Blood Vessels, Tissues and Organs*, helps support strong blood vessels, promoting healthy circulation and improved skin elasticity. Highest-quality grape seed extract with citrus bioflavonoids. Costs up to 60 cents less per day than similar products.

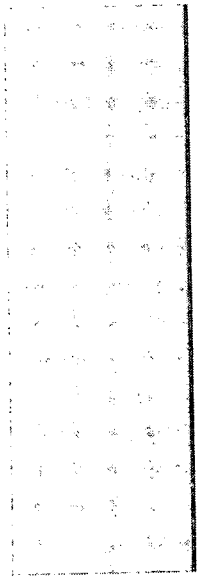
PROVEX-PLUS*.
More Protection for Tissues, with ginkgo biloba*. More antioxidant protection for those who live in polluted areas, or who want more ProVex* power. Patented extraction process ensures quality.

THE VITALITY PAK* PRENATAL.
Protection for Mom & Baby. Unique formulation designed specifically for the needs of pregnant and nursing mothers. Includes recommended levels of iron & folic acid with patented Fructose Compounding.

VITA-BEARS*.
Protection for Kids, with 20 crucial nutrients for growing bodies, wild cherry fruit-juice flavor and a fun koala-shape make them a hit with your kids. With patented Fructose Compounding to promote mineral absorption.

PERSONAL CARE PRODUCTS include everything we use for ourselves in the course of the day. Toothpaste, mouthwash, dental floss, soap, bath & shower gels, bubble bath, shave gel, after-shave & cologne, shampoo, conditioner, styling gel, facial care, purifying facial masque, eye make-up remover, cleansing cream, facial toner, moisturizers, make-up base and powder, alpha-hydroxy cream, hair spray, perfume, hand & body lotion, deodorant, patented fat conversion activity bar, meal replacement drink for weight control (tastes great!) and much more.

The color dye in our products is vegetable dye and if you leave it in the sun, it will turn clear. The products are colored so you can easily and quickly tell one from the other. MELALEUCA'S SAFE PRODUCTS for people and the environment saves us problems both now and in the future. Obvious problems are from dangerous chemicals; "other behavior and health disorders caused by chemicals in our home include coughing, wheezing, nasal congestion, burning eyes, headache, burning tingling and flushing of the skin, muscle aches, irritability, mental confusion, uncoordination and hyperactivity" . . . according to William Rea, M.D. of Dallas, past president of the American Academy of Environmental Medicine.



You may request a more extensive cost comparison (a documentation prepared by a lawyer) on 45 Melaleuca products showing an average of 27% below retail for these products. Just request it by fax or email. You may also request, by fax or email, a price comparison of Melaleuca's prices with Wal-Mart's prices which shows conclusively that Melaleuca's prices are lower than Wal-Mart's. And even though Wal-Mart's "return merchandise policy" is the leader in the industry, Melaleuca's "return merchandise policy" surpasses every company in the world. For example: You may take Melaleuca's Vitality Pak* consisting of MELA-VITA* & MELA-CAL* (both mineral & vitamin supplements working together) for a period of 90 days, and if you subjectively do not think you "feel better," you may return all of the empty bottles for a full refund - no questions asked. This is an unequivocal, unconditional guarantee. This guarantee is based on superior quality over the competition together with Melaleuca's patented Fructose Compounding whereby minerals are encompassed in a fructose molecule thereby tricking the intestines thus gaining entrance into the blood stream yielding a 95% assimilation (compared to almost no assimilation of many store-brand vitamins and minerals that pass right through the body. Melaleuca's supplements are pharmaceutical grade, pure quality, and contain what is on the label.

Notice: Did you know that what is on the label in the stores is not always what is in the product? Did you know that the stores with a "sole profit motive" are buying vitamin C very cheap from China which contains trace amounts of mercury, lead, & arsenic. The FDA allows this, because they think that you will take only 200 mg. a day which is such a small amount that these metals will not accumulate sufficiently to damage your health. Did you know that a prostate formula can cost over twice as much as Melaleuca's high quality formula called PROSTAVAN* and still not be standard extracts. Standard extracts can cost over 3 times more than

PROSTAVAN* which has high quality extracts. PROSTAVAN* has reduced PSI in men from a high of 52 to as low as one which is normal. OPC in PROVEX*, PROVEX-PLUS*, & PROVEXCV* come from a new exclusive kind of grape seed & grape skin with the highest-quality flavonoid concentrations - laboratory tested to contain significant amounts of flavonoids with powerful antioxidant & platelet inhibiting properties. From a new exclusive extraction process, these grape skins are never exposed to sulfur dioxide (S02) which can cause an allergic reaction in some people, nor are the grape seeds ever exposed to fermentation which is quite common in order to save money and which significantly lowers the flavonoid content. Melaleuca is the largest manufacturer of OPC in the world. (See Melaleuca PROVEX* brochures just 39 cents & 49 cents. Why not order one when you order your monthly product? The brochures are so well done and contain a wealth of information. We like to order a new brochure each time we order our monthly product. There are 24 brochures at 39-49 cents each. You may also order from Melaleuca, Inc., 12 booklets at 99 cents each, 25 audio tapes at $2.99 each, and 4 videos at $3.99-$9.99 each.) When "natural" performs much superior over "chemical" and is nontoxic, nonpoisonous, and noncarcinogenic, why would you continue to subsidize the great chemical industry, especially when you have to pay higher prices? Did you know that the two leading causes of death of our children are cancer and poisoning in the home - both stem from the products parents bring home from the store?! It's time to think about it!

Retail Sales Jobs & Career Information

Action Sports Sales Jobs
Agri Sales Jobs
Alternative Health Products Sales Jobs
Alternative Products Sales Jobs
Automobile Sales Jobs Houston Tx
Automotive Jobs After Sales
Automotive Sales As A Second Career
Aviation Sales Manager Open Jobs
Best Online Sales Careers
Beverage Sales Careers
Beverage Sales Jobs
Car Sales As A Career
Car Sales Career Salary
Career Fair
Career Fishing Sales
Career In Scientific Apparatus Sales
Career Info On Export Sales Manager
Career Information + Sales Promotion
Career Opportunities In Furniture Sales
Careers In Picture Frame Sales
Careers In Vacation Ownership Sales
Catering Sales Manager And Jobs
Customer Service Jobs Retail Sales Wholesale
Early Learning Jobs
Sales Representative
Electrical Sales Jobs
Fire Equipment Sales Jobs
Funeral Home / Cemetery Supply Sales Jobs
Getting Into Sales Career

Nutraceutical Or Herbaceutical Sales Jobs

Various sales jobs to be filled.
Enhance your sales career with the various employment resources we provide. Including access to our jobs database of vacant jobs to apply for.

"Executive Search Consultants for the Medical Imaging and Medical...
We are dedicated to providing our clients with the highest quality service, and therefore subscribe to the highest professional ethical standards.

Add Your Site!

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Graduate Career Fairs - Sales
Graduate Sales Representative
Career Fairs
Hair Care Product Sales Jobs
Hardware Sales Jobs
Home Party Sales Jobs
How To Break Into A Sales Career
How To Interview For Sales Rep Jobs
Independent Cotractor Jobs For Profressional
Inside Sales Jobs
Rochester New York
Institutional Debt Sales Jobs
International Traveling Sales Jobs
Irrigation Sales Career
Irrigation Sales Career Agriculture
Jobs Customer Support Engineer
Sales Technical
Jobs For Insurance Sales Trainers
Johnson And Johnson Careers Sales
Laser Sales Jobs
Marriott Sales Jobs
Medical Device Companies Sales & Markering
Medical Sales Career Placement
Medical Sales Management Jobs Georgia
National Retail Sales Jobs
New England Sales Jobs
Nuclear Medicine Sales Careers
Nuclear Medicine Sales Jobs
Nutraceutical Or Herbaceutical Sales Jobs
Optical Equipment Sales Careers
Orthpaedic Equipment Sales Career
Outside Sales Careers In Illinois

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Outside Sales Jobs In Bc
Pet Industry Sales Jobs
Pharcutcul Sales Jobs
Pharmaceutical Sales Career Websites
Pharmaceutical Sales Jobs In Dubai
Pharmaceutical Sales Jobs In Seattle
Pharmaceutical Sales Jobs Tampa
Pharmeceutical Sales Careers
Pharmicutical Sales Jobs
Pharmisutical Sales Jobs
Phoenix Outside Sales Jobs
Produce Sales Jobs
Real Estate Sales Career Colorado
Recycling Equipment Sales Jobs
Rehab Equipment Sales Jobs
Rehabilitation Products Sales Jobs
Retail Sales And Job Description
Retail Sales Management
Merchandising Jobs
Salary Plus Commision Sales Jobs
Sales And Marketing Jobs In Agriculture
Sales And Marketing Merchandiser Jobs
Sales Books Jobs
Shopping Business Books
Sales Career Info For Selling Sun Rooms
Sales Jobs In Plastic Packaging
Sales Jobs In The Uk
Sales Jobs In The Wine Industry
Sales Jobs Metasearch
Sales Jobs New York Metro
Sales Jobs Police And Security
Sales Manager Jobs In Tampa Florida
Sales Rep Career Centers

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Sales Representative
Jobs Kansas City
Sammy Hagar Career
Record Sales
Scientific
Instruments Career
Sales
Security Sales Jobs
Telcommunications
Sales Career
Top Independent
Sales Rep Jobs
Top Medical Sales
Jobs Houston
Top Sales Jobs In
The Us
Toyota Sales Career
Why A Sales Career
Why Career In Sales
Why Career Sales
Why Have A Sales
Career
Why Sales As Career
Wine And Spirits
Sales Jobs
Wine Sales Jobs In
South Florida

ADD CATEGORY

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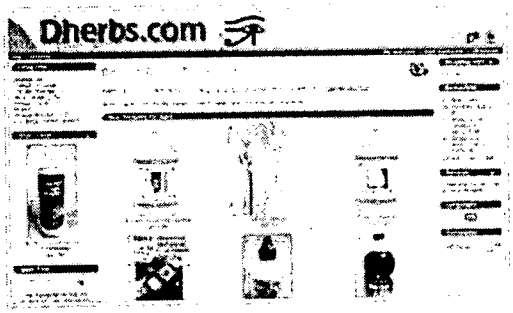
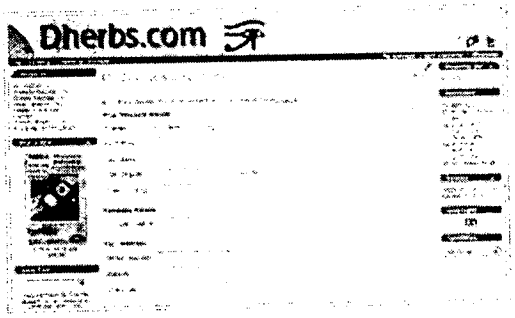
Web Development Portfolio





Dherbs.com E-Commerce

Launch Web site

Dherbs was in need of an e-commerce solution to sell their various herbaceutical products. We chose to implement the open source shopping cart OSCommerce. It is a cost effective choice for the company and is compatible with various credit card merchants.

<< previous

XEL 000542

Free Email Newsletter
Health News
Headlines
Embolization for Fibroids

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Acronym Expander
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Forums & Support Areas
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Meet Our Editorial Advisors
Ob/Gyn Journals
Medline
PowerPoint Presentations

Practice Tools
Build your own web page
Education & Career
Employment Opportunities
Find a CV
Medical Web Sites
Resident CVs
Search for Web Sites

Images & Videos
Audio/Video
Image Library
Conference Calendar
OB-GYN Calendar
OB-GYN Upcoming Meetings
Conference Coverage
Conference Interviews
Medical Resources
Academic Departments of OBGYN
Academic Links
Acronyms Explained
Associations and Societies
CMEs
Doctoral Theses
Hospital Links
Journal Review
McGill University Student Projects
Medline Knowledge-finder
Ob/Gyn Journals
OBGYN Links
Student Resources
News and Views
Free Email Newsletter
Health News
Vendor Directory
Add your company

Study evaluates effects of berberine on bone mineral density in murine model

Osteoporosis
February 27, 2003

2003 FEB 27 - (**NewsRx.com** & **NewsRx.net**) -- According to recent research from Japan, "the effects of berberine in senescence accelerated mice P6 (SAMP6) were investigated to learn whether the alkaloid affects bone mineral density (BMD)."

"Oral administration of berberine (10 mg/kg/d) to male and female mice for 22 weeks resulted in an increase in BMD in both sexes. A decreased concentration of deoxypyridinoline (Dpd) in urine was only observed in female mice," said H.Y. Li and colleagues, Toyama Medical and **Pharmaceutical** University, Institute Natural Medicine.

"There was no effect on body or tibia **weight**or on the concentration of procollagen type I carboxyterminal extension peptide (PICP) in serum," researchers concluded (Effect of berberine on bone mineral density in SAMP6 as a senile osteoporosis model. Biological and Pharmaceutical Bulletin, 2003;26(1):110-111).

For additional information, contact S. Kadota, Toyama Medical and Pharmaceutical University, Institute Nat Med, 2630 Sugitani, Toyama 9300194, Japan.

To subscribe to the journal *Biological & Pharmaceutical Bulletin*, contact the publisher: Pharmaceutical Society Japan, 2-12-15-201 Shibuya, Shibuya-Ku, Tokyo, 150, Japan.

The information in this article comes under the major subject areas of Herbaceutical, Complementary and Alternative Medicine, and **Osteoporosis** This article was prepared by Women's Health Weekly editors from staff and other reports.

return to OBGYN.net Headline News ... (2001 archives)

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Search
Equipment
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Supplies
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Professional Services
Supplies
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Awards Given
Become a sponsor
Contact Information
Family Album
How to Get Involved
Linking to OBGYN.net
Meet Our Editorial Advisors
Our Sponsors
Our Staff

XEL 000544

B2B For Trade - View Companies - Health & Beauty - Weight Loss

Statistics: Companies: **110,200+**, Trade Leads: **63,900+**, Products: **16,900+**, Contacts / Replies: **214,200+**
There are currently **477** users online browsing our B2B network. 18:41 GMT, Thursday, March 30, 2006
Manufacturers **Distributors / Wholesalers** **Trading Companies** **Agents** **Buying Offices** **Importers / Exporters**

7 Companies found that match your criteria.
Classification: Health & Beauty - Weight Loss
Manufacturers
Showing results from 1 to 7.

Company Index A B C D E F G H I J K L M N O P Q R S T U V W X Y Z 0 1 2 3 4 5 6 7 8 9

Bid	Logo	Company - Description
0	No Logo	**E-Two One Sdn. Bhd.** *Member since 24 March, 2004, Malaysia - Selangor*

Primary Business Type(s): Manufacturer, Distributor / Wholesaler
Buy & Sell Offers: 1 Trade Lead posted by E-Two One Sdn. Bhd.
Products: **0** - No Current Products

0 A1

Emphatec
Emphatec is service providing company wholly owned by me. Our basic expertise lies in sourcing the quality and economic pharmaceutical, nutraceutical cosmecutical and herbaceutical formulations. We are in the field of providing assistance to our ...
Member since 5 December, 2005, India - Maharashtra

Primary Business Type(s): Manufacturer, Importer / Exporter
Buy & Sell Offers: **0** - No Current Trade Leads
Products: **0** - No Current Products

0 A1 No Logo

Enya Technology
Enya Technology is a one-stop product trading company. We currently carry healthcare, & jewellery products. We also provide Singapore-based educational tours to enhance the

XEL 000545

skills of SMEs handmade jewellery makers from all over the world. ...
Member since 3 February, 2006, Singapore - All

Primary Business Type(s): Manufacturer, Trading Company, Importer / Exporter
Buy & Sell Offers: **0** - No Current Trade Leads
Products: 1 Product on sale by Enya Technology

0 No Logo **EsthEdeS Institute International Inc**
Member since 4 March, 2005, Singapore - All

Primary Business Type(s): Manufacturer
Buy & Sell Offers: 1 Trade Lead posted by EsthEdeS Institute International Inc
Products: **0** - No Current Products

0 No Logo **Etumax Corporation**
Member since 3 January, 2005, Malaysia - Selangor

Primary Business Type(s): Manufacturer
Buy & Sell Offers: **0** - No Current Trade Leads
Products: **0** - No Current Products

0 No Logo **Experiences Cosmetics**
Member since 26 April, 2004, France - Ile-de-France

Primary Business Type(s): Manufacturer, Trading Company
Buy & Sell Offers: 1 Trade Lead posted by Experiences Cosmetics
Products: **0** - No Current Products

0 No Logo **Ezee Soulnature Healthcare P L**
Herbal Wellness Products: Natural Cosmetics, Personal Care Products & Food Supplements Ezee Soulnature Healthcare is seeking exclusive distributors/ licensee for its range of products in various countries. The exclusive country license...
Member since 22 November, 2004, India - Delhi

Primary Business Type(s): Manufacturer
Buy & Sell Offers: 2 Trade Leads posted by Ezee Soulnature Healthcare P L
Products: **0** - No Current Products

Related Site Sections:
Trade Leads: Health & Beauty - Weight Loss
Product Showroom: Health & Beauty - Weight Loss
Biz Keywords: Health & Beauty - Weight Loss
ODP: Health: Beauty
ODP: Shopping: Health
ODP: Business: Consumer Goods and Services: Beauty
ODP: Business: Healthcare: Products and Services

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Browse Companies
Browse Products
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Welcome to B2B For Trade, B2B Marketplace designed for **Global Manufacturers**, distributors, exporters and importers. Online Import Export Marketplace for all trading companies to introduce and advertise themselves in front of thousands of **Buyers and Sellers**. Now offers a brand new **FREE Product Catalog** feature to advertise your **Products and Services**.

B2B For Trade is an innovative B2B marketplace designed to help you find new business partners from all over the world. To announce your company to the whole world, among other **Featured Companies**: Simply, **Add Your Company** Description and **Add Your Logo**. You can easily search through the **Company Directory** and the **Trade Leads** by both country and industry

XEL 000546

classification. To **Send Your Offers** by geographical location and primary **Industry Classification** to tens, hundreds or even to thousands of companies use our **Targeted Trade Leads** feature. Even **Bid** on your Trade Leads and Company to get them into **top positions** within this exciting B2B marketplace. Get your special **Biz Keyword** at no extra cost now!

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Privacy Policy

5,631,184 Visitors

Since July 1, 2003

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SECTION VI. PHYSIOLOGICALLY FUNCTIONAL HIGH POTENCY WHOLE HERB CAPSULES (HERBACEUTICALS)

More than half of today's medicines were derived from plants. Some primates in the wild have been known to self-select medicinal herbs for treatment of various diseases. Today, herbaceuticals are used not only to heal the body of various physiological disruptions, but also to make the body better able to take care of itself. In line with these mainstream acceptance of herbaceuticals, analytically verified or standardized extracts are now the norm. With standardized extracts, herbaceuticals from PharmaBiosis, Inc., have gained better scientific reliability and efficacy. Along with our standardized extracts and their consistent biochemical properties, we at PharmaBiosis are always cognizant of the "roots" of our supplements. This earth-centered awareness is in line with our belief that all life forms are interdependent and that medicines, nutraceuticals, herbaceuticals and nutritionally balanced foods are synonymous paradigms for healthy lifestyles.

In this section, a partial list of our physiologically functional herbaceuticals is itemized as to constituents and some of their many medicinally therapeutic functions:

- **PharmaBiosis High Potency and High Quality Echinacea Root** – The Immune Booster Helps fight infections

- **PharmaBiosis High Potency and High Quality St. John's Wort** – The Natural Sedative & Pain Reliever Helps in pain relief

- **PharmaBiosis High Potency and High Quality Ginkgo Biloba** – The Natural Cardiovascular & Brain Nutraceutical Helps promote mental acuity
- **PharmaBiosis High Potency and High Quality Saw Palmetto** – for Diuresis and Reproductive Health Helps promote sexual health

These, and other herbaceuticals or herbaceutical combinations not listed here, can be obtained by contacting PharmaBiosis, Inc., at the e-mail, phone, fax or mailing address listed on the cover of this catalog.

About our Program . . .

Over the last 50 years, researchers at the great Spas of Europe have developed weight loss and wellness programs which combine the power of herbal remedies with the precision of modern pharmaceuticals. The resulting "herbaceutical" formulations have helped thousands of patients achieve safe, effective and long lasting weight reduction.

Now, through a partnership with the health care providers at PNLabs.Com, a web based version of the program is available to our patients.

Your participation in the program begins with an evaluation by your PNLabs certified Provider. If your medical history and physical examination qualify you for the program, your metabolic data and specialized blood test results will be downloaded via the web to our centralized processing computer. There, our patented software program will match each patient's metabolic requirements with the appropriate "herbaceutical' formulation. These unique formulations will decrease your appetite and increase your ability to burn what you eat rather than store it as fat. When combined with our prescribed exercise and nutrition guidelines, the **Physician's Weight Management Program** has been shown to effectively result in significant weight reduction and the resultant increase in physical and emotional well being.

And most importantly, always under the supervision of your PNLabs certified health care provider.

XEL 000549

PRE-LAUNCH UPDATE

HAWAII HERBALTECH CORP

LAUNCHING NOVEMBER 22, 2002

JOIN OUR PRE-LAUNCH DISCUSSION LIST

topica

Join HawaiiHerbalTech!

your email Join

HOW TO ACHIEVE FINANCIAL INDEPENDENCE...

...IN THE NEW GLOBAL ECONOMY!

XEL 000550

This update is designed to keep you informed of the organizational development schedule for **Hawaii HerbalTech Corporation**. This eliminates confusion and stops the rumor mill from distributing erroneous information. If you did not hear it here, it isn't so!

INSTANT INFORMATION BY E-MAIL AUTORESPONDER

OR PDF FILE DOWNLOAD

- **OPPORTUNITY INFORMATION AUTORESPONDER**
- **DISTRIBUTOR APPLICATION AUTORESPONDER**
- **COMPENSATION PLAN AUTORESPONDER**

Click here to download the Distributor Application PDF and the Distributor Agreement as PDF files. You can then print them out and use them to complete your own application process and sponsor new distributors. You can also redistribute the PDF files online from your websites or as email attachments to your prospects.

You will need to have Adobe PDF Reader on your computer to open this PDF file. It is a free download at: Get Acrobat Reader

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FAX-ON-DEMAND: 1-402-951-5501 (*from your fax machine*) Request Document # **300**. Instantly receive seven (7) pages of exciting information including an application and dealer agreement

---

[redacted]

LAUNCH DATE:

We have set **November 22, 2002** for the highly anticipated launch date of Hawaii HerbalTech's™ dynamic new network marketing program. You will be kept informed along the way by this newsetter. It is our intention to publish this update only once per month until November 1, 2002, and then weekly.

XEL 000551

TEMPORARY WEBSITE AVAILABLE:

Until the official launch of our Hawaii HerbalTech™ Mega-Site and CyberSponsor™ System we will maintain and update our temporary informational site at: **http://www.hawaiiherbaltech.com**

For those of you who are ***pre-building*** a team, this site will provide you...*and your potential team members*...with up-to-date information on the development of the company and its programs.

MARKETING TOOLS:

In addition to some of the most revolutionary herbal product formulations in the alternative healthcare industry...you will discover that our marketing tools are state-of-the-art. Our collateral material...i.e. brochures, packaging, product labeling, etc. is being designed by one of the top creative talents in the world today. The quality of both our products and our promotional material will set us head-and-shoulders above the competition....and give you the image you will be proud to represent.

As we progress, we will have available full color sales sheets, sponsoring brochures, and broadcast quality audio and visual materials. Web **banners** are available now.

We are commited to providing our distributors with every available marketing tool....and then some. We'll be **far beyond Wave4!**

MAJOR KICK-OFF LEAD GENERATION PROGRAM:

Our early builders will reap the business-building power of a significant initial [company paid] advertising and lead generation system. Working closely with the experts at **Cutting Edge Media** and **Money Makers Monthly** we are designing a **full-color, full-page, display advertising** and **full color card deck promotional program** that will generate a flood of leads....all **FREE** to you!*

This first Lead Generation Co-op will be 100% company funded. Subsequent co-ops will be available in shares at a share cost which reflects the individual ad schedule.

* (Available to our top 100 pre-launch distributors. If you have signed up and purchased your initial **Fast Start Pak** for $75.00 prior to November 22, 2002. *The 100 distributors with the largest pre-launch downlines who have all five front-line positions filled, will receive this as a FREE BONUS for their pre-launch efforts!*)

** [Founding Equity Partners (see website) are automatically included in this pre-launch advertising package and will be placed in the *top twenty five positions* in the overall compensation matrix. Regular distributor numbers will begin at the 26th position.]

This program will provide each participating distributor with a private voice mailbox where you can

pick up your fresh leads daily. Leads are assigned on a purely rotational basis.

Think about this for a moment. Just for being one of our early pre-launch team builders....you will not only be on the ground floor of a company that many savvy marketing pro's are already calling the next mega-healthcare marketing company....but you will have earned a share of a huge kick-off ad program. Now, that's the way to get started!

---

5 x 6 COMPRESSED POWERMATRIX COMPENSATION SYSTEM:

(subject to revision)

Hawaii HerbalTech Corporation has chosen a dynamic, but easy to explain, highly profitable **5 x 6 Compressed PowerMatrix Compensation System**.

Minimum monthly purchase to qualify for commissions on the first three levels is $75.00 (CV). Qualification on levels 4 through 6 require a $100.00 (CV) per month purchase.

The plan pays a whooping 50% of CV (Commission Value) over the first three levels:

- 15% of CV on the first level
- 30% of CV on the second level
- 5% of CV on the third level
- 5% of CV on the fourth level
- 5% of CV on the fifth level
- 2% of CV on the sixth level

=62% PAYOUT!

40% WEEKLY FAST START BONUS!

Our *WEEKLY FAST START BONUS* assures you of fast cash flow from your sales efforts. Regular downline commissions start on the second monthly purchase by a new distributor. The sponsoring distributor receives an immediate 40% bonus (paid weekly). Active business builders will find this fast cash flow an exciting profits source...and a great way to get new distributors off with a *fast-track* commission source.

$1,000 PRE-LAUNCH FAST BUILDER BONUS:

As a special incentive to our early pre-launch business builders you will be eligible to win a ***$1000.00 Fast Start Bonus*** if your downline organizations purchase volume is $7500.00 or higher prior to the official launch date of November 22, 2002.

The top volume (CV) distributor during this same period will win an **all expense paid trip for two to fabulous Las Vegas** for five nights. Round trip air fare from any U.S. city, deluxe accomodations are included. It's our way of saying Mahalo (thank you) for your efforts.

FAST START PAK:(hhfsp-1)

Our **Pre-Launch FAST START MARKETING PAK** will be ready to ship on May 1, 2002. The price

is $75.00. (CV=$75.00) It will include:

- Hawaii Herbaceuticals ™Opportunity Audio Tape
- Compensation System Brochure
- Distributor Applications and Agreements
- "*Herbaceutical Health Tips*" Newsletter
- One bottle of Hawaiian Toxi-Clear™

(Note: Bottled product will not ship until the official launch date. Fast Start Pak bottled product orders will be automatically shipped on that date.

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XEL 000555

Deadly Bird Flu

Post Reply

November 19th, 2004 #1

X-C

Posts: n/a

Deadly Bird Flu

http://story.news.yahoo.com/news?tmp..._hongkong_dc_2

I say it is a matter of *when* the bird flu hits. Any predictions? It will be a very scary time for everyone, no doubt. But if it does hit, I predict it will be more isolated in Asia.

Quote

November 20th, 2004 #2

mrtiger's Avatar

mrtiger
My Head humps-humps

Join Date: June 17th, 2004
Posts: 162
Rep Power: 0

Re: Deadly Bird Flu

Never heard of the bird flu. I should look into that.☺

Quote

November 20th, 2004 #3

Mihail
Love well, Whip well.
ADVANCED MEMBER

Join Date: January 19th, 2003
Location: Novistrana
Age: 23
Posts: 9,759
Rep Power: 16

Re: Deadly Bird Flu

never heard of a bird flu either, I suggest people stop letting birds cough on them, or eating dead birds they find around their yard.

When I take action, I'm not going to fire a $2 million missile at a $10 empty tent and hit a camel in the butt. It's going to be decisive.

-George W. Bush

Quote

November 19th, 2004 #4

X-C

Posts: n/a

Re: Deadly Bird Flu

The bird flu will be the beginning of the next plague.

Quote

#5

November 29th, 2004

~~Cataphract~~

Pure Owned by GF
No longer welcome here
USER

Join Date: January 31st, 2004
Age: 19
Posts: 1,526
Rep Power: 0

Re: Deadly Bird Flu

Yeah, yeah, they said that about SARS. But disease is becoming more prevalent nonetheless.

Quote

#6

November 29th, 2004

Majïç MushrøøM

Undead Warrior of Virtue
SUPER MODERATOR

Join Date: November 29th, 2003
Location: Noman's Land
Age: 20
Posts: 11,734
Rep Power: 16

Re: Deadly Bird Flu

It will be interesting to hear about how far this illness spreads after a given period of time, as will it be to hear what precautions to take and what remedies there are for it.

Quote

#7

November 29th, 2004

Spyder F-16's Avatar

Spyder F-16

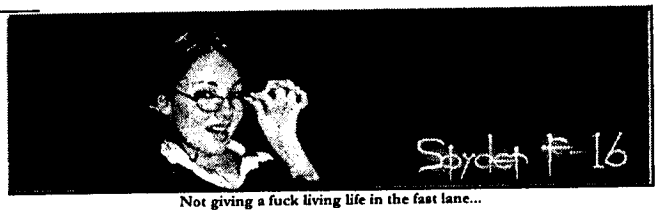
Amerika ist Wunderbar
Captain

Join Date: February 2nd, 2003
Location: Bullseye 206, 95. 12 O'clock High, Angels 10. Hot
Age: 25
Posts: 2,839
Rep Power: 9

Re: Deadly Bird Flu

Flu strains are Viral. Theres not much you can do except vaccines. And there isnt going to be vaccines for this until 2006 from what i've heard.

Heck, I never get the flu and I dont get a shot anyways 😊



Not giving a fuck living life in the fast lane...

Quote

#8

November 29th, 2004

XEL 000557

AegenemmnoN
Remember the 5th of November
MODERATOR

Join Date: August 19th, 2003
Location: the Shire. and i have a house in Minas Tirith
Posts: 8,204
Rep Power: 14

Re: Deadly Bird Flu

oh well. everyone is now going to die from the DEADLY BIRD FLU!
AAAAAAAHHHHHHHHHHHHHHH!!!!!!!!!!!!!

jesus chrispy. unless it actually happens, no need to worry over it. its stupid that people get so worked up over these kinds of things.

^ My God...YES!

Last edited by AegenemmnoN : November 29th, 2004 at 10:08 PM.

Quote

#9

November 29th, 2004

~~Cataphract~~
Pure Owned by GF
No longer welcome here
USER

Join Date: January 31st, 2004
Age: 19
Posts: 1,526
Rep Power: 0

Re: Deadly Bird Flu

Heck, I never get the flu and I dont get a shot anyways 😁

Yeah. I can't stand people who every time they get a cold they run out and buy tons of different medicines. I don't even take vitamin C. I take *nothing* at all.

Most of the time, the best way to battle a cold or a flu or whatever is simply not to take any strange medicines. Allow your body to do the job it was meant to do (work up its own immunity). Also, eat healthy foods and drink healthy drinks. I haven't had a cold in over a year. But these pillpushers (the pharmaceutical companies) want you to think that if you don't buy Advils or Excedrins or Robitussins or whatever, the sickness isn't going to go away.

And then, on the other hand, you have those people who buy a million types of herbs. Most of the time, they have no idea what they are buying, but it's an herb, and herbs are good for you! Unfortunately, they do not help most types of sicknesses. The "herbaceutical" companies are just as bad as the pharmaceutical companies.

Also, I have never gotten a headache or migraine in my life (I'm a student at Northeastern University, dual major in electrical and computer engineering). I've never gotten chickenpox (though I just got a shot a few months ago, requirement for college medical forms). I'm not allergic to poison ivy or poison oak at all. The only three types of illnesses I've ever had are the common cold, the flu, and Lyme disease (caused by insect bites...you get big rashes on certain parts of your body).

Last edited by Cataphract : November 29th, 2004 at 10:17 PM.

Quote

#10

November 30th, 2004

XEL 000558

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3. Shawnee Moon **Herbaceuticals**
... Victoria Fortner & Shawnee Moon **Herbaceuticals**, with over thirty years of experience in identifying, gathering, preparing, combining, administerin...
http://www.shawneemoon.com/

4. Tradeblanket
Shawnee Moon **Herbaceuticals** is proud to offer to it's customers exclusive access to the arts and crafts. ... Please e-mail request to: Shawnee Moon **Herbaceu**...
http://www.shawneemoon.com/tradeblank...

5. Herborium **Herbaceuticals** - Order
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http://www.herborium.com/Order.asp

6. Herborium **Herbaceuticals** - Order
Order UK Please use our Secure Shopping Cart to charge orders to your Visa, Master Card, Discover or American Express. This is the ...
http://www.herborium.com/Order.asp?Re...

7. Welcome to TeaTech
TeaTech?, Inc. is a Utah Corporation wholly owned by Xel **Herbaceuticals**?, Inc. headquartered in Salt Lake City, Utah. Xel **Herbaceuticals**, Inc. ...
http://www.xelherb.com/

8. Fore Golfers Herbs
... Fore! Golfers **Herbaceuticals** are designed with the golfer in mind. Whether ... Fore! Golfers **Herbaceuticals** line of product offers a solution...
http://www.globalhealthmall.com/New_g...

9. magart
... Aubrey Organics. Hair Care * **Herbaceuticals** Rose Petal Lightener gave Carmen golden honey highlights. * Naturcolor Woodruff Blonde ...
http://giftcards.beautysurfsalons.com...

10. TEA TECH
... TeaTech?, Inc. is a Utah Corporation wholly owned by Xel **Herbaceuticals**?, Inc. headquartered in Salt Lake City, Utah. Xel **Herbaceuticals**, Inc. ...
http://shop.store.yahoo.com/enkuerosn...

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XEL 000559

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http://www.adfree4u.com/search/class....

12. Links
products, health, newsletters, employees, links, e-mail Jennifer, LINKS Shawnee Moon **herbaceuticals**.
http://www.jennifersphamacy.com/link...

13. Health Links
... worried. Cameron-Swift **Herbaceuticals** If you?d like an alternative to traditional medicine then why not ask the herbalist? Type ...
http://www.euphony.net/lifestyles/hea...

14. GTW Members | Business Directory
... seegerpeople.com. Cellular Accessory Online Catalog www.e-cellularaccessories.com, Shawnee Moon **Herbaceuticals** www.shawneemoon.com. Express ...
http://members.gtw.net/directory_busi...

15. Angel Investor News.com
... HERBORIUM offers a unique portfolio of all natural, proprietary **herbaceuticals** supported by clinical experience and the innovative use of interactive ....
http://www.angel-investor-news.com/en...

16. Adverse Drug Events
... cause the problem. A patient may fail to tell a doctor about his or her usage of **herbaceuticals** and dietary supplements. This can ...
http://www.therubins.com/geninfo/adve...

17. OrderDog.com - A Store's Best Friend!
... Cones, Carrollton, GA Health From The Sun? **, New Port, NH Heather Loraine Cosmetics, El Cajon, CA Herb Pharm? **, Williams, OR **Herbaceuticals** Inc...
http://www.orderdog.com/default.asp?p...

18. product
... HELIO'S NUTRITION **HERBACEUTICALS** HERBAL-V HERBASWAY HERBATINT HERBS ETC HERBS FOR KIDS HERBS OF LIGHT HERITAGE HOBE HOLGRAIN CRACKERS HOME HEALTH HOME HEAL...
http://www.naturalmarketplace.net/pro...

19. Navigation
... In addition to being the owner/president of Shawnee Moon **Herbaceuticals**, an herbal remedies company, Victoria also lectures nationally on herbal medicines.
http://www.sa.niu.edu/nations/Leaders...

20. Sponsors/Participants
... Other Participants. Artemis Essentials. **Herbaceuticals**. Integrated Healing Systems Unified Healing Technologies. Ideally Struktured Water. [News Release]. ...
http://aztec.asu.edu/makingscents/con...

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21. The Flow of Qi - Site Directory
... Sam's General Store. Shawnee Moon **Herbaceuticals**. Steady Shopper.com. Stronglite. What is Acupressure? What is Alternative Health? What is Massage Therapy?...
http://www.flowofqi.com/adirect.html

22. Products I Love-Household
... Result is rich, vibrant, complex color and soft, silky hair. Formulas available specifically for covering gray. **Herbaceuticals**, Inc. Made in Italy. ...
http://www.livrite.com/prod-house.htm

23. Suppliers Available Through OrderDog?
... From The Sun? **, New Port, NH FAX Heather Loraine Cosmetics, El Cajon, CA ELECTRONIC INVOICE Herb Pharm? **, Williams, OR FAX **Herbaceuticals** Inc., ...
http://www.orderdog.com/uploads/order...

24. Napa
... West Napa 224-3117. **Herbaceuticals** 902 Enterprise Way Napa, Ca 94559 800 462-0666. Herbalife Distributor 4020 Wisteria Way Napa, CA 94558-1943 252-6282. ...
http://www.napayellowpages.com/napa_v...

25. moreparticipants
... Previous Show Write-Up. Advanced Botanical Research. organic rice & soy beverages. Maine Coast Sea Vegetable Co. **Herbaceuticals**. Universe Music.
http://www.aromaherbshow.com/index_01...

26. keratin.com :: View topic - Naturcolor?
... Reply with quote. hi - you may contact Naturcolor (**Herbaceuticals**) directly at 800-784-8212. Author: frisco Guest Post Wed Jun 25, 2003 1:01 am, Reply wi...
http://www.keratin.net/forums/viewtop...

27. Health and Wellness Resources
... Northants. Djehuty **Herbaceuticals** helping people with serious questions in regards to a life threatening health problems. Benegal ...
http://www.excitepc.com/1whey2health/...

28. BUSINESS OPPORTUNITY
... growth characteristics. You can benefit from this dynamic growth by joining the Hawaii **Herbaceuticals**? marketing team today. By ...
http://www.e-comprofits.com/busop.html

29. The Potential of Herbal Products for Nutraceutical and ...
... In some countries the regulatory bodies are becoming more open minded to allowing herbal products to be developed as nutraceuticals or even "**herbaceuticals**...
http://www.phytochemistry.freeserve.c...

30. Bulk Drugs
... Description, : Consultancy , technology transfer in the pharmaceutical bulk drugs , intermediates, **herbaceuticals** , nutriceuticals & speciality ch...
http://www.indianyellowpages.com/indi...

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XEL 000561

Health - Dr. Sean Kenniff, M.D.

Ginkgo Biloba - An Ancient remedy for the failing mind

The scientific community has finally recognized the therapeutic potential of Ginkgo Biloba Extract (GBE) for the treatment of a variety of medical conditions. Most notably, a considerable performance and memory function of patients suffering form Alzheimer's disease. While a growing body of medical evidence has confirmed the potency of this "herbaceutical" in the treatment of memory disorders, the future therapeutic applications of GBE will probably include Intermittent Claudication, Stroke, brain and spinal cord injury, Macular Degeneration, Myocardial Infraction, Tinnitus, Raynaud's Phenomenon, and Congestive Heart Failure.

According to the fossil record, the Ginkgo trees, also known as the maideuhair tree, first appeared approximately 200 million years ago. Indigenous to China and the Southeastern United States, it is considered by some authorities to be the world's longest living species of tree. Individual trees have been reported to live as long as one thousand years, and its medical use in China for respiratory and neurological ailments have been well documented for over five thousand. It is a resilient and tenacious plant, capable of hearty growth in a variety of environmental conditions.

The medical benefits of GBE are derived from its two primary constituents – The bioflavinoids and terpene lactones. Bioflavinoids serve as potent antioxidants and free-radical scavengers in the brain and many other tissues of the body. The bioflavinoids are also responsible for GBE's ability to inhibit platelet aggregation, thus preventing atherosierosis. The terpene lactone component of GBE, also inhibants platelet aggregation, but additionally they exert a neuroprotecttive effect on the neurons of the central nervous system. This constituent has also been shown to increase blood flow to the brain and other organs.

The medical evidence for the treatment of Alzheimer's disease and Vascular dementia is impressive and well established. A 1998 study, published in the Archives of Neurology, reviewed the available published material and compiled the data. Their analysis showed a small but significant improvement in the cognitive functioning of patients with Alzheimer's disease who were administered 120mg to 240mg of GBE daily. Several well-controlled follow-up studies have reproduced this promising result, or have shown a significant slowing of mental decline. In fact, for statistically similar to the best currently available pharmacological therapy.

Some recent studies with GBE have demonstrated a significant Improvement on working memory of healthy volunteers. After the administration of two daily doses of

GBE, a clear improvement on memory testing was noted, particularly in the 50-59 year-old range group. Recent animal data has suggested that there may be a significant neuroprotective effect in spinal cord injury, brain injury, stroke, and degenerative disorders of the brain.

Recommended doses range from 10mg to 240mg daily. Higher doses are under investigation. There have been a few reports of spontaneous bleeding, even inside the brain, but these side effects are considered rare events. There are some potentially hazardous medical interactions one should be aware of before starting Ginkgo Biloba. Particularly if you are taking aspirin (or aspirin containing products), warfarin (aka, Coumadin), Ticlopidine (aka, Ticlid), or any other anticoagulant, GBE therapy should be avoided. Of course check with your pharmacist, physician, or healthcare provider before starting any nutritional supplement or medication.

Sean Kenniff, MD

Study evaluates effects of berberine on bone mineral density in murine model

Osteoporosis
February 27, 2003

2003 FEB 27 - (**NewsRx.com** & **NewsRx.net**) -- According to recent research from Japan, "the effects of berberine in senescence accelerated mice P6 (SAMP6) were investigated to learn whether the alkaloid affects bone mineral density (BMD)."

"Oral administration of berberine (10 mg/kg/d) to male and female mice for 22 weeks resulted in an increase in BMD in both sexes. A decreased concentration of deoxypyridinoline (Dpd) in urine was only observed in female mice," said H.Y. Li and colleagues, Toyama Medical and Pharmaceutical University, Institute Natural Medicine.

"There was no effect on body or tibia weight or on the concentration of procollagen type I carboxyterminal extension peptide (PICP) in serum," researchers concluded (Effect of berberine on bone mineral density in SAMP6 as a senile osteoporosis model. Biological and Pharmaceutical Bulletin, 2003;26(1):110-111).

For additional information, contact S. Kadota, Toyama Medical and Pharmaceutical University, Institute Nat Med, 2630 Sugitani, Toyama 9300194, Japan.

To subscribe to the journal *Biological & Pharmaceutical Bulletin*, contact the publisher: Pharmaceutical Society Japan, 2-12-15-201 Shibuya, Shibuya-Ku, Tokyo, 150, Japan.

The information in this article comes under the major subject areas of Herbaceutical, Complementary and Alternative Medicine, and Osteoporosis. This article was prepared by Women's Health Weekly editors from staff and other reports.

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http://www.usadirectworldwide.com/products_services.shtml Cached - Site Info

Sarati - Company History
... sulfate-free hair, bath & beauty products; all natural toothpaste; hair removal products; anagen hair inhibitors; natural **herbaceutical** formulations; liposomal ...
http://www.sarati.com/page.asp?template=Company%20History Cached - Site Info

Chinese Herbs
... Wang&Pei **Herbaceutical** - manufacturers of RiteMyelin, used to alleviate the symptoms of multiple sclerosis. Year of the Tiger Herb Co. ...
http://www.theopinionsite.com/chinese-herbs.htm Cached - Site Info

Feminine Moisture Plus
... Quantity: Sarati International Inc. has researched and developed a new and unique **Herbaceutical** solution which is an effective answer to this condition. ...
http://www.nativebalance.com/catalog/feminine_moisture_plus_14458... Cached - Site Info

Yahoo! Business and Economy>Shopping and Services>Health> ...
... RiteHerbs **Herbaceutical** International Open site in a new window - manufacturers of RiteMyelin, used to alleviate the symptoms of multiple sclerosis. ...
http://asia.yahoo.com/business_and_economy/shopping_and_services/... Cached - Site Info

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... While a growing body of medical evidence has confirmed the potency of this **"herbaceutical"** in the treatment of memory disorders, the future therapeutic ...
http://www.highermindsradio.com/march2k/ht03/health.htm Cached - Site Info

Osteoporosis: Study evaluates effects of berberine on bone ...
... The information in this article comes under the major subject areas of **Herbaceutical**, Complementary and Alternative Medicine, and Osteoporosis. ...
http://www.obgyn.net/newsheadlines/womens_health-Osteoporosis-200... Cached - Site Info

We offer a complete line of Transdermal Rebalancing Creams, ...
... Sarati International Inc. has researched and developed a new and unique **Herbaceutical** solution, which is an effective answer to this condition. ...
http://www.hersolutions.com/feminine_moisturizer.htm Cached - Site Info

[PDF] AGRICULTURE.
... are great opportunities for focussing on higher value, organic consumer products, such as horticultural products, processed foods and **herbaceutical** products. ...

XEL 000567

http://www.vic.greens.org.au/elections/state/policy/pdfs/Agricult... Cached - Site Info

PRE-LAUNCH UPDATE
... Distributor Applications and Agreements; "**Herbaceutical** Health Tips" Newsletter; One bottle of Hawaiian Toxi-Clear™. (Note: Bottled ...
http://www.e-comprofits.com/prelup.html Cached - Site Info

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Dr.Wang
... Member of Tianjin Traditional Chinese Medicine Society. Dr. Wang is the inventor of RiteMyelin™ and President of Wang&Pei **Herbaceutical**. ...
http://www.multiple-sclerosis-rm.com/dr__wang.htm Cached - Site Info

Natural Progesterone Cream SALE $9.98 NATURAL PROGESTERONE CREAM
... Sarati International Inc. has researched and developed a new and unique **herbaceutical** solution which is an effective answer to this condition. ...
http://www.progesteroneonline.com/ Cached - Site Info

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... We are fulfilling a critical need as the request for effective plant and **herbaceutical** formulations are now greater than ever before, as women are taking more ...
http://www.progesteroneonline.com/progesterone_002.htm Cached [Search only in www.progesteroneonline.com] - Site Info

Yahoo! Directory Chinese > Brand Names
... control. RiteHerbs **Herbaceutical** International - manufacturers of RiteMyelin, used to alleviate the symptoms of multiple sclerosis. ...
http://dir.yahoo.com/Business_and_Economy/Shopping_and_Services/H... Cached - Site Info

Info Center
... analyze medical images. Riley Fletcher Organisation Ltd, Warwick: Specializes in **herbaceutical** remedies. Smartbead Technologies ...
http://www.fairfaxcountyeda.org/02releases/jul24-02.htm Cached - Site Info

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Â cosmetic container
... importers/exporters And distributors in the following industries: Â Pharmaceutical Â Nutraceutical Â Cosmeceutical Â **Herbaceutical** www.labtechresearch ...
http://www.searchdemon.co.uk/index.asp?keyword=%C2%A0cosmetic%20c... Cached - Site Info

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http://www.usadirectworldwide.com/products_services.shtml Cached - Site Info

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Sarati - Company History
... sulfate-free hair, bath & beauty products; all natural toothpaste; hair removal products; anagen hair inhibitors; natural **herbaceutical** formulations; liposomal ...
http://www.sarati.com/page.asp?template=Company%20History Cached - Site Info

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http://www.multiple-sclerosis-rm.com/ Cached - Site Info

MS Society,Stirling - Research etc
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Herbaceuticals: an overview for counselors.(Practice & Theory)

Magazines

Journal of Counseling and Development; 9/22/2005; Ingersoll, R. Elliott

While more information on psychotropic medications is becoming available to counselors (Ingersoll, 2000; Ingersoll, Bauer, & Burns, in press), there is little published information on herbaceuticals. In this article, I use the word" herbaceuticals" because it is more accurate than "herbal medicines" or "herbal drugs?' The compounds discussed in this article, under U.S. federal law, cannot be advertised as medicines or drugs, so it would be confusing to refer to them as such. It must be noted, however, that many herbaceutical compounds contain pharmacologically active elements as ...

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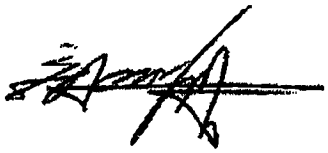

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(12) **United States Patent**
Zhao et al.

(10) **Patent No.: US 6,908,632 B1**
(45) **Date of Patent: Jun. 21, 2005**

(54) **BLOOD GLUCOSE MODULATING COMPOSITIONS AND METHODS**

(75) Inventors: **Chunsheng Zhao**, Beijing (CN); **Jingyan Wang**, Beijing (CN); **Yan Zhang**, Beijing (CN); **Weiti Yin**, Beijing (CN); **Decheng Zhang**, Shanghai (CN); **Jia-Shi Zhu**, San Diego, CA (US)

(73) Assignee: **Pharmanex, LLC**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/420,347**

(22) Filed: **Apr. 21, 2003**

Related U.S. Application Data

(60) Provisional application No. 60/374,196, filed on Apr. 19, 2002.

(51) **Int. Cl.**[7] **A61K 35/78**

(52) **U.S. Cl.** **424/765**; 424/774; 424/725

(58) **Field of Search** 424/776, 765, 424/725; 514/866

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Primary Examiner—Christopher R. Tate
(74) *Attorney, Agent, or Firm*—Thorpe North & Western, LLP

(57) **ABSTRACT**

Loquat extracts and methods for the preparation and use thereof in modulating blood glucose metabolism are disclosed and described. In one aspect, the present invention includes a Loquat extract having a standardized corosolic acid content, and a method for the production thereof.

5 Claims, 5 Drawing Sheets

using compositions employing a Loquat (Pi Pa Ye "PPY") extract obtained using an extraction process in accordance with one embodiment of the present invention.

FIG. 2 shows a graphical representation of the fasting blood glucose results obtained in normal subjects by administration of compositions employing a Loquat (Pi Pa Ye "PPY") extract obtained using an extraction process in accordance with one embodiment of the present invention.

FIG. 3 shows a graphical representation of the fasting blood glucose results for 0, 7, and 14 days, obtained in normal subjects by administration of compositions employing a Loquat (Pi Pa Ye "PPY") extract obtained using an extraction process in accordance with one embodiment of the present invention.

FIG. 4 shows a graphical representation of oral glucose tolerance results upon receipt of a glucose bolus dose, achieved by normal subjects after 5–7 days of administration of compositions employing a Loquat (Pi Pa Ye "PPY") extract obtained using an extraction process in accordance with one embodiment of the present invention.

FIG. 5 shows a graphical representation of the STZ-induced diabetic subjects enrolled in a clinical study using compositions employing a Loquat (Pi Pa Ye) extract obtained using an extraction process in accordance with one embodiment of the present invention.

FIG. 6 shows a graphical representation of the fasting blood glucose results obtained in STZ-induced diabetic subjects by administration of compositions employing a Loquat (Pi Pa Ye "PPY") extract obtained using an extraction process in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Before the present blood glucose modulating compositions and accompanying methods are disclosed and described, it is to be understood that this invention is not limited to the particular process steps and materials disclosed herein, but is extended to equivalents thereof, as would be recognized by those ordinarily skilled in the relevant arts. It should also be understood that terminology employed herein is used for the purpose of describing particular embodiments only and is not intended to be limiting.

It must be noted that, as used in this specification and the appended claims, the singular forms "a," "an," and, "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to an "excipient" includes reference to one or more of such excipients.

Definitions

In describing and claiming the present invention, the following terminology will be used in accordance with the definitions set forth below.

The terms "formulation" and "composition" may be used interchangeably herein. The terms "drug," "active agent," "bioactive agent," "pharmaceutically active agent," "neutraceutical active agent," "pharmaceutical," and "neutraceutical," are also used interchangeably to refer to an agent or substance that has measurable specified or selected physiologic activity when administered to a subject in an effective amount. These terms of art are well-known in the pharmaceutical, neutraceutical, and medicinal arts.

The term "extract" when used in connection with a plant, refers to one or more active agents, or a composition containing such, that is obtained from the plant, or a portion thereof, including the flower, fruit, seed, peel, leaf, root, and bark. As will be recognized by those of ordinary skill in the art, extracts may be either crude or refined to a selected degree in order to isolate specified active agents. A number of extraction processes that can be employed to produce the compositions of various types will be recognized by those of ordinary skill in the art.

As used herein, "Loquat" refers to the plant species Eriobotrya japonica, (Thunb.) Lindl. of the family rosaceae, also known by various common names such as Rosaceae Advance, Champagne, Early Red, Japanese medlar, Pi Pa Ye, Japanese plum, Nispero, etc., including all well known strains, variations, and hybrids thereof, grown anywhere in the world.

As used herein, in connection with pieces of Loquat source material, "small" refers to a piece having a size that allows reasonable extraction of active agents from the piece. Those of ordinary skill in the art will recognize a variety of specific piece sizes that will allow the active agents to be removed into a liquid, or other medium.

The terms "effective amount," and "sufficient amount" may be used interchangeably and refer to an amount of an ingredient which, when included in a composition, is sufficient to achieve an intended compositional or physiological effect. Thus, a "therapeutically effective amount" refers to a non-toxic, but sufficient amount of an active agent, to achieve therapeutic results in treating a condition for which the active agent is known to be effective. Various biological factors may affect the ability of a substance to perform its intended task. Therefore, an "effective amount" or a "therapeutically effective amount" may be dependent on such biological factors. Further, while the achievement of therapeutic effects may be measured by a physician or other qualified medical personnel using evaluations known in the art, it is recognized that individual variation and response to treatments may make the achievement of therapeutic effects a subjective decision. The determination of an effective amount is well within the ordinary skill in the art of pharmaceutical, nutraceutical, herbaceutical, and health sciences. See, for example, Meiner and Tonascia, "Clinical Trials: Design, Conduct, and Analysis," *Monographs in Epidemiology and Biostatistics*, Vol. 8 (1986), incorporated herein by reference.

As used herein, "carrier" or "inert carrier" refers to a polymeric carrier, or other carrier vehicle with which a bioactive agent, such as a cortisol moderator, and other anti-stress agents may be combined to achieve a specific dosage formulation. As a generally principle, carriers must not react with the bioactive agent in a manner which substantially degrades or otherwise adversely affects the bioactive agent.

As used herein, "subject" refers to a mammal that may benefit from the administration of a stress moderating composition or method as recited herein. Most often, the subject will be a human.

As used herein, "administration," and "administering" refer to the manner in which a bioactive agent, such as corosolic acid, or various sesqiterpenoids, is presented to a subject. Administration can be accomplished by various art-known routes such as oral, parenteral, transdermal, inhalation, implantation, etc. Thus, an oral administration can be achieved by swallowing, chewing, or sucking of an oral dosage form comprising the bioactive agent. Parenteral administration can be achieved by injecting a bioactive composition intravenously, intra-arterially, intramuscularly,

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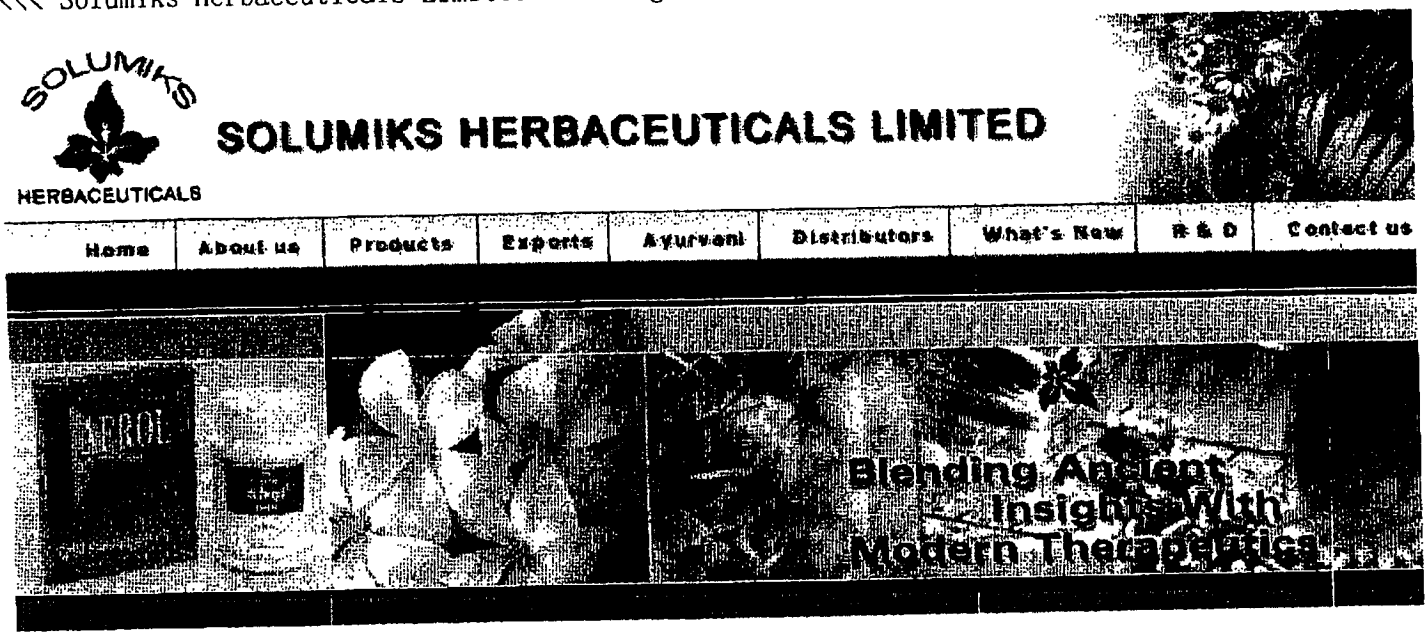

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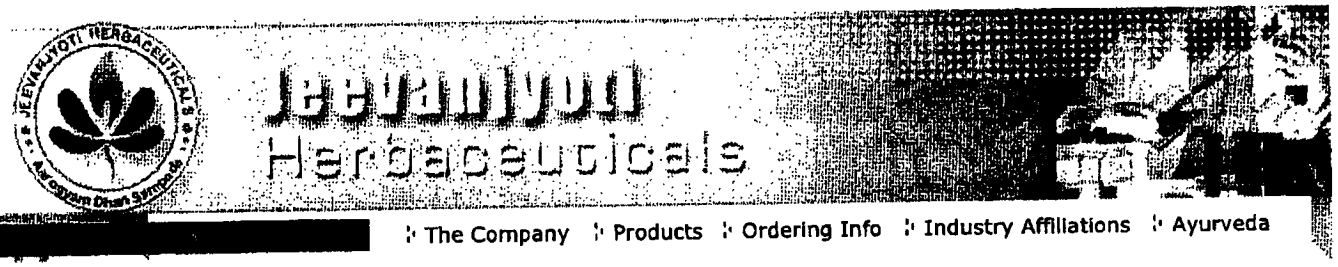

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(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2005/0238735 A1**

Page et al. (43) **Pub. Date: Oct. 27, 2005**

(54) **ORALS DOSAGE NONI FORMULATIONS**

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(73) Assignee: **Lifesmart Nutrition**

(21) Appl. No.: **10/345,098**

(22) Filed: **Jan. 15, 2003**

Related U.S. Application Data

(63) Continuation of application No. 09/834,178, filed on Apr. 12, 2001, now abandoned.

Publication Classification

(51) **Int. Cl.**[7] **A61K 35/78**

(52) **U.S. Cl.** **424/725**

(57) **ABSTRACT**

The present invention provides a Noni extract formulation which reduces or eliminates the strong disagreeable Noni taste, while simultaneously increasing the efficiency of a Noni extract dose. In one aspect, a Noni extract is uniformly dispersed in a caramel composition having an insulin response enhancing amount of sugar. In another aspect, the caramel composition may include an effective amount of an invert sugar.

ORALS DOSAGE NONI FORMULATIONS

THE FIELD OF THE INVENTION

[0001] The present invention relates generally to a composition and method for administering Noni plant extracts. More particularly, it concerns a Noni plant extract formulation which eliminates unpleasant Noni taste and enhances Noni metabolism and absorption.

BACKGROUND OF THE INVENTION

[0002] *Morinda citrifolia*, a small evergreen tree commonly referred to as "Indian Mulberry," is indigenous to various south pacific costal regions and islands, and has been used for centuries in traditional folk medicine to treat a variety of ailments. Today, known best as the "Noni plant," many people believe that *Morinda citrifolia* extract is useful in treating diabetes, cancer, ulcers, heart trouble, high blood pressure, kidney and bladder disorders, as well as a myriad of other physical conditions.

[0003] Noni plant extract is most often prepared for oral dosage delivery as a liquid infusion or tincture of the Noni plant fruit. Unfortunately, fresh Noni fruit and liquid preparations thereof generally have a strong disagreeable taste and odor. Additionally, because liquid oral formulations are often bulky, may require refrigeration, and are messy if spilled, they are inconvenient for multiple daily dose regimens. This is especially true for individuals who lead an active lifestyle and may travel throughout the day.

[0004] In order to alleviate the problems associated with liquid oral dosages of Noni plant extract, a variety of powdered forms have become available which may be delivered as an oral dosage tablet or capsule. Such formulations are thought to eliminate the strong disagreeable Noni plant taste and smell. However, it has been found that the Noni taste may still be experienced to an unpleasant degree as a residual taste after oral consumption of tablets or capsules.

[0005] Additionally, metabolism and absorption of orally administered Noni extract by body tissues has been found to be less than optimal. Particularly, as with many other substances, cellular metabolism and absorption of Noni is enhanced in the presence of insulin. Unfortunately, Noni's therapeutically active ingredients are very susceptible to degradation by the digestive forces of the upper gastrointestinal tract. Therefore, administration of a Noni dose in close proximity to a nourishment event that is sufficient to significantly raise insulin levels actually reduces Noni dosage efficacy.

[0006] As a result, research and development efforts continue to pursue Noni fruit extract dosage formulations which are easily consumable, portable, and that maximize metabolism and absorption by the body.

SUMMARY OF THE INVENTION

[0007] Accordingly, the present invention provides a Noni extract formulation which includes a caramel or taffy base having an effective amount of a Noni extract dispersed therein. In one aspect, the amount of Noni extract may be from about 1% to about 25% w/w of the formulation. In another aspect, he amount of Noni extract may be from about 5% to about 15% w/w of the formulation.

[0008] A wide variety of Noni plant types may be utilized in connection with the present invention or producing an acceptable Noni extract. In one aspect, the source of the Noni extract may be a member of the group consisting of Tahitian Noni plants, Hawaiian Noni plants, Samoan Noni plants, and mixtures thereof. In another aspect, the Noni extract may be obtained from a Samoan Noni plant.

[0009] Numerous active agents in Noni extract have been indicated as causing the positive health benefits imparted. One such agent is polysaccharide. In one aspect, the Noni extract used in the present invention may include a therapeutically effective amount of a polysaccharide. In another aspect, the amount of polysaccharide may be from about 2% to about 5% w/w of the Noni extract. In yet another aspect, the amount of polysaccharide may be about 3% w/w of the Noni extract.

[0010] An additional active agent which is reputed to play a role in imparting positive health benefits is proxeronine and its activating enzyme proxeroninase. In one aspect, the Noni extract used in the present formulation may include a therapeutically effective amount of proxeronine. In another aspect, the amount of proxeronine may be from about 0.1% to about 50% w/w of the Noni extract. In yet another aspect, the amount of proxeronine may be about 5% w/w of the Noni extract.

[0011] The amount of sugar in the caramel or taffy base of the present invention may be an amount sufficient to mask or reduce the objectionable Noni extract taste, and may also be sufficient to rapidly enhance insulin levels. The total sugar in the caramel base may include an effective amount of an invert sugar. In one aspect, the amount of invert sugar may be from about 1% to about 20% w/w of the formulation. In another aspect the amount of invert sugar may be from about 3% to 15% w/w of the formulation.

[0012] A variety of invert sugar types may be utilized with the present invention to provide a heightened sweetening effect. In one aspect, the invert sugar may be a mixture of dextrose (i.e. D-glucose) and fructose. In another aspect, the dextrose and the fructose may each be present in an amount of about 50% w/w of the invert sugar. In yet another aspect, the invert sugar may be provided by rice syrup and include a mixture of glucose and maltose. In a further aspect, the amount of rice syrup may be from about 15% to about 40% w/w of the formulation.

[0013] The present invention additionally provides a Noni extract formulation which includes a caramel or taffy base having an insulin enhancing amount of sugar and invert sugar, and a therapeutically effective amount of a Noni extract, wherein said invert sugar is present in an amount sufficient to reduce a disagreeable taste imparted by the Noni extract, and the formulation has a total dosage size or amount that is insufficient increase upper gastro intestinal tract digestive activity to a level or degree which substantially inactivates one or more active agents, or a substantial portion thereof, in the Noni extract.

[0014] The present invention also encompasses a method for making a Noni extract. In one aspect, a method of making a Noni extract formulation comprising the steps of: a) preparing a caramel or taffy base containing an effective amount of an invert sugar in a conventional manner in a heated liquid caramel phase form; b) partially cooling said

heated liquid caramel phase to a temperature at which Noni extract is stable; c) adding a desired amount of Noni extract to said partially cooled liquid caramel phase; d) agitating said partially cooled liquid caramel phase until the Noni extract is substantially uniformly dispersed therein; and e) further cooling said partially cooled liquid caramel phase to a solid thereby resulting in said Noni extract formulation.

[0015] In one aspect, the temperature of said partially cooled liquid caramel phase may be between about 160° F. to about 220° F. at the time said Noni extract is added. In another aspect, the temperature is from about 180° F. to 200° F.

[0016] In one aspect, the amount of Noni extract added may be from about 0.1% to 24% w/w of the Noni formulation. In another aspect, the amount of Noni extract may be from about 9% to 13% w/w of the Noni formulation.

[0017] In one aspect, the invert sugar is provided by an effective amount of rice syrup. Further, the present method may additional include the step of dividing the Noni extract formulation into individual serving size portions.

[0018] Another method included in the present invention is a method of increasing the efficacy of a Noni extract dose. Such a method may include the steps of: a) distributing an amount of Noni extract into a caramel composition containing an insulin enhancing amount of sugar and an invert sugar; and b) orally administering the composition.

[0019] In one aspect, the amount of invert sugar may be from about 1% to about 20% w/w of the formulation. In another aspect, the amount of invert sugar may be about 3% to 15% w/w of the formulation. In a further aspect, the invert sugar includes a mixture of dextrose and fructose. In yet another aspect, the dextrose and the fructose may each be present in an amount of about 50% w/w of the invert sugar. In an additional aspect, the invert sugar may be provided by rice syrup and includes a mixture of glucose and maltose. In yet another aspect, the amount of rice syrup is from about 15% to about 40% w/w of the formulation.

[0020] The method of enhancing the efficacy of a Noni extract dose may additionally include the step of administering the composition at a time when digestive juices in the upper gastrointestinal tract are at a minimum. Additionally, Noni formulation may be administered in a total amount that is insufficient to increase upper gastro intestinal tract digestive action to a level which substantially inactivates one or more active agents, or a substantial portion thereof contained in the Noni extract.

[0021] If addition to the above-recited methods, the present invention includes a method of reducing or eliminating an objectionable taste caused by Noni extract. Such a method may include the steps of: a) distributing the Noni extract into a caramel composition containing a sufficient amount of invert sugar to reduce or eliminate any disagreeable taste caused by the Noni extract.

[0022] In one aspect, the amount of invert sugar may be from about 1% to about 20% w/w of the formulation. In another aspect, the amount of invert sugar may be from about 3% to 15% w/w of the formulation. In a further aspect, the invert sugar may include a mixture of dextrose and fructose. In yet. another aspect, the dextrose and the fructose are each present in an amount of about 50% w/w, of the invert sugar. In an additional aspect, the invert sugar may be provided by rice syrup and includes a mixture of glucose and maltose. In another aspect, the amount of rice syrup is from about 15% to about 40% w/w of the formulation.

[0023] There has thus been outlined, rather broadly, the more important features of the invention so that the detailed description thereof that follows may be better understood, and so that the present contribution to the art may be better appreciated. Other features of the present invention will become clearer from the following detailed description of the invention, taken with the accompanying claims, or may be learned by the practice of the invention.

DETAILED DESCRIPTION

[0024] Definitions

[0025] Before the present oral delivery Noni formulations are disclosed and described, it is to be understood that the present invention is not limited to the particular process steps and materials disclosed herein, but is extended to equivalents thereof as would be recognized by those ordinarily skilled in the relevant arts. It should also be understood that terminology employed herein is used for the purpose of describing particular embodiments only and is not intended to be limiting.

[0026] In describing and claiming the present invention, the following terminology will be used.

[0027] The singular forms "a," and, "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to a caramel containing "a Noni component" includes one or more Noni components, reference to "a sugar" includes reference to one or more sugars, and reference to "the flavorant" includes reference to one or more flavorants.

[0028] In describing and claiming the present invention, the following terminology will be used in accordance with the definitions set forth below.

[0029] As used herein, "Noni,""Noni fruit,""Noni plant, ""Noni agent," and "Noni extract," refer to an extract made from the fruit of all strains and hybrids of the plant *Morinda citrifolia*, or of plants significantly related to it, grown anywhere in the world including blends, mixtures, and combinations of such strains and relatives.

[0030] The terms "formulation" and "composition" may be used interchangeably herein.

[0031] As used herein, a "sugar" refers to any type of simple carbohydrate, such as a mono or disaccharide, or a combination thereof, either naturally obtained, refined from a natural source, or artificially produced, which may act as a suitable sweetener in a caramel composition.

[0032] As used herein, "inactivate" refers to a reduction, or substantial reduction in therapeutic action which would be imparted by an active agent when administered to the body.

[0033] As used herein, "invert sugar" refers to a combination of two or more sugars, either naturally obtained, refined from a natural source, or artificially produced, that produces a greater sweetness than a single type of sugar. By way of example without limitation, an invert sugar may include a mixture of fructose and D-glucose in substantially

equal parts. One example of a naturally obtained invert sugar is rice syrup. Rice syrup is generally obtained by culturing rice with certain enzymes to break down starches, straining off the liquid, and cooking the remaining portion until a desired consistency is reached. The resultant product contains a mixture of soluble complex carbohydrates, maltose, and glucose. In such a case, the combination of maltose and glucose act much like the more traditional combination of fructose and D-glucose.

[0034] As used herein, "chew" and "chew base" may be used interchangeably and refer to either a caramel or taffy base.

[0035] As used herein, "caramel," and "caramel base," may be used interchangeably, and refer to a smooth, chewy composition made with sugar, butter or other fats, cream or milk or milk solids, and flavoring. Such ingredients may be unaltered natural products, natural products which are processed or refined, or may be fully synthesized products.

[0036] As used herein, "taffy," or "taffy base" refers to a chew candy or confection which is made with various types of sugars, including but not limited to simple sugars, invert sugars, brown sugars, and molasses, which is boiled until very thick and then pulled until it is glossy and holds its shape.

[0037] As used herein, "artificial sweetener" refers to a sweetening agent which does not provide a substantial amount of calories when consumed, as compared to the calories provided by an amount of sugar required to impart an equivalent sweetening effect. A variety of artificial sweeteners are known to those skilled in the art, including without limitation, saccharin, aspartame, sucralose, etc.

[0038] As used herein, an "effective amount," and "sufficient amount" may be used interchangeably and refer to an amount of an ingredient which, when included in a chew composition, is sufficient to achieve an intended compositional or physiological effect. For example, a "sufficient amount" of invert sugar would be the minimum amount needed to reduce or eliminate an off or disagreeable taste caused by an amount of Noni extract. Further, a "therapeutically effective amount" refers to an amount of a Noni extract which is sufficient to achieve a desired physiological effect. The determination of an effective amount is well within the ordinary skill in the art of pharmaceutical, neutraceutical, herbaceutical, cosmetic, and medical sciences. See, for example, Meiner and Tonascia, "Clinical Trials: Design, Conduct, and Analysis," Monographs in Epidemiology and Biostatistics, Vol. 8 (1986), incorporated by reference in its entirety.

[0039] As used herein, "an insulin enhancing amount," or "an insulin level enhancing amount" of a substance refers to an amount of sugar or other nutritional agent that is sufficient to produce or raise the amount of insulin in the blood to a level which increases the metabolism and absorption of Noni fruit extract, or the active agents contained therein, to a rate or amount which is greater than at a lover insulin level. Various methods for measuring and determining various insulin levels and their effect on the metabolism and absorption of various nutritional components are well known to those in the art.

[0040] As used herein, "active agent" refers to an agent contained in a Noni extract which imparts, or is capable of imparting or inducing a measurable physiological effect when administered to the body. Examples of active agents include proxeronine, proxeroninase, polysaccharides, terpenes, alkaloids, vitamins, minerals, etc.

[0041] As used herein, "polysaccharide" refers to a compound containing a combination of nine or more monosaccharides which are linked together by glycosidic bonds.

[0042] Concentrations, amounts, and other numerical data may be expresses or presented herein in a range format. It is to be understood that such a range format is used merely for convenience and brevity and thus should be interpreted flexibly to include not only the numerical values explicitly recited as the limits of the range, but also to include all the individual numerical values or sub-ranges encompassed within that range as if each numerical value and sub-range is explicitly recited.

[0043] As an illustration, a concentration range of "about 0.1% w/w to about 25% w/w" should be interpreted to include not only the explicitly recited concentration of about 0.1% to about 25% w/w, but also include individual concentrations and the sub-ranges within the indicated range. Thus, included in this numerical range are individual concentrations such as 2% w/w, 5% w/w, and 6% w/w, and sub-ranges such as from 1% w/w to 3% w/w, from 2% w/w to 6% w/w, from 8% w/w to 18% w/w, from 5% w/w to 20% w/w, etc. The same principle applies to ranges reciting only one numerical value.

[0044] Similarly, a range recited as "less than about 5.8% w/w" should be interpreted to include all of the values and ranges as elaborated above for the range of "from about 0.1% w/w to about 25% w/w." Furthermore, such an interpretation should apply regardless of the breadth of the range or the characteristics being described.

[0045] Invention

[0046] The present invention is drawn to an oral dosage Noni extract formulation which includes a therapeutically effective amount of Noni extract contained in a chewy confection type vehicle such as a caramel or taffy. Such a formulation provides significantly improved taste, convenience, and efficiency aspects over conventional liquid, tablet, or capsule formulations.

[0047] Single Noni formulation dosage sizes typically range from about 4 to about 12 grams total weight and are individually wrapped for convenient transport and administration. The amount of Noni extract contained in a chew of this size may be from about 0.5 to 1.5 mg. In one aspect, the total weight for a single dosage may be about 8.6 grams, and the amount of Noni extract contained therein may be about 500 mg.

[0048] The Noni component of the present invention is generally included as a powder, and may be obtained by any process of active ingredient extraction known to those skilled in the art. By way of example, without limitation, extraction techniques, such as infusion, tincture, etc. followed by removal of the liquid portion and concentration of the extract may be used. One such method for producing a powdered Noni extract is described in U.S. Pat. No. 5,288,491 which is incorporated herein by reference in its entirety.

[0049] The amount of Noni component contained in the formulation may be varied according the knowledge of one

skilled in the art in order to achieve a particularly desired result. However, the Noni content will be generally from about 1% w/w to about 25% w/w of the formulation. In one aspect, the amount may be from about 5% w/w to about 15% w/w of the formulation. In another aspect, the amount may be about 6% w/w of the formulation.

[0050] A variety of beneficial active ingredients are contained within Noni extract. By way of example, without limitation, beneficial ingredients include vitamins, minerals, enzymes, terpenes, proteins, polysaccharides, and alkaloids. Of these ingredients, significant health effects such as anti-cancer and blood pressure lowering effects have been generally attributed to the alkaloids and polysaccharides.

[0051] The beneficial alkaloid ingredients have been identified as proxeronine and an enzyme known as proxeroninase. The action of proxeronine and proxeroninase, also known as proxeronase, in forming an alkaloid known as xeronine are more fully disclosed and described in U.S. Pat. Nos. 4,409,144, and 4,543,212, each of which are incorporated herein by reference in their entirety. Further, the positive health imparting properties of xeronine, as well as information on the formation thereof is described by Dr. Neil Soloman in his book entitled *The Noni Phenomenon: Discover the Powerful Tropical Healer that Fights Cancer, Lowers High Blood Pressure, and Relieves Chronic Pain* (1999), which is incorporated herein by reference.

[0052] In one aspect, the Noni extract contained in the present formulation may have a proxeronine content of from about 0.01% w/w to about 95% w/w of the total Noni extract. In another aspect, the proxeronine content may be from about 5% w/w to about **[text missing or illegible when filed]** w/w of the total Noni extract. The total amount of proxeronine contained in a specific amount of the present Noni formulation may be readily determined by those ordinarily skilled in the art. Simply, using the concentration of proxeronine in the Noni extract, and the amount of extract in the formulation, the total proxeronine amount in the formulation may be calculated.

[0053] The amount of the proxeroninase in the Noni extract will generally have an activity sufficient to activate at least a portion of the proxeronine contained therein under proper conditions. In one aspect, the activity of proxeroninase may be sufficient to activate at least 50% of the proxeronine. In another aspect, the activity of proxeroninase may be sufficient to activate at least 75% of the proxeronine. In yet another aspect, the activity of the proxeroninase may be sufficient to activate 100% of the proxeronine.

[0054] Various sources attribute many of the positive health benefits of Noni to its polysaccharides content, including water soluble polysaccharides. For example, Hirazumi et al., *An immunomodulatory polysaccharide-rich substance from the fruit juice of citrifolia (noni) with anti-tumor activity*, Phytother Res. August 1999: 13(5):380-7, which is incorporated herein by reference, reports that the anti-cancer effects of Noni are attributed to the polysaccharide content.

[0055] In one aspect, the Noni extract utilized in the present invention may have a polysaccharide content of from about 0.01% w/w to about 25% w/w of the total Noni extract. In one aspect, the polysaccharide content may be from about 1% w/w to about 10% w/w of the total Noni extract. In yet another aspect, the polysaccharide content may be from about 2% w/w to about 5% w/w of the total Noni extract. The total amount of polysaccharides contained in a specific amount of the present Noni formulation may be readily calculated by one skilled in the art using the amount of polysaccharide in the Noni extract and the amount of Noni extract in the formulation.

[0056] The capability of invert sugar to combat the disagreeable taste of Noni fruit extract is due to its particular nature. Invert sugar is generally a combination of the simple sugars dextrose (D-glucose) and fructose which provides a sweetness exceeding that of a single type of sugar. In one aspect, invert sugar may be a product of the action of the enzyme invertase on sucrose to form a mixture of levulose fructose) and D-glucose (dextrose). However, invert sugar, as defined herein, may be any combination of simple sugars which imparts a heightened sweetness. In one aspect, the invert sugar used may be that containing an equal parts mixture of D-glucose and fructose. In another aspect, the invert sugar used may be a combination of maltose and glucose.

[0057] The timing of the sweetening effect of each of the invert sugar components is complimentary. This time variation in part explains the increased sweetness and reduction of objectionable taste. Particularly, the glucose, and maltose or fructose, as simple sugars, provide an initial burst of sweetness as the invert sugar enters the mouth. This quick sweetening masks the initial distaste of Noni extract. The sucrose and corn syrup solids used in making the chew base, being either a disaccharide or starch hydrolysis product, provide a sustained sweetening power during chewing. Further, the maltose or fructose, while involved in the above two mentioned states, are also believed to provide a lingering sweetness which masks the objectionable Noni extract aftertaste or residual taste.

[0058] Notably, a variety of artificial sweeteners may also be used to mask the objectionable Noni extract taste. In one aspect, one or more artificial sweeteners may be used in addition to the sugars present in the chew formulation. In another aspect, one or more artificial sweeteners may take the place of a portion of the sugars present in the chew formulation.

[0059] In addition to improving the taste and convenience of a Noni fruit dose, the chew vehicle of the present oral delivery formulation also improves the overall dosage efficacy. As noted above, many of the beneficial Noni agents, such as proxeronine and proxeronase are very susceptible to degradation by the digestive forces of the upper gastrointestinal tract. Therefore, it is recommended that Noni be taken on an empty stomach. However, when taken on an empty stomach, a portion of a Noni fruit dose may escape metabolism and absorption by the body tissues due to low blood insulin levels.

[0060] As such, the chew vehicle of the present invention is a particularly well suited vehicle for administering Noni on an empty stomach because of the total amount of combined sugars which are present. Particularly, the total amount of combined sugars in the chew is sufficient to raise insulin levels to a point which enhances Noni agent metabolism and absorption by the cells. Further, the total dosage size of the Noni chew formulation is relatively small and does not by itself facilitate significant production of digestive substances in the upper gastrointestinal tract.

[0061] Thus, because of its small size, the present Noni formulation prevents loss of Noni extract due to digestion in

the upper gastrointestinal tract. Further, because of its high sugars content, the present Noni formulation enhances Noni extract metabolism and absorption in the tissues and organs. As such, the combination of high sugar content and small total administration volume allow the Noni formulation of the present invention to maximizes the efficacy of a Noni dose.

[0062] The caramel or taffy composition of the present invention may be a preparation of any combination of ingredients which is known to those ordinarily skilled in the art of making caramel, taffy, or other confections, and is not limited except by a requirement to contain an effective amount of Noni extract.

[0063] While no limitation on the form of Noni extract used in the present invention is made, in one aspect, the Noni extract may be a powder. In another aspect, the Noni extract may be a liquid. Further, in one aspect, the Noni extract may be obtained from the fruit of a Tahitian Noni plant. In another aspect, the Noni extract may be obtained from the fruit of a Hawaiian Noni plant. In yet another aspect, the Noni extract may be obtained from the fruit of an Asian Noni plant. In yet another aspect, the Noni extract may be obtained from the fruit of a Samoan Noni plant. In a further aspect, the Noni extract may be obtained from a mixture of any of the above sources.

[0064] In addition to the Noni extract active ingredient, other active ingredients may be included in the formulation of the present invention which impart a positive health benefit. As will be recognized by those skilled in the art, a wide variety of positive health benefit imparting ingredients may be selected from herbal and botanical extracts, as well as medicinal compounds and be added as desired in order to achieve a specific therapeutic result. Such additions may be made by the skilled artesian without undue experimentation.

[0065] Generally, herbal and botanical extracts are made from all kinds of herb and botanic sources and formulated based on their therapeutic function. For example, anti-flu, bone/joint, brain function, cardiovascular, circulatory, diet, depression, digestion, energy, eye vision, general health, immune system, liver, men's health respiratory, rest, urinary tract, women's health, etc. In one aspect, herbal and botanical extracts for inclusion in the present formulation can be selected from, but not limited to, Ginseng, Ginko Biloba, Dong Quai, Hawthorn berry, St. John's Wort, Saw Palmetto, Kava Kava, Rose Hips, Echinacea, Licorice Root, Grape seed, Chammomile, Sea Buckthorn, Aloe Vera, Cinnamon Bark, Cordyceps, Ho Shou Wu, Dandelion, Gynostemma, mushroom, Notginseng, Dan Shen, and mixtures thereof may be included.

[0066] In one aspect, vitamins either water soluble or oil soluble may be added. Water soluble vitamins specifically contemplated by the present invention include, but are not limited to: vitamin B_1, B_2, B_3, B_5, B_6, B_{12}, B_{13}, B_{15}, B_{17}, biotin, choline, folic acid, inositol, para-aminobenzoic acid (PABA), vitamin C, and vitamin P. Additionally, oil soluble vitamins include, but are not limited to: vitamin A, vitamin D, vitamin E, and vitamin K.

[0067] Other health imparting substances which may be combined with the desired Noni extract in the formulation of the present invention include amino acids, ionic minerals, and naturally occurring anti-oxidants. The amino acids contemplated include: alanine, arginine, carnitine, gamma-aminobutyric acid (GABA), glutamine, glycine, histidine, lysine, methionine, N-acetyl cysteine, ornithine, phenylalanine, taurine, tyrosine, and valine, but are not limited thereto. Additionally, the ionic minerals contemplated by the present invention for inclusion in an embodiment of the formulation include both anions and cations. Finally, the naturally occurring anti-oxidants contemplated for the formulation of the present invention include: grape seed, beta-carotene, and co-enzyme Q-10, but are not limited thereto.

[0068] In one aspect, the amount of invert sugar contained in the prepared chew composition of the present invention may be from about 1% to about 20% w/w of the chew composition. In another aspect, the amount of invert sugar may be from about 3% w/w to 15% w/w of the chew composition. In yet another aspect, the amount of invert sugar may be from about 5% w/w to about 10% w/w of the chew composition. These amounts of invert sugar are in addition to the amount of table sugar (sucrose) or corn syrup solids required by the particular caramel or taffy recipe employed.

[0069] As defined above, a basic caramel formulation also contains butter or other fats, and either cream, milk, or milk products. Further, a basic taffy formulation may also contain molasses. The exact types and amounts of each of these ingredients may vary depending on the desired characteristics of the final product. Such exact amounts and types may be readily determined by one ordinarily skilled in the art.

[0070] Other ingredients known to the applicant as useful for making a Noni extract containing chew include but are not limited to: water, corn syrup, hydro soy oil, emulsifiers, lecithin, whey solids, sweetened condensed skim milk, flavorants, and vanillin.

[0071] In one aspect, the chew base, which is used as the vehicle for containing the Noni extract of the present invention may be partially or entirely made utilizing natural ingredients. Natural invert sugar sources such as rice syrup and sugar sources such as evaporated cane juice (turbinado sugar) may be used as one or more sweetening ingredients. Sweetened and condensed whole or skim milk and whey may be used as milk product ingredients. Coconut oil and mono and diglycerides from vegetable or other natural sources may be used as oil and fat ingredients. Further ingredients which may be used include without limitation Soya lecithin, and natural flavorings, including chocolate and vanilla.

[0072] Those of ordinary skill in the art will recognize that the amount of each of the above-recited natural ingredients may be varied in order to achieve a particularly desired result. However, in one aspect, the amount of rice syrup may be from about 10% w/w to about 40% w/w of the formulation. In another aspect, the amount of rice syrup may be about 36% w/w of the formulation. Of particular note is that in general, rice syrup is approximately 48% maltose and glucose and 52% complex carbohydrates. As such, the range of effective invert sugar component provided by the rice syrup may be from about 5% w/w to about 20% w/w.

[0073] In one aspect, the amount of turbinado sugar may be from about 15% w/w to about 20% w/w of the formulation. In another aspect, the amount may be about 18% w/w of the formulation.

[0074] In one aspect, the amount of sweetened and condensed milk may be from about 13% w/w to about 18% w/w of the formulation. In another aspect, the amount may be about 14% w/w.

[0075] In one aspect, the amount of whey may be from about 10% w/w to about 17% w/w of the formulation. In another aspect, the amount may be about 13% w/w.

[0076] In one aspect, the amount of coconut oil may be from about 1% w/w to about 5% w/w of the formulation. In another aspect, the amount may be about 2%.

[0077] In one aspect, the amount of mono and diglycerides may be from about 0.25% w/w to about 2% w/w of the formulation. In another aspect, the amount may be about 0.5% w/w.

[0078] In one aspect, the amount of Soya lecithin may be from about 0.05% w/w to about 0.2% w/w of the formulation. In another aspect, the amount may be about 0.1% w/w.

[0079] In one aspect amount of chocolate flavor may be from about 4% w/w to about 8% w/w of the formulation. In another aspect, the amount may be about 6% w/w.

[0080] In one aspect, the amount of vanilla flavor may be from about 0.1% w/w to about 0.4% w/w of the formulation. In another aspect, the amount may be about 0.2% w/w.

[0081] A method for making the Noni formulation of the present invention encompasses all methods for making caramel or taffy which are known to those ordinarily skilled in the art thereof, and is unlimited, other than to the conditions under which the Noni may be added. Particularly, the Noni must not be exposed to conditions which will cause it to become unfit for its intended purpose by changing forms, decomposition of active ingredients, etc. To this end, some restriction may be applied to the time of Noni addition, and the temperature to which it is subjected.

[0082] Therefore, in a one aspect of the invention, the Noni extract is uniformly distributed throughout the chew composition, and is added to a heated chew composition after the composition has been cooled to a temperature at which Noni active ingredients will not degrade. In another aspect, in order to achieve uniform distribution, and ensure Noni extract stability, the temperature will be from about 160° F. to about 220° F., and most preferably, the temperature will be about 180° F. to about 200° F.

[0083] In order to achieve uniform distribution of the Noni extract, the chew composition must be sufficiently agitated after adding the creatine. In one aspect, the chew composition is continuously cooled and agitated after the addition of the Noni extract until the composition is sufficiently solid that agitation is not practical. At this point the chew is ready to be divided into individual pieces for packaging. When a taffy base is used, the composition may be pulled after cooling until the desired consistency is reached, prior to division for individual packaging.

[0084] Because of the heating and stirring process under which most caramel or taffy compositions are prepared, the amount of ingredient added during processing will vary somewhat from the amount retained in the finally prepared chew composition. This is mostly due to the evaporation of water out of the various components which yields a final composition having a greater percentage of some ingredients which are unaffected by the removal of water. Therefore, a desired Noni extract amount in the prepared chew composition as enumerated above, Noni is added during processing in an amount of about 0.1% to about 24% w/w of the chew composition. In one aspect, the Noni extract is added during processing in an amount of about 4% to about 14% of the chew formulation. In another aspect, the Noni extract is added during processing in an amount of about 5% w/w of the chew formulation.

[0085] Additionally, in order to achieve the desired amount or invert sugar enumerated above, invert sugar is added during processing in an amount of about 1% to about 9% w/w of the chew composition. In one aspect, the invert sugar amnount added during processing is about 5% w/w of the caramel composition.

[0086] The flavors of the final chew composition are unlimited. Any desired flavor may be imparted, as long as attaining the flavor would not render any essential ingredient unfit for its intended purpose. Flavors particularly preferred include but are not limited to: chocolate, strawberry, raspberry, orange, lemon, grape, apple, coffee, and toffee.

[0087] The example provided below is illustrative of only one embodiment of making a Noni extract containing chew of the present invention. While the processing conditions and ingredients may be preferred, no limitation thereto is to be inferred.

EXAMPLE

[0088] To the pot of a standard sized gas fired Savage cooker with agitation, was added a blend of 5.12 lbs. of sugar, 14.85 lbs. of corn syrup (43DE), and 2.51 pounds of water. Agitation was begun at about 100 rpm, and heating of the mixture was commenced. During the heating and agitation, 3.65 lbs. of hyrdo soy oil(98 F), 0.08 lbs. of lecithin, and 0.34 lbs. of an emulsifier were weighed into the pot. The temperature was increased during the addition of the ingredients until the temperature of the mixture was approximately 230° F.

[0089] Approximately 2.81 lbs. of whey solids were dissolved in about 8 lbs. water, and then 2.25 lbs. of invert sugar **[text missing or illegible when filed]**levulose and D-glucose), and 6.16 lbs. of sweetened condensed skim milk were added to the whey and water to form a milk mixture. The milk mixture was added to the pot and heating continued until the combined mixture reached a temperature of approximately 235° F.

[0090] The mixture contained in the pot was cooled to 232° F. while stirring continued, and 1.40 lbs. of cocoa liquor, 0.11 lbs. of vanillin, and 0.07 lbs. of butter flavoring were added. Mixing was continued, and the composition temperature was allowed to cool to about 200° F. Upon reaching the temperature of about 200° F., 4.70 lbs. of Noni extract was added to the caramel composition. Mixing was continued, and the composition allowed to cool to a temperature of about 180° F.

[0091] Once a temperature of about 180° F. was reached, the caramel composition was removed from the pot and transferred to a cooling table. The composition was allowed to rest upon the cooling table until it reached a temperature of about 91° F., at which time the composition was cut and wrapped into individual pieces.

[0092] The above described process yielded a Noni extract containing caramel composition having the following components in the amounts specified:

Ingredient	% Amount of Composition	Ingredient	% Amount of Composition
Water	10	Whey Solids	6.93
Sucrose	12.76	Sweetened Cond. Milk	10.78
Corn Syrup	29.76	Chocolate Flavor	3.42
Hydro Soy Oil	10.78	Vanillin	0.27
Emulsifier	0.20	Butter Flavor	0.16
Lecithin	0.20	Noni Extract	11.72
Invert Sugar	4.04		

[0093] The Noni extract formulation having the components enumerated above showed excellent flavor, texture, and dissolution qualities in the mouth.

[0094] It is to be understood that the above-described arrangements are only illustrative of the application of the principles of the present invention. Numerous modifications and alternative arrangements may be devised by those skilled in the art without departing from the spirit and scope of the present invention and the appended claims are intended to cover such modifications and arrangements. Thus, while the present invention has been described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred embodiments of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications, including, but not limited to, variations in size, materials, shape, form, function and manner of operation, assembly and use may be made without departing from the principles and concepts set forth herein.

What is claimed is:

1. A Noni extract formulation comprising a chew base having a therapeutically effective amount of a Noni extract dispersed therein.

2. The Noni formulation of claim 1, wherein the amount of Noni extract is from about 1% to about 25% w/w of the formulation.

3. The Noni formulation of claim 2, wherein the amount of Noni extract is from about 5% to about 15% w/w of the formulation.

4. The Noni formulation of claim 1, wherein the Noni extract is obtained from a member of the group consisting of Tahitian Noni plants, Hawaiian Noni plants, Samoan Noni plants, and mixtures thereof.

5. The Noni formulation of claim 1, wherein the Noni extract is obtained from a Samoan Noni plant.

6. The Noni formulation of claim 1, wherein the Noni extract includes a therapeutically effective amount of a polysaccharide.

7. The Noni formulation of claim 6, wherein the amount of polysaccharide is from about 2% to about 5% w/w of the Noni extract.

8. The Noni formulation of claim 6, wherein the amount of polysaccharide is about 3% w/w of the Noni extract.

9. The Noni formulation of claim 1, wherein Noni extract includes a therapeutically effective amount of proxeronine.

10. The Noni formulation of claim 9, wherein the amount of proxeronine is from about 0.1% to about 50% w/w of the Noni extract.

11. The Noni formulation of claim 9, wherein the amount of proxeronine is about 5% w/w of the Noni extract.

12. The Noni formulation of claim 1, wherein the chew base includes an effective amount of an invert sugar.

13. The Noni formulation of claim 12, wherein the amount of invert sugar is from about 1% to about 20% w/w of the formulation.

13. The Noni formulation of claim 13, wherein the amount of invert sugar is about 3% to 15% w/w of the formulation.

14. The Noni formulation of claim 12, wherein the invert sugar comprises a mixture of dextrose and fructose.

15. The Noni formulation of claim 14, wherein the dextrose and the fructose are each present in an amount of about 50% w/w of the invert sugar.

16. The Noni formulation of claim 12, wherein the invert sugar is provided by rice syrup and includes a mixture of glucose and maltose.

17. The Noni formulation of claim 16, wherein the amount of rice syrup is from about 15% to about 40% w/w of the formulation.

18. A method of making a Noni extract formulation comprising the steps of:

a) preparing a chew base containing an effective amount of an invert sugar in a conventional manner in a heated liquid phase form;

b) partially cooling said heated liquid phase to a temperature at which Noni extract is stable;

c) adding a desired amount of Noni extract to said partially cooled liquid phase;

d) agitating said partially cooled liquid phase until the Noni extract is substantially uniformly dispersed therein; and

e) further cooling said partially cooled liquid phase to a solid thereby resulting in said Noni extract formulation.

19. The method of claim 18, wherein the temperature of said partially cooled liquid caramel phase is between about 160° F. to about 220° F. at the time said Noni extract is added.

20. The method of claim 19, wherein the temperature is from about 180° F. to 200° F.

21. The method of claim 18, wherein the amount of Noni extract is from about 0.1% to 24% w/w of the Noni formulation.

22. The method of claim 18, wherein the amount of Noni extract is from about 9% to 13% w/w of the Noni formulation.

23. The method of claim 18, wherein the invert sugar is provided by an effective amount of rice syrup.

24. The method of claim 18, further comprising the step of: dividing the Noni extract formulation into individual serving size portions.

25. A method of increasing the efficacy of a Noni extract dose comprising the steps of:

a) distributing an amount of Noni extract into a chew composition containing an insulin level enhancing amount of sugar and an invert sugar; and

b) orally administering the composition.

26. The method of claim 25, wherein the amount of invert sugar is from about 1% to about 20% w/w of the formulation.

27. The method of claim 25, wherein the amount of invert sugar is about 3% to 15% w/w of the formulation.

28. The method of claim 25, wherein the invert sugar comprises a mixture of dextrose and fructose.

29. The method of claim 25, wherein the dextrose and the fructose are each present in an amount of about 50% w/w of the invert sugar.

30. The method of claim 25, wherein the invert sugar is provided by rice syrup and includes a mixture of glucose and maltose.

31. The method of claim 30, wherein the amount of rice syrup is from about 15% to about 40% w/w of the formulation.

32. The method of claim 25, wherein the step of administering the composition is performed at a time when digestive juices in the upper gastrointestinal tract are at a minimum.

33. The method of claim 25, wherein the chew composition is administered in a total dosage that is insufficient to increase upper gastro intestinal tract digestive action to a level which substantially inactivates one or more active agents in the Noni extract.

34. A method of reducing or eliminating an undesirable taste caused Noni extract comprising the step of:

a) distributing the Noni extract into a chew composition containing a sufficient amount of invert sugar to reduce or eliminate any disagreeable taste caused by the Noni extract.

35. The method of claim 34, wherein the amount of invert sugar is from about 1% to about 20% w/w of the formulation.

36. The method of claim 34, wherein the amount of invert sugar is about 3% to 15% w/w of the formulation.

37. The method of claim 34, wherein the invert sugar comprises a mixture of dextrose and fructose.

38. The method of claim 37, wherein the dextrose and the fructose are each present in an amount of about 50% w/w of the invert sugar.

39. The method of claim 34, wherein the invert sugar is provided by rice syrup and includes a mixture of glucose and maltose.

40. The method of claim 39, wherein the amount of rice syrup is from about 15% to about 40% w/w of the formulation.

41. A Noni extract formulation comprising a chew base having an insulin level enhancing amount of sugar and invert sugar, and a therapeutically effective amount of a Noni extract, wherein said invert sugar is present in an amount sufficient to reduce a disagreeable taste imparted by the Noni extract, and the formulation has a total dosage size that is insufficient to increase upper gastro intestinal tract digestive activity to a degree which substantially inactivates one or more active agents in the Noni extract.

42. A Noni extract formulation comprising a chew base having an insulin level enhancing amount of sugar and invert sugar, and a therapeutically effective amount of a Noni extract.

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(54) **SEA BUCKTHORN COMPOSITIONS AND ASSOCIATED METHODS**

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(57) **ABSTRACT**

Compositions having an effective amount of a Sea Buckthorn extract and an inert carrier and methods of use therefor are disclosed and described. Such methods of use include may include controlling serum lipid concentrations in a subject, and controlling the body weight of a subject, among others.

SEA BUCKTHORN COMPOSITIONS AND ASSOCIATED METHODS

PRIORITY DATA

[0001] This application claims priority to U.S. patent application Ser. No. 60/462,354, filed on Apr. 10, 2003, which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to Sea Buckthorn extract compositions and uses thereof. Accordingly, the present invention involves the areas of botany, nutritional and health sciences, as well as medicine and pharmaceutical/nutraceutical sciences.

BACKGROUND OF THE INVENTION

[0003] Physical fitness and good cardiovascular health have long been advocated by the medical community as factors that significantly enhance the quality and length of an individual's life. While ideal body weight will vary from person to person, general guidelines such as the Body Mass Index (BMI) have been established for determining whether a person's ideal weight. Many adverse health issues have now been directly linked to being overweight, especially with being obese.

[0004] The consequences of obesity include heighten risk of developing a number of adverse health conditions, such as type II diabetes, high blood pressure, heart disease, high cholesterol, breathing problems, sleep apnea, gallstones, arthritis, blood vessel problems, skin infections, rashes, sex hormone problems, gout, heartburn, gastroesophageal reflux disease (GERD), liver problems, and certain types of cancer. Obesity also often facilitates emotional problems, such as low self-esteem, depression, and certain eating disorders, and further prevents the obese individual from pursuing or engaging in various activities, such as swimming and other physical activities. As a result of the above-recited issues, obesity ultimately causes a significant decrease in overall quality of life, and increases the chance of premature death.

[0005] One of the adverse health conditions that is most directly linked to obesity is serum lipid disorders. While serum lipid disorders can be inherited, or otherwise experienced outside of obesity, the majority of serum lipid disorders are obesity induced. A variety of specific serum lipid disorders have been well established, such as elevated levels of triglycerides, cholesterol, and lipoproteins in the serum, commonly referred to as "high cholesterol,""high triglycerides,""hyperlipidemia," and "acquired hyperlipoproteinemia." One specific contributor to these lipid disorders can be excess ingestion of lipids or fatty substances. These lipid disorders have been linked to the development of atherosclerosis, heart disease, obesity, type I diabetes, type II diabetes, hypothyroidism, cushing's syndrome and renal failure. However, reduction of serum lipid concentrations to normal levels can reduce the health risks imposed by these conditions. Also, weight loss can be a factor in reducing these heath complications.

[0006] In view of the enormity of the obesity and weight problems faced by much of the world's population, a number of weight loss solutions have been sought. Myriads of special diets and exercise regimens have been developed. However, because of the considerable effort and perceived discomfort associated with dieting and exercise, a number of weight loss facilitating nutritional supplements and pharmaceutical formulations have been introduced.

[0007] Such dietary supplements and formulations have been touted to be fat trapping products, fat burning products, appetite suppressants, and laxatives or diuretics. Each of these individual categories of dietary supplements has unfavorable side effects, which decrease user compliance and most often do not result in the desired loss of weight. Fat trapping products, such as chitosan, supposedly work by preventing fat absorption into the body. Chitosan is derived from shellfish and may have allergenic potential with people with shellfish allergies. Fat burning products are claimed to increase the basal metabolic rate to burn calories, but this may not be safe for all people. MaHuang (Ephedra) are a class of these compounds and have been linked to high blood pressure, increased heart rate, heart palpitations, stroke, and even death. Also, laxative or diuretic abuse can be dangerous because it may result in excessive mineral loss and dehydration.

[0008] As a result, nutritional and pharmaceutical formulations that safely, and effectively, facilitate or contribute to weight loss continue to be sought through ongoing research and development efforts. Further, formulations that safely and effectively control or lower serum lipid concentrations continue to be sought

SUMMARY OF THE INVENTION

[0009] Accordingly, the present invention provides formulations and methods for reducing body weight in a subject. In one aspect of the present invention, such a formulation may include, or consist essentially of, an effective amount of a Sea Buckthorn extract. In another aspect, additional active ingredients may be combined with the Sea Buckthorn extract. Such formulations may be suitably prepared into a number of dosage forms for administration to a subject by combination with yet additional ingredients such as an inert carrier. Examples of suitable dosage forms include without limitation oral, parenteral, and transdermal or transmucosal dosage forms.

[0010] In another aspect of the present invention, Sea Buckthorn formulations may be used in methods of controlling serum lipid concentrations in a subject. Such methods can include the steps of providing a composition containing a therapeutically effective amount of a Sea Buckthorn extract, and administering the composition to a subject. In some cases, controlling serum lipids may include lowering certain types of lipids in a subject, such as triglyceride, total cholesterol, and/or low-density lipoproteins. In other cases, controlling serum lipids may include elevating certain types of lipids, such as high-density lipoproteins

[0011] In another aspect of the present invention, Sea Buckthorn formulations may be used in methods of controlling the body weight of a subject. In some aspects, such methods can include providing a composition containing a therapeutically effective amount of sea buckthorn extract, and administering the composition to a subject. In some cases, controlling body weight may include reducing the body weight of the subject. In other cases, controlling body weight may include managing or maintaining a health weight by preventing weight gain.

[0012] In another aspect, the administration of Sea Buckthorn extract may stimulate production or release of cholecystokinin into the serum. Such activities may cause, or at least contribute to, the weight and serum lipid control effects recited herein.

[0013] There has thus been outlined, rather broadly, the more important features of the invention so that the detailed description thereof that follows may be better understood, and so that the present contribution to the art may be better appreciated. Other features of the present invention will become clearer from the following detailed description of the invention, taken with the claims, or may be learned by the practice of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0014] A. Definitions

[0015] In describing and claiming the present invention, the following terminology will be used in accordance with the definitions set forth below.

[0016] The singular forms "a,""an," and, "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a carrier" includes reference to one or more of such carriers, and reference to "an excipient" includes reference to one or more of such excipients.

[0017] As used herein, the terms "formulation" and "composition" may be used interchangeably and refer to a combination of a pharmaceutically active agent with one or more additional ingredients such as an inert carrier. The terms "drug,""active agent,""bioactive agent,""pharmaceutically active agent,""nutraceutical active agent,""pharmaceutical," and "nutraceutical," are also used interchangeably to refer to an agent or substance that has measurable specified or selected physiologic activity when administered to a subject in an effective amount. These terms of art are well known in the pharmaceutical, nutraceutical, and medicinal arts.

[0018] As used herein, "administration," and "administering" refer to the manner in which a formulation or composition is introduced into the body of a subject. Administration can be accomplished by various art-known routes such as oral, parenteral, transdermal, inhalation, implantation, etc. Thus, an oral administration can be achieved by swallowing, chewing, sucking of an oral dosage form comprising the drug. Parenteral administration can be achieved by injecting a drug composition intravenously, intra-arterially, intramuscularly, intrathecally, or subcutaneously, etc. Transdermal administration can be accomplished by applying, pasting, rolling, attaching, pouring, pressing, rubbing, etc., of a transdermal preparation onto a skin surface. These and additional methods of administration are well known in the art.

[0019] The terms "effective amount," and "sufficient amount" may be used interchangeably and refer to an amount of an ingredient which, when included in a composition, is sufficient to achieve an intended compositional or physiological effect. Thus, a "therapeutically effective amount" refers to a non-toxic, but sufficient amount of an active agent, to achieve therapeutic results in treating a condition for which the active agent is known to be effective. Various biological factors may affect the ability of a substance to perform its intended task. Therefore, an "effective amount" or a "therapeutically effective amount" may be dependent on such biological factors. Further, while the achievement of therapeutic effects may be measured by a physician or other qualified medical personnel using evaluations known in the art, it is recognized that individual variation and response to treatments may make the achievement of therapeutic effects a subjective decision. The determination of an effective amount is well within the ordinary skill in the art of pharmaceutical, nutraceutical, herbaceutical, and health sciences. See, for example, Meiner and Tonascia, "Clinical Trials: Design, Conduct, and Analysis, "*Monographs in Epidemiology and Biostatistics*, Vol. 8 (1986), incorporated herein by reference.

[0020] The term "extract" when used in connection with a plant, refers to one or more active agents, or a composition containing such, that is obtained from the plant, or a portion thereof, including the flower, fruit, seed, peel, leaf, root, and bark. As will be recognized by those of ordinary skill in the art, extracts may be either crude or refined to a selected degree in order to isolate specified active agents. A number of extraction processes that can be employed to produce the compositions of various types will be recognized by those of ordinary skill in the art.

[0021] The term "Sea Buckthorn," refers to the plant species *hippophae rhamnoides*, including all strains and hybrids thereof, grown anywhere in the world.

[0022] As used herein, "carrier" or "inert carrier" refers to a polymeric carrier, or other carrier vehicle with which a bioactive agent, such as a Sea Buckthorn extract, may be combined to achieve a specific dosage form. As a generally principle, carriers must not react with the bioactive agent in a manner which substantially degrades or otherwise adversely affects the bioactive agent. Other "inactive" ingredients may also be used in creating Sea Buckthorn extract formulations having specifically desired properties or dosage forms, and will be readily recognized by those of ordinary skill in the art.

[0023] As used herein, "subject" refers to a mammal that may benefit from the administration of a weight controlling and/or reducing, cholecystokinin serum concentration stimulating, or serum lipid controlling and/or reducing composition or method as recited herein. Most often, the subject will be a human.

[0024] Concentrations, amounts, solubilities, and other numerical data may be presented herein in a range format. It is to be understood that such range format is used merely for convenience and brevity and should be interpreted flexibly to include not only the numerical values explicitly recited as the limits of the range, but also to include all the individual numerical values or sub-ranges encompassed within that range as if each numerical value and sub-range is explicitly recited.

[0025] For example, a concentration range of 0.1 to 5 mg/kg should be interpreted to include not only the explicitly recited concentration limits of 0.1 mg/kg and 5 mg/kg, but also to include individual concentrations such as 0.2 mg/kg, 0.7 mg/kg, 1.0 mg/kg, 2.2 mg/kg, 3.6 mg/kg, 4.2 mg/kg, and sub-ranges such as 0.3-2.5 mg/kg, 1.8-3.2 mg/kg, 2.6-4.9 mg/kg, etc. This interpretation should apply regardless of the breadth of the range or the characteristic

being described, and should apply to ranges having both upper and lower numerical values, as well as open-ended ranges reciting only one numerical value.

[0026] B. The Invention

[0027] Sea Buckthorn is known by the scientific name *hippophae rhamnoides*, and has been shown to be a source of many vitamins, including vitamin A, E, C, B1, B2, K, and P. It has also been reported that Sea Buckthorn is a significant source of various fatty acids, such as linoleic, alpha linoleic, oleic, palmitic, and palmitoleic acids. See, Yang et al., *J. Nutr. Biochem.* 10:622-630 (1999), which is incorporated herein by reference. These desirable ingredients such as antioxidants, carotenoids, carotenes, tocopherols, flavonoids, fatty acids, sterols and phytosterols, have attracted attention to Sea Buckthorn for a myriad of uses, such as in treatment of various skin conditions, prevention and treatment of cancer.

[0028] In accordance with the present invention, it has been discovered that extracts of Sea Buckthorn provide activity in controlling and/or reducing the body weight of a subject when administered in an effective amount. Further, it has been discovered that Sea Buckthorn extracts provide activity in controlling and/or lowering the serum lipid concentrations of a subject. Without wishing to be bound by theory, it is thought that the weight reducing activity may be attributed, at least in part, to the effect that a Sea Buckthorn extract has on stimulating production and/or release of cholecystokinin (CCK) in the subject, thereby increasing the serum concentration of cholecystokinin. As discussed in U.S. Pat. Nos. 6,207,638, and 6,429,190, each of which is incorporated herein by reference, cholecystokinin is a peptide that is released following the consumption of food, and is known to induce feelings of satiety and fullness. Cholecystokinin may also be involved in the rate of gastric emptying. Therefore, cholecystokinin stimulation may produce an appetite suppressing effect. Accordingly, the present invention provides compositions and methods for controlling and/or reducing the body weight of a subject, controlling and/or lowering the serum lipid concentrations of a subject, and stimulating release of cholecystokinin into the serum of a subject. Accordingly, an aspect of the present invention can include a Sea Buckthorn composition having a therapeutically effective amount of Sea Buckthorn extract and an inert carrier.

[0029] An aspect of the present invention includes methods of controlling serum lipid concentrations in a subject. Such methods may include providing a composition containing a therapeutically effective amount of a Sea Buckthorn extract and an inert carrier, and administering the composition to a subject. Accordingly, controlling the serum lipid concentration may be reducing serum lipid concentrations in a subject. In another aspect, controlling the serum lipid concentration may be preventing the serum lipid concentration from increasing. Additionally, the reduced serum lipids may be a triglyceride, total cholesterol, a low-density lipoprotein, and combinations thereof. In still another aspect, controlling the serum lipid concentration may be elevating high-density lipoprotein serum concentrations.

[0030] Another aspect of the present invention includes methods of controlling the body weight of a subject. Such methods may include providing a composition containing a therapeutically effective amount of Sea Buckthorn extract and an inert carrier, and administering the composition to a subject. In one aspect, controlling the body weight may be reducing the body weight of the subject. In another aspect, controlling the body weight may be preventing the body weight of the subject from increasing.

[0031] In an aspect of the present invention, the therapeutically effect amount of a Sea Buckthorn extract may increase the serum cholecystokinin concentration in the subject. In another aspect, the cholecystokinin serum concentration increase may occur by stimulating cholecystokinin production. In still another aspect, the cholecystokinin serum concentration increase may occur by an increased rate in the release of cholecystokinin from cholecystokinin producing cells. In a further aspect, the increased cholecystokinin serum concentration may cause appetite suppression.

[0032] In accordance with a Sea Buckthorn extract being a source for many nutritionally valuable vitamins, such as Vitamin C and Vitamin E, it has been discovered that compositions having a Sea Buckthorn extract can be used in a method of increasing immune function. For example, administration of a Sea Buckthorn extract may increase the function of lymphocytes. Accordingly, it is an aspect of the present invention to administer a therapeutically effective amount of a composition having a Sea Buckthorn extract and an inert carrier to a subject may increase the immune function of said subject.

[0033] Additionally, the presence of sterols within a Sea Buckthorn extract allows its use for cholesterol control. While not wishing to be bound to any particular theory, the mechanism of sterols on lowering cholesterol may be linked to the inhibition of cholesterol re-absorption from the gastrointestinal tract. Accordingly, phytosterols may inhibit the re-absorption of endogenous cholesterol, which may further lead to decreased serum levels of cholesterol. In an aspect of the present invention, the administration of a therapeutically effective amount of a composition having Sea Buckthorn extract to a subject may decrease the concentration of serum cholesterol.

[0034] Further, it is known that the age dependent degradation of the macular area of the retina, known as age-related macular degeneration or AMD, may be caused by light induced oxidation. Additionally, cataracts may be caused by light induced oxidation. As Sea Buckthorn extracts have been found be a source of antioxidants, including carotenoids, Vitamin C, Vitamin E, carotenoids, and others, one aspect of the present invention includes methods for providing compositions having Sea Buckthorn extracts as a source for antioxidants, which can be administered for eye health maintenance. In one aspect, a composition having a Sea Buckthorn extract can be administered as a source for antioxidants. In another aspect, a composition having Sea Buckthorn extract can be administered for ocular maintenance.

[0035] In accordance with the present invention, a composition that includes, or consists essentially of, a therapeutically effective amount of a Sea Buckthorn extract may be administered to a subject in order to obtain a desired weight controlling and/or reducing, serum lipid controlling and/or lowering, or cholecystokinin release stimulating effect. In one aspect, such a composition may consist essentially of a therapeutically effective amount of a Sea Buckthorn extract. In another aspect, the Sea Buckthorn extract may be com-

bined with inert carriers and other inactive ingredients in order to create a specific dosage form. Accordingly, the inert carrier may be selected from the group consisting of calcium carbonate, calcium silicate, calcium magnesium silicate, calcium phosphate, kaolin, sodium hydrogen carbonate, sodium sulfate, barium carbonate, barium sulfate, magnesium sulfate, magnesium carbonate, activated carbon, water, isopropyl alcohol, ethyl alcohol, polyvinyl pyrrolidone, propylene glycol, polyethylene glycol stearyl alcohol, stearic acid, sorbitan monooleate, microcrystalline cellulose, sodium carboxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, sorbitol, mannitol, xylitol, starches, gelatins, lactose, acacia, carbomer, dextrin, guar gum, lactose, liquid glucose, maltodextrin, polymethacrylates, and combinations thereof.

[0036] In yet another aspect, such a composition may include additional active agents in addition to the Sea Buckthorn that are included to provide and intended effect, or specifically desired result. In still another aspect of the invention, the composition may further include an active ingredient selected from the group consisting of herbal extracts, botanical extracts, vitamins, minerals, amino acids, proteins, enzymes, and combinations thereof.

[0037] Examples of herbal extract agents and botanical extract agents that may be added to a Sea Buckthorn composition include without limitation, Ginseng, Ginko Biloba, Dong Quai, Hawthorn berry, St. John's Wort, Saw Palmetto, Kava Kava, Rose Hips, Echinacea, Licorice Root, Grape seed, Chammomile, *Aloe Vera*, Cinnamon Bark, Cordyceps, Ho Shou Wu, Dandelion, Gynostemma, mushroom, Notginseng, Dan Shen, etc. Additional examples of herbal extract can include, without limitation, Green tea plant, Causena Lansium, Crocus Sativus, Danshen (*saliva miltiorrhize*), Dongui (Radix *angelicae sinesis*), Eucommia, Evening primrose, *Gastrodia elata*, Hopes, Epimedium, Lemon balm, Mishmi bitter (*coptis sinesis*), Morning star (*Uncaria rhychophylla*), Passion flower, Physostigmine, Securinega Suffructicosa, Scutellaria baicalensis, Siberian cork tree (*phellodendron amurense*), Skullcap, Valerian, and mixtures thereof.

[0038] In an aspect of the present invention, fruit extracts and vegetable extracts can be included in a composition having a Sea Buckthorn extract. Examples of fruit extracts that may include apple, apricot, banana, blue berry, cranberry, cherry, fig, grape, grapefruits, hawthorn berry, huckleberry, kiwi fruit, kumquat, lemon, lime, mango, melon, nectarine, noni fruit, orange, papaya, peach, pear, persimmon, pineapple, plum, pomegranate, raspberry, strawberry, tangerine, watermelon, and mixtures thereof. Additionally, examples of vegetable extracts may include artichoke, avocado, asparagus, beans, bell pepper, broccoli, brussels sprout, cabbage, cauliflower, carrot, celery, cucumber, eggplant, green bean, lettuce, onion, parsley, pea, potato, pumpkin, radish, radicchio, rhubarb, spinach, tomato, zucchini, and mixtures thereof.

[0039] Some examples of acceptable vitamins that can be included in a composition with a Sea Buckthorn extract can include both water-soluble and oil soluble vitamins. Water-soluble vitamins can include B1, B2, B3, B4, B5, B6, B12, B13, B15, B17, biotin, choline, folic acid, inositol, para-amino benzoic acid (PABA), Vitamin C, Vitamin P, and mixtures thereof. Additionally, oil soluble vitamins include Vitamin A, Vitamin D, Vitamin E, Vitamin K, and mixtures thereof.

[0040] Also, examples of acceptable minerals that can be present in a composition having a Sea Buckthorn extract can include calcium, potassium, iron, chromium, phosphorous, magnesium, zinc, copper and mixtures thereof, as well as any other minerals essential to the human body.

[0041] Additionally, examples of acceptable amino acids include but are not limited to alanine arginine, carnitine, gamma-aminobutyric acid (GABA), glutamine, glycine, histidine, lysine, methionine, N-acetyl systeine, ornithine, phenylalanine, taurine, tyrosine, valine, and mixtures thereof.

[0042] Additionally, a composition containing a Sea Buckthorn extract can include additional antioxidants. Specific examples of acceptable antioxidants which can be incorporated into a Sea Buckthorn composition may include but are not limited to polyphenols such as catechin, beta-carotene, coenzyme Q10, grapnel, and mixtures thereof.

[0043] The Sea Buckthorn extract utilized in the present invention may be derived from any part of the Sea Buckthorn plant, and may take a variety of physical forms. However, in one aspect, the extract may be an oil. In another aspect, the extract may be a pulp. In yet another aspect, the extract may be water-soluble infusion extract. In a further aspect, the extract may be a dry, or lyophilized powder. In an additional aspect, the extract may be an emulsion. Moreover, the extract may be obtained from various portions of the Sea Buckthorn plant. In one aspect, the extract may be obtained from the fruit. In another aspect, the extract may be obtained from the leaves. In yet another aspect, the extract may be obtained from the stems or branches. In a further aspect, the extract may be obtained from the seeds. The Sea Buckthorn compositions of the present invention may be formulated into a variety of suitable dosage forms for the administration thereof. Many different dosage forms are well known to those of ordinary skill in the art and may be used for the administration of the Sea Buckthorn extract. In one aspect, the formulation may consist of the Sea Buckthorn extract prepared and administered to a subject directly. In another aspect, the extract may be combined with a suitable carrier and/or other inactive ingredients to provide a specific dosage form.

[0044] In one aspect, the Sea Buckthorn formulation may be provided as an oral dosage form. A variety of oral dosage forms are will known to those of ordinary skill in the art, and specific formulation ingredients may be selected in order to provide a specific result. Examples of oral dosage forms include without limitation, oral dosage forms, such as powders, tablets, capsules, gel capsules, liquids, syrups, elixirs, and suspensions. Additionally, oral dosage forms encompass food preparations, such as bars and beverages. Accordingly, in one aspect of the present invention, the Sea Buckthorn composition may be a dosage form selected from the group consisting of beverages, effervescent beverages, liquids, syrups, elixirs, suspensions, tablets, powders, capsules, gel capsules, confections, candies, bars, lozenges, and combinations thereof.

[0045] In another aspect, the Sea Buckthorn formulation may be provided as a transdermal or parenteral dosage form. A number of specific transdermal and parenteral dosage

forms are known to those of ordinary skill in the art. Examples of transdermal dosage forms include without limitation, lotions, gels, creams, pastes, ointments, transmucosal tablets and adhesive devices, adhesive matrix-type transdermal patches, liquid reservoir transdermal patches, etc.

[0046] The amount of Sea Buckthorn extract included in the formulation need only be an amount that is sufficient to provide a desired therapeutic effect. As noted above, a variety of factors, such as individual physiology, the presence or absence of other compounds in the body, etc. may affect amount of Sea Buckthorn extract required to provide a therapeutic effect. Moreover, the amount of extract required to obtain weight reducing results may differ from the amount required to provide a serum lipid lowering effect. However, in one aspect, the amount of Sea Buckthorn extract may be an amount sufficient to stimulate the production and/or release of cholecystokinin. In another aspect, the amount may be sufficient to effect a body weight reduction. In another aspect, the amount may be sufficient to lower serum lipid concentrations. Those of ordinary skill in the art will be able to measure the physiological effect of the Sea Buckthorn extract and adjust the dosage amount accordingly.

[0047] As noted above, the Sea Buckthorn formulations of the present invention may optionally include one or more additional active agents. Both natural and synthetically produced active agents may be included. Those of ordinary skill in the art will be able to select from a wide range of specific ingredients in order to provide a desired therapeutic effect. In one aspect, the additional active ingredient may be a natural ingredient, such as an herbal or botanical extract. In another aspect, the additional active ingredient may be synthetically produced.

[0048] One specific type of additional active ingredient that may be used is an additional body weight reducing compound, such as a thermogenic compound (i.e. metabolism increasing compound). A wide range of compounds have been taught to produce a weight reducing effect, and are known to those of ordinary skill in the art. Examples of specific thermogenic compounds that may be used include without limitation, Ma Huang extract (ephedra), citrus aurantum extract (zhi shi, bitter orange, and synephrine), yohimbine extract (yohimbine), coleus extract (forskolin), and guarana (caffeine) and other stimulant compounds.

[0049] In another aspect of an embodiment of the invention, the additional active agent may be an essential dietary component, including without limitation vitamins and minerals, amino acids, proteins, and enzymes. Additional active ingredients that have a positive health imparting effect include without limitation, anti-inflammatory ingredients, natural analgesics, essential oils, antioxidants, and hormones. Further, anti-stress, or cortisol reducing agents, such as Ashwagandha, Beta-sitosterol, Epimedium, Garlic, L-Theanine, Magnolia bark extract, and Phosphatidylserine, as well as blood glucose modulating agents, such as corosolic acid may be included. A discussion of cortisol reducing compositions is included in copending patent application Ser. No. 60/390,424, which is incorporated by reference. A discussion of blood glucose modulating compositions is included in copending patent application Ser. No. 60/374,196, which is incorporated herein by reference.

[0050] As discussed above, the present invention additionally encompasses methods for using the Sea Buckthorn formulations disclosed herein. In one aspect, the present invention provides a method for stimulating cholecystokinin release in a subject, which includes administering an effective amount of a Sea Buckthorn extract to the subject. In another aspect, the present invention provides a method for reducing body weight in a subject, which includes administering an effective amount of a Sea Buckthorn extract to the subject. In yet another aspect, the present invention provides a method for lower serum lipids in a subject, which includes administering an effective amount of a Sea Buckthorn extract to the subject. Such extracts may be provided as part of any of the formulations disclosed herein, or may simply be administered directly to the subject.

[0051] In one aspect of the invention, the serum lipid lowering effect may lower total serum lipids. In another aspect, the serum lipids lowered may be triglycerides. In yet another aspect, the serum lipids lowered may be total cholesterol. In yet another aspect, the serum lipids lowered may be low-density lipids (LDL). As will be recognized by one of ordinary skill in the art, the extent of lowering, and actual lipids affected may be dictated by a number of factors, including Sea Buckthorn dosage amount, other active ingredients administered, level of initial serum lipid concentration, presence of interfering compounds in the serum, hereditary factors, etc.

[0052] While the above-recited formulations and methods have been primarily described in the context of treating a condition such as obesity or high serum lipids, it is to be understood that the present invention additionally encompasses methods for preventing such conditions. Such methods of prevention follow substantially the compositions and methods heretofore outlined, and may be further adjusted by one of ordinary skill in the art to more properly reflect a stratagem of maintenance or prevention, rather than of treatment. For example, the amount of Sea Buckthorn extract administered may be an amount sufficient to prevent or maintain the afore-mentioned conditions, rather than to abate them.

[0053] In accordance with the above described compositions and methods of use thereof, a Sea Buckthorn composition can be administered on a daily basis as needed or according to a specific and customized dosing regimen. Accordingly, administering the composition can include a single daily dose, and can further include multiple doses per day. In one aspect, administering the composition to the subject can be part of a sustained dosing regimen. In another aspect, the regimen can be less than about 1 year. In another aspect, the regimen can be less than about 6 months. In another aspect, the regimen can be less than about 3 months. In another aspect, the regimen can be less than about 1 month.

[0054] The examples provided below are illustrative of various embodiments of using Sea Buckthorn extract for weight loss and reduction of serum lipids in accordance with the present invention. While certain Sea Buckthorn extracts and/or additional ingredients, or combinations of ingredients, may be preferred, no limitation thereto is to be inferred. Rather, the type of Sea Buckthorn formulation desired will dictate which specific components, and amounts thereof, are included in addition to the Sea Buckthorn extract. It is to be

understood the following examples were conducted on animals, where human formulations may vary with respect to the amount and concentration of any and/or all ingredient(s). These examples are provided to convey a more full understanding of the range of effective Sea Buckthorn formulations included in the present invention, and in no way to act as a limitation thereon.

EXAMPLES

Example 1

High Caloric Rat Model

[0055] The effect of Sea Buckthorn on weight loss in a high caloric rat model was observed. Female Sprague-Dawley rats with an initial average weight of about 160 grams were fed with high calorie forage diet for 20 days. The high calorie forage consisted of lard (15%), sugar (10%), yolk powder (5%), and basic forage (70%). Each group consisted of 10 rats, and were administered with various formulations with or without Sea Buckthorn. The various formulations had the compositions are set forth in Table 1.

TABLE 1

Formulation Compositions

Ingredient	A	B	C
Alisma Extract	50 (mg/kg)	50 (mg/kg)	50 (mg/kg)
Epimedium Extract	50 (mg/kg)	50 (mg/kg)	50 (mg/kg)
Semen Raphani Extract		1 (g/kg)	1 (g/kg)
Sea Buckthorn Extract (fruit oil + seed oil, v/v = 1)			2.5 (ml/kg)

[0056] A comparison of the effects of Sea Buckthorn on the change in body weight of rats dosed with the various formulations is set for forth in Table 2.

TABLE 2

Impact of Sea Buckthorn on Body Weight of HIgh Calorie Fed Rats

	Dosage		
Day	A	B	C
0	165.6 ± 10.38 (g)	162.6 ± 7.6 (g)	163.6 ± 11.27 (g)
7	193.1 ± 8.45	196.3 ± 13.96	184.2 ± 11.06
14	228.8 ± 20.21	229.10 ± 15.52	202.7 ± 13.19
20	234.3 ± 17.22	232.6 ± 17.08	216.3 ± 14.53

[0057] A comparison of the rat group dosed with formulation A compared to the rate group dosed with formulation B showed there was not a significant change in the weight gain induced by the high calorie forage. However, when Sea Buckthorn was added, as in the rat group dosed with formulation C, it appeared to decrease the rate of weight gain induced by the high caloric forage in comparison with both the rat groups dosed with formulations A and B. Also, the addition of Sea Buckthorn showed a decrease in weight gain as early as the 7th day after initiation of feeding the rats the high calorie forage.

Example 2

Normal Mouse Model

[0058] The effect of Sea Buckthorn on weight loss in a normal mouse model was observed. Normal male Kun Ming mice with an initial average weight of about 18-22 grams were all fed with a normal calorie chow for 7 days. The mice groups were administered with various formulations with or without Sea Buckthorn. The dosages administered were: fruit juice (20 ml/kg), fruit oil (20 ml/kg, and seed oil (20 ml/kg). After 7 days the impact of fruit juice, fruit oil, or seed oil fractions of Sea Buckthorn on the body weight of the mice was observed compared to a control group not supplemented with Sea Buckthorn is set forth in Table 3.

TABLE 3

Impact of Sea Buckthorn on Body Weight of Normal Mice

Dosage	Control	Fruit Juice	Fruit Oil	Seed Oil
Weight ± SD (g)	27.4 ± 1	26.0 ± 3	25.1 ± 2	24.8 ± 3
Number of mice	9	9	8	9
p (compared to control)		0.24	0.031	0.047

[0059] The results indicate that Sea Buckthorn can be effective in lowering the body weight of normal mice. More particularly, the results indicated that the Sea Buckthorn fruit oil and seed oil significantly lowered the body weight of mice fed with normal calorie chow.

Example 3

Sea Buckthorn Fruit Compound

[0060] The effect of a Sea Buckthorn fruit compound on weight loss in a normal mouse model was observed. Normal male Kun Ming mice with an initial average weight of about 18-22 grams were all fed with a normal calorie chow for 7 days. The mice groups were administered with or without a Sea Buckthorn fruit compound formulation. The Sea Buckthorn fruit compound formulation contained fruit powder (710 mg/kg), 10% crude flavone powder (80 mg/kg), and fruit oil (4 ml/kg). A comparison of the impact of a Sea Buckthorn fruit compound formulation on the body weight of the mice was observed compared to a control group not supplemented with Sea Buckthorn is set forth in Table 4.

TABLE 4

Impact of Sea Buckthorn on Body Weight of Normal Mice

Dosage	Control	Sea Buckthorn Fruit Compound
Weight ± SD (g)	29.5 ± 1	28.3 ± 1
Number of mice	12	12
p (compared to control)		0.031

[0061] The results indicate that Sea Buckthorn can be effective in lowering the body weight of normal mice. More particularly, the results indicated that the Sea Buckthorn fruit compound significantly lowered the body weight of mice fed with normal calorie chow.

Example 4

Hyperlipidic Animal Models

[0062] The effect of Sea Buckthorn on the serum lipid concentrations in hyperlipidic animals was observed. Stud-

ies were conducted to determine the effect of Sea Buckthorn on serum lipids in various hyperlipidic animal models.

[0063] In one study, control and experimental rats were all fed a high-fat diet for 8 weeks, where the experimental group was administered with a formulated Sea Buckthorn product. The results of the study indicated that Sea Buckthorn decreased serum total cholesterol (TC) and decreased low-density lipoprotein cholesterol (LDL) by 30-36% in the experimental group compared to the control group ($p<0.05$).

[0064] In another study, acute hyperlipidemic mice were injected (i.p.) with 57% yolk emulsion (20 ml/kg). These mice were administered a formulated Sea Buckthorn product for seven days, which resulted in a 21-22% decrease in TC and LDL ($p<0.05$).

[0065] In another study, endogenous hyperlipidic rabbits were fed a cholesterol-free, casein-rich diet. These rabbits were also administered a formulated Sea Buckthorn product for 4 weeks, which did not result in significant changes in serum TC and LDL.

[0066] In another study, mixed endogenous-exogenous hyperlipidic rabbits showed Sea Buckthorn reduced serum TC and LDL by about 17-23% in comparison. The findings show Sea Buckthorn can be effective in substantially reducing both TC and LDL in exogenous hyperlipidemic animals.

[0067] Accordingly, it can be concluded that Sea Buckthorn extract was capable of reducing serum lipids. While not wishing to be bound by theory, it is believed that Sea Buckthorn may be capable of reducing serum TC and LDL by inhibiting or reducing the animal's capability of lipid absorption. Also, it is believed that Sea Buckthorn may be capable of reducing serum TC and LDL by accelerating the metabolism of cholesterols. Additionally, it is believed that Sea Buckthorn may be capable of reducing serum TC and LDL by accelerating the excretion of cholesterols. Further, it is believed that Sea Buckthorn may be able to reduce serum TC and LDL concentrations by any of these aforementioned processes alone or in combination.

[0068] It is to be understood that the above-described examples are only illustrative of the application of the principles of the present invention. Numerous modifications and alternative arrangements may be devised by those skilled in the art without departing from the spirit and scope of the present invention and the appended claims are intended to cover such modifications and arrangements. Thus, while the present invention has been described above with particularity and detail in connection with what is presently deemed to be the most practical and/or preferred embodiments of the invention, it will be apparent to those of ordinary skill in the art that these examples not intended to be limiting in nature.

What is claimed is:

1. A method of controlling serum lipid concentrations in a subject comprising:

(a) providing a composition containing a therapeutically effective amount of a sea buckthorn extract and an inert carrier, and

(b) administering the composition to a subject.

2. A method as in claim 1, wherein the controlling is reducing serum lipid concentrations in a subject.

3. A method as in claim 2, wherein the serum lipid is a triglyceride.

4. A method as in claim 2, wherein the serum lipid is total cholesterol.

5. A method as in claim 2, wherein the serum lipid is a low-density lipoprotein.

6. A method as in claim 1, wherein the controlling is preventing a concentration increase in a serum lipid selected from the group consisting of triglycerides, cholesterol, low density lipoprotein, and combinations thereof.

7. A method as in claim 1, wherein the controlling is elevating high density lipoprotein serum concentrations.

8. A method as in claim 1, wherein the inert carrier is selected from the group consisting of calcium carbonate, calcium silicate, calcium magnesium silicate, calcium phosphate, kaolin, sodium hydrogen carbonate, sodium sulfate, barium carbonate, barium sulfate, magnesium sulfate, magnesium carbonate, activated carbon, water, isopropyl alcohol, ethyl alcohol, polyvinyl pyrrolidone, propylene glycol, polyethylene glycol stearyl alcohol, stearic acid, sorbitan monooleate, microcrystalline cellulose, sodium carboxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, sorbitol, mannitol, xylitol, starches, gelatins, lactose, acacia, carbomer, dextrin, guar gum, lactose, liquid glucose, maltodextrin, polymethacrylates, and combinations thereof.

9. A method as in claim 1, wherein the sea buckthorn extract is administered orally.

10. A method as in claim 9, wherein the oral administration is performed using a dosage form selected from the group consisting of beverages, effervescent beverages, liquids, syrups, elixirs, suspensions, tablets, powders, capsules, gel capsules, confections, candies, bars, lozenges, and combinations thereof.

11. A method as in claim 1, wherein the composition further comprises an active ingredient selected from the group consisting of herbal extracts, botanical extracts, vitamins, minerals, amino acids, proteins, enzymes, and combinations thereof.

12. A method as in claim 1, wherein the composition further comprises a cortisol controlling agent selected from the group consisting of ashwagandha, beta-sitosterol, Epimedium, garlic, L-theanine, magnolia bark extract, phosphatidylserine, and combinations thereof.

13. A method of controlling the body weight of a subject comprising:

(a) providing a composition containing a therapeutically effective amount of sea buckthorn extract and an inert carrier, and

(b) administering the composition to a subject.

14. A method as in claim 13, wherein the controlling is reducing the body weight of the subject.

15. A method as in claim 13, wherein the controlling is preventing the body weight of the subject from increasing.

16. A method as in claim 13, wherein the therapeutically effect amount of sea buckthorn extract increases serum cholecystokinin concentration in the subject.

17. A method as in claim 16, wherein the cholecystokinin serum concentration increase occurs by stimulating cholecystokinin production.

18. A method as in claim 16, wherein the cholecystokinin serum concentration increase occurs by an increased rate in the release from cholecystokinin producing cells.

19. A method as in claim 16, wherein the increased cholecystokinin serum concentration causes appetite suppression.

20. A method as in claim 13, wherein administering the composition to the subject is part of a sustained dosing regimen.

21. A method as in claim 20, wherein the regimen is less than about 1 year.

22. A method as in claim 21, wherein the regimen is less than about 6 months.

23. A method as in claim 22, wherein the regimen is less than about 3 months.

24. A method as in claim 23, wherein the regimen is less than about 1 month.

25. A method as in claim 13, wherein administering the composition to the subject includes a single daily dose.

26. A method as in claim 13, wherein administering the composition to the subject includes multiple doses per day.

27. A method as in claim 13, wherein the inert carrier is selected from the group consisting of calcium carbonate, calcium silicate, calcium magnesium silicate, calcium phosphate, kaolin, sodium hydrogen carbonate, sodium sulfate, barium carbonate, barium sulfate, magnesium sulfate, magnesium carbonate, activated carbon, water, isopropyl alcohol, ethyl alcohol, polyvinyl pyrrolidone, propylene glycol, polyethylene glycol stearyl alcohol, stearic acid, sorbitan monooleate, microcrystalline cellulose, sodium carboxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, sorbitol, mannitol, xylitol, starches, gelatins, lactose, acacia, carbomer, dextrin, guar gum, lactose, liquid glucose, maltodextrin, polymethacrylates, and combinations thereof.

28. A method as in claim 13, wherein the sea buckthorn extract is administered orally.

29. A method as in claim 28, wherein the oral administration is performed using a dosage form selected from the group consisting of beverages, effervescent beverages, liquids, syrups, elixirs, suspensions, tablets, powders, capsules, gel capsules, confections, candies, bars, lozenges, and combinations thereof.

30. A method as in claim 13, wherein the composition further comprises an active ingredient selected from the group consisting of herbal extracts, botanical extracts, vitamins, minerals, amino acids, proteins, enzymes, and combinations thereof.

31. A method as in claim 13, wherein the composition further comprises a cortisol controlling agent selected from the group consisting of ashwagandha, beta-sitosterol, Epimedium, garlic, L-theanine, magnolia bark extract, phosphatidylserine, and combinations thereof.

32. A sea buckthorn composition comprising

(a) a therapeutically effective amount of sea buckthorn extract; and

(b) an inert carrier.

33. A composition as in claim 32, wherein the inert carrier is selected from the group consisting of calcium carbonate, calcium silicate, calcium magnesium silicate, calcium phosphate, kaolin, sodium hydrogen carbonate, sodium sulfate, barium carbonate, barium sulfate, magnesium sulfate, magnesium carbonate, activated carbon, water, isopropyl alcohol, ethyl alcohol, polyvinyl pyrrolidone, propylene glycol, polyethylene glycol stearyl alcohol, stearic acid, sorbitan monooleate, microcrystalline cellulose, sodium carboxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, sorbitol, mannitol, xylitol, starches, gelatins, lactose, acacia, carbomer, dextrin, guar gum, lactose, liquid glucose, maltodextrin, polymethacrylates, and combinations thereof.

34. A composition as in claim 32, wherein the composition is a dosage form selected from the group consisting of beverages, effervescent beverages, liquids, syrups, elixirs, suspensions, tablets, powders, capsules, gel capsules, confections, candies, bars, lozenges, and combinations thereof.

35. A composition as in claim 32, wherein the composition further comprises an active ingredient selected from the group consisting of herbal extracts, botanical extracts, vitamins, minerals, amino acids, proteins, enzymes, and combinations thereof.

36. A composition as in claim 32, wherein the composition further comprises a cortisol controlling agent selected from the group consisting of ashwagandha, beta-sitosterol, Epimedium, garlic, L-theanine, magnolia bark extract, phosphatidylserine, and combinations thereof.

37. A composition as in claim 32, wherein the sea buckthorn extract is obtained from a portion of the sea buckthorn plant selected from the group consisting of the sea buckthorn fruit, the sea buckthorn leaves, the sea buckthorn stems and branches, the sea buckthorn seeds, and combinations thereof.

38. A composition as in claim 32, wherein the composition reduces serum lipid concentrations in a subject in need thereof when administered to said subject.

39. A composition as in claim 32, wherein the composition reduces the body weight of a subject in need thereof when administered to said subject.

40. A composition as in claim 32, wherein the composition increases the serum concentration of cholecystokinin in the subject when administered to said subject.

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(54) **PHARMACEUTICAL DOSAGE FORMS FOR HIGHLY HYDROPHILIC MATERIALS**

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(57) **ABSTRACT**

Pharmaceutical dosage forms having a highly hydrophilic fill material and a shell encapsulating the fill material are disclosed and described. Generally, the shell has at least one plasticizing agent therein in order to provide the shell with an effective plasticity. In one aspect, the shell may have included therein an amount of plasticizing agent that is sufficient to provide the shell with an effective plasticity upon migration of a portion of the plasticizing agent into the fill material. In another aspect, the plasticizing agent may have a solubility in the fill material of less than about 10% w/w. In yet another aspect, a combination of a plasticizing agent, and a plasticizing agent having a solubility in the fill material of less than about 10% w/w, may be presented in a total amount sufficient to provide the shell with an effective plasticity upon migration of plasticizing agent into the fill material.

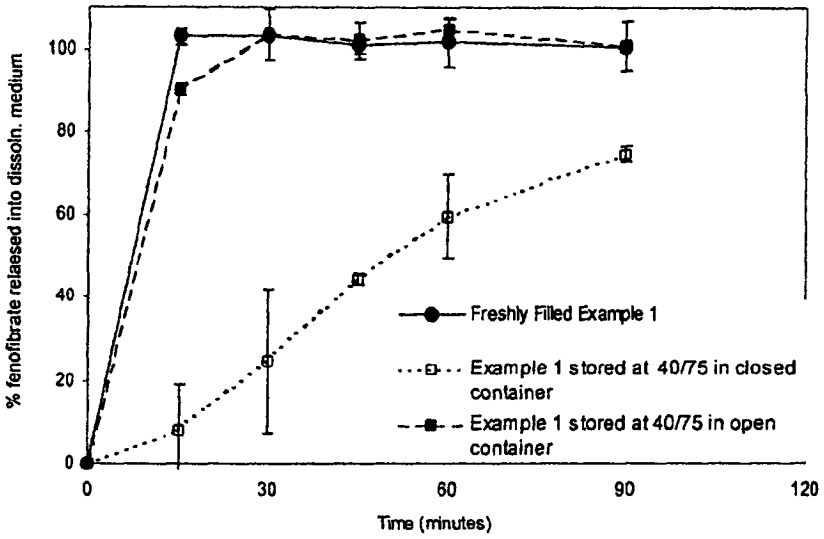
% fenofibrate relaesed into dissoln. medium
100
80
60
40
20
0
0
30
60
90
120
Time (minutes)
Freshly Filled Example 1
Example 1 stored at 40/75 in closed container
Example 1 stored at 40/75 in open container

FIG. 1

PHARMACEUTICAL DOSAGE FORMS FOR HIGHLY HYDROPHILIC MATERIALS

PRIORITY DATA

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. **09/898,553**, filed on Jul. 2, 2001, which is a continuation of U.S. patent application Ser. No. 09/258,654, filed Feb. 26, 1999, now issued as U.S. Pat. No. 6,294,192. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/877,541, filed on Jun. 8, 2001, which is a continuation of U.S. patent application Ser. No. 09/345,615, filed on Jun. 30, 1999, now issued as U.S. Pat. No. 6,267,985. Each of the above-recited patents and patent applications, as well as each of the additional references set forth in this patent application are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to pharmaceutical dosage forms that include a highly hydrophilic fill material and shell that encapsulates the fill material. Accordingly, the present invention involves the fields of chemistry, pharmaceutical sciences, and medicine.

BACKGROUND

[0003] Oral capsules are a well-known dosage form for administering various agents into the body through the gastrointestinal tract. Generally speaking, such capsules have two basic components, namely, a fill material that includes a pharmaceutically active agent, and a shell that encapsulates the fill material. Upon administration, the fill material is released and absorbed by the body as the shell degrades under various digestive forces.

[0004] Many specific constituents have been used to form the shell of various capsule formulations. One basic component is a matrix, or film forming material, such as gelatin, hydroxypropyl methyl cellulose (HPMC), gums, or other polymeric materials. Other, additives are often included in the shell to control the physical characteristics thereof. One such additive is a plasticizing agent that is used to control the softness or pliability of the shell. Regardless of whether the shell is prepared to be a hard or soft shell, certain amounts of plasticizing agents are important in order to keep the shell from becoming overly brittle.

[0005] Since its first inception, the concept of a capsule dosage form has evolved to include a variety of specific formulations which attain certain desired physical and performance properties. For example, in addition to a solid fill material, liquid or semi-solid fills have been employed in order to enable a more rapid release and an increased absorption of the pharmaceutically active agent. Further, both hard and soft shells have been used in order to vary the release timing of the pharmaceutically active agent. In short, by the variation of the shell and fill material constituents, improved capsule dosage forms have been produced.

[0006] One common constituent of the fill material is a carrier, or vehicle in which the pharmaceutically active agent to be delivered is dissolved or dispersed. Traditionally, fat soluble vitamins, such as vitamin E and digestible oils, such as triglycrides and fatty acids have been employed as the major constituent either as the active ingredient itself or as the carrier or vehicle for dissolving or dispersing the active ingredient. In general, these non-hygroscopic and non-glycerol solublizing materials enjoy good compatibility with traditional gelatin capsule shells that utilize glycerol as the plasticizer. However, the performance of these dosage forms frequently suffer from inconsistent and poor absorption of the active ingredients due to the lack of water dispersibility of such fill materials in vivo.

[0007] As a result, many types of carriers with improved water dispersibility have been sought and used. One class of vehicle that has been used in the fill is liquid polyethylene glycols (PEG) with a molecular weight of 100-600. However, since PEG is not a surfactant, it provides insufficient solubilization for a wide range of active ingredients once administered to the GI tract. Further, these materials suffer from the disadvantage of making the capsules brittle upon storage because their hygroscopic nature tend to draw water and other constituents, such as plasticizers out of the shell over time, as reported in U.S. Pat. Nos. 4,744,988 and 4,780,316.

[0008] Excessive brittleness interferes with the functionality of capsule dosage forms in a number of ways. First, an excessively brittle capsule may actually crack or burst prior to administration, thus allowing the fill material to leak therefrom. Further, a capsule that is too brittle may take too long to dissolve in gastric juices, and therefore the encapsulated active ingredient may not be released and absorbed as it intended to be. These and other issues caused by capsule embrittlement most often render the dosage form useless and a embrittlement inhibiting composition is required to impart physical stability and durability to the capsule.

[0009] Another problem that has been recognized with many fill materials, such as 1,2-propylene glycols), is their propensity to migrate into the shell, and thus overly soften it. One example of this phenomenon is contained in U.S. Pat. No. 5,985,321. Overly softened shells experience a several performance disadvantages, and further, the loss of propylene glycol from the fill material may upset an established balance of constituents that is required for sufficient drug loading capacity of the formulation and proper delivery and absorption of the active ingredient in the gastrointestinal tract. Therefore, propylene glycol was added to the shell as well to counteract the migration of it from the fill.

[0010] As a result, capsule dosage forms that include a fill material containing constituents capable of holding and delivering a wide variety of drugs, such as hygroscopic and hydrophilic carriers, that limit the movement of constituents from the shell into the fill material, and from the fill material into the shell, thus maintaining desired shell integrity and performance, continue to be sought through ongoing research and development efforts.

SUMMARY OF THE INVENTION

[0011] Accordingly, the present invention encompasses pharmaceutical dosage forms having a highly hydrophilic fill material that is encapsulated by a shell which maintains an effective plasticity despite the hydrophilicity of the fill material.

[0012] In one aspect, the dosage form may include a fill material may having a carrier of at least about 40% w/w of a hydrophilic surfactant, and at least one pharmaceutically

active agent, and a shell encapsulating the fill material which contains at least one plasticizing agent in an amount sufficient to maintain an effective shell plasticity upon migration of a portion of the plasticizing agent into the fill material.

[0013] In another aspect, the dosage form may include a fill material having a carrier of at least about 40% w/w of a hydrophilic surfactant, and at least one pharmaceutically active agent, and a shell encapsulating the fill material which contains an effective amount of a plasticizing agent having a solubility of less than 10% w/w in the fill material.

[0014] In yet another aspect of the invention, the dosage form may include a fill material having a carrier of at least about 40% w/w of a hydrophilic surfactant, and at least one pharmaceutically active agent, and a shell encapsulating the fill material, said shell containing a first plasticizing and a second plasticizing agent, said second plasticizing agent having a solubility in the fill material of less than about 10% w/w agent, wherein the first and second plasticizing agents are present in amounts sufficient to maintain an effective shell plasticity upon migration of a portion of either plasticizing agent into the fill material.

[0015] It is also an aspect of the present invention that the plasticizing agent(s) is present in an amount that the disintegration of the dosage form and/or the release of the fill material is not significantly alterted (becomes slower or incomplete) after storage.

[0016] It is another aspect of the present invention that the plasticizing agent(s) is present in an amount that the disintegration of the dosage form and/or the release of the fill material is not significantly alterted (becomes slower or incomplete) after storage, even if there is any chemical degradation or denaturation occurring in the shell, such as crosslinking of gelatin capsules by aldehyde substances.

[0017] There has thus been outlined, rather broadly, various features of the present invention so that the detailed description thereof that follows may be better understood, and so that the present contribution to the art may be better appreciated. Other features of the present invention will become clearer from the following detailed description of the invention, taken with the accompanying claims, or may be learned by the practice of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] **FIG. 1** is a graphical representation of release rate testing results achieved by oral dosage forms containing a highly hydrophilic fill material as used in the present invention, and traditional shell compositions used for moderately to low hydrophilic materials, such as PEG, following storage under varying conditions for a period of 4 weeks, as compared to freshly made conventional oral dosage forms.

DETAILED DESCRIPTION OF THE INVENTION

[0019] Before the present pharmaceutical dosage forms are disclosed and described, it is to be understood that the present invention is not limited to the particular process steps and materials disclosed herein, but is extended to equivalents thereof as would be recognized by those ordinarily skilled in the relevant arts. It should also be understood that terminology employed herein is used for the purpose of describing particular embodiments only and is not intended to be limiting.

[0020] Definitions

[0021] In describing and claiming the present invention, the following terminology will be used.

[0022] The singular forms "a,""an," and, "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to a fill material containing "a hydrophilic carrier" includes one or more hydrophilic carriers, reference to "an additive" includes reference to one or more of such additives, and reference to "the plasticizing agent" includes reference to one or more of such agents.

[0023] The terms "composition" and "formulation may be used interchangeably herein.

[0024] As used herein, "matrix forming material" and "film forming material may be used interchangeably, and refer to materials that are known to those of ordinary skill in the art as suitable for use in forming a shell of a typical capsule dosage form. Examples of such materials include without limitation, various gelatins, hydroxypropyl methyl cellulose (HPMC), starches, polymers, and gum acacia.

[0025] As used herein "shell" refers to a barrier that encapsulates, surrounds, or encompasses at least a portion of a material or an object. In the pharmaceutical arts, capsule dosage forms are well known to include a shell as an essential component that surrounds a fill material. A variety of specific materials and methods for the formation of such shells, are well known to those of ordinary skill in the art.

[0026] As used herein, an "effective amount," and "sufficient amount" may be used interchangeably, and refer to an amount of a substance that is sufficient to achieve an intended purpose or objective. For example, a sufficient, or effective amount of a suspending agent would be the minimum amount of agent required to effectively suspend one substance, such as a pharmaceutically active agent, in a carrier. The determination of an effective amount is well within the ordinary skill in the art of pharmaceutical, neutraceutical, herbaceutical, cosmetic, and medical sciences. See, for example, Meiner and Tonascia, "Clinical Trials: Design, Conduct, and Analysis,"*Monographs in Epidemiology and Biostatistics*, Vol. 8 (1986).

[0027] As used herein, "pharmaceutically active agent, ""bioactive agent,""therapeutic agent,""active agent," and "drug" may be used interchangeably herein, and refer to a substance, such as a chemical compound or complex, that has a measurable beneficial physiological effect on the body, such as a therapeutic effect in treatment of a disease or disorder, when administered in an effective amount. Further, when these terms are used, or when a particular active agent is specifically identified by name or category, it is to be understood that such recitation is intended to include the active agent per se, as well as pharmaceutically acceptable, pharmacologically active derivatives thereof, or compounds significantly related thereto, including without limitation, salts, esters, amides, prodrugs, active metabolites, isomers, fragments, analogs, etc.

[0028] Concentrations, amounts, solubilities, particle size, wavelength, and other numerical data may be expressed or presented herein in a range format. It is to be understood that such a range format is used merely for convenience and brevity and thus should be interpreted flexibly to include not only the numerical values explicitly recited as the limits of

the range, but also to include all the individual numerical values or sub-ranges encompassed within that range as if each numerical value and sub-range is explicitly recited.

[0029] As an illustration, a concentration range of "about 4% w/w to about 60% w/w" should be interpreted to include not only the explicitly recited concentration of about 4% w/w to about 60% w/w, but also include individual concentrations and the sub-ranges within the indicated range. Thus, included in this numerical range are individual concentrations such as 4% w/w, 10% w/w, 23% w/w, and 46% w/w, and sub-ranges such as from 10% w/w to 50% w/w, from 20% w/w to 40% w/w, from 25% w/w to 35% w/w, from 15% w/w to 20% w/w, etc.

[0030] This same principle applies to ranges reciting only one numerical value. Furthermore, such an interpretation should apply regardless of the breadth of the range or the characteristics being described.

[0031] Invention

[0032] Applicants have discovered pharmaceutical dosage forms having a shell that retains an effective plasticity while encapsulating a highly hydrophilic fill material. Such dosage forms present a number of advantages including increased freedom in formulating, processing and manufacturing specific dosage forms, increased absorption and/or efficacy of the active ingredient, more consistent performance of the dosage form with respect to disintegration of the dosage and dissolution/ solubilization of the active ingredient and improved storage stability.

A. Shell Formulations

[0033] The shell of the present invention may be either a hard or soft capsule shell, and includes a number of fundamental constituents as will be recognized by those of ordinary skill in the art, namely a matrix forming material, and at least one plasticizing agent. A wide variety of matrix forming materials are suitable for use in the dosage forms of the present invention, and the selection of specific materials may be based, at least in part, on factors such as the specific results to be achieved. Examples of specific materials include without limitation, gelatins, including type A gelatins, such as the gelatin derived from acid-treated pigskins, and type B gelatins, such as those derived from alkali-treated bovine bones and hides, hydroxypropyl methylcellulose (HPMC), starches, and gum acacia. Other specific matrix forming materials that may be particularly desired in view of a given overall dosage form can be determined by those of ordinary skill in the art.

[0034] The specific amount of matrix forming material used in the shell formulation may be determined in part by a variety of factors, including the type of shell to be formed (i.e. hard or soft), and by the amount and type of other constituents or additives that are to be included in the shell. However, in one aspect, the amount of matrix forming material may be from about 20% w/w to about 70% w/w of the shell. In another aspect, the amount may be from about 30% w/w to about 50% w/w of the shell.

[0035] Many plasticizing agents are known, and may also be used in the shell of the present dosage form. One basis for selecting a particular plasticizing agent may be the solubility of that agent in a specific hydrophilic fill material to be used. In one aspect, the plasticizing agent may have a solubility of less than about 10% w/w in the fill material. In another aspect, the solubility of the plasticizing agent in the fill material may be less than about 5% w/w. In yet another aspect, the solubility may be less than about 1% w/w. In a further aspect, the solubility of the plasticizing agent may be less than about 0.5% w/w. Lowered solubility in the specific hydrophilic fill material substantially impedes the migration of the plasticizing agent out of the shell and into the fill material. Examples of specific plasticizing agents displaying such limited solubilities in many hydrophilic surfactant materials include without limitation: sorbitol, sorbitanes, xylitol, maltitol, maltitol syrup, partially dehydrated hydrogenated glucose syrups, hydrogenated starch hydrolysate, polyhydric alcohols having an equilibrium relative humidity of greater than or equal to 80%, carrageenan, polyglycerol, non-crystallizing solutions of sorbitol, glucose, fructose, glucose syrups, and mixtures and equivalents thereof.

[0036] Whether the plasticizing agent selected and used is one that has a low solubility in the fill material or not, in accordance with one aspect of the invention, the plasticizing agent may be presented in an amount that is sufficient to maintain an effective shell plasticity upon migration of a portion of the plasticizing agent from the shell and into the fill and/or may be present in a sufficient amount to maintain a desirable dissolution/disintegration profile with respect to the rate and the extent release and/or dispersing of the encapsulated active agent in a specific dissolution medium or upon administration inside the GI tract. The exact amount of plasticizing agent required to compensate for the plasticizing agent anticipated to be lost may depend on a variety of factors, such as the specific fill material and solubility of the plasticizing agent therein. However, those of ordinary skill in the art will be able to readily determine approximate amounts required to maintain effective shell plasticity based on the known characteristics presented by a given dosage form, and will further be able to identify specific amounts through routine experimentation with the dosage form. In one aspect of the invention, such an amount of plasticizing agent may be from about 4% w/w to about 60% w/w of the shell. In another aspect, the amount may be from about 10% w/w to about 35% w/w.

[0037] An additional option for maintaining effective shell plasticity and/or a desirable dissolution/disintegration profile of the encapsulated active agent in view of the highly hydrophilic fill material is to include a combination of plasticizing agents in the shell in a total amount sufficient to maintain effective shell plasticity upon migration of a portion of either or both agents into the fill material. In one aspect of the invention, such a combination may include a first plasticizing agent, and a second plasticizing agent having a limited solubility in the fill material as recited above. The total amounts and ratios of each ingredient required to maintain an effective plasticity may be determined by one of ordinary skill in the art in the manners already indicated. While a variety of ratios and amounts are contemplated, in one aspect, the total amount of combined plasticizing agent may be within the ranges already established for plasticizing agents herein.

[0038] In addition to the components of a matrix forming material and the at least one plasticizing agent, the shells used in the dosage forms of the present invention may include additional additives as required, in order to achieve a specifically desired formulation or result. Examples of

such additives may include without limitation, coloring agents, antioxidants, preservatives, surfactants, and mixtures thereof. Specific amounts of these additives, as well as others not specifically recited will be readily determined by those of ordinary skill in the art, consistent with a working knowledge thereof, and the principles set forth herein.

[0039] In addition to the above recited devices and methods for maintaining the flexibility, or plasticity of a shell encapsulating a highly hydrophilic material, another approach encompassed by the present invention, is the use of a hydrophobic coating on a surface of the shell. Specifically, it is thought that by placing a hydrophobic coating along an inner surface of the shell, that water and plasticizer may be effectively stopped from migrating into the the fill material, or at least that such migration may be slowed. Further, when such a coating is provided along an outer surface of the shell it is thought that the coating prevents the absorption of moisture from the outside environment, and its resultant migration into the fill material, or that at least, such is slowed. In addition to slowing or preventing the migration of water and plasticizers into the fill material, use of such coatings is thought to prevent or slow the migration of plasticizers from the shell and into the fill material. Such migration is known to cause over-softening or "sweating" of the shell, which can be can be as detrimental to the performance of the dosage form as embrittling of the shell.

[0040] Either coating may be used separately in various embodiments of the present invention, or a combination of coatings may be used. Such coatings may further be employed with virtually any specific dosage form or shell formulation as contemplated herein. Further, a variety of hydrophobic, or water impermeable materials may be used for the coating as will be recognized by those of ordinary skill in the art, such as oils, petroleum waxes, etc.

B. Fill Material

[0041] The fill materials of the present oral dosage forms contain at least one pharmaceutically active agent, or drug, and a carrier, or vehicle, in which the drug is dissolved or dispersed. As a general matter, the carrier typically includes a hydrophilic surfactant in a significantly higher amount than found in a typical emulsion pre-concentrate or a typical microemulsion pre-concentrate. It is thought that such amounts present a number of performance and efficacy advantages, including without limitation increased solubility of the active agent in the fill material, increased dispersibility of the fill material in the gastrointestinal tract. Thus, larger doses of a therapeutic agent can be consistantly delivered and absorbed with greater speed and efficiency.

[0042] In general, the fill material of the present invention includes at least about 40% w/w of a hydrophilic surfactant. However, in one aspect, the hydrophilic surfactant may comprise at least about 50% of the carrier. In yet another aspect, the hydrophilic surfactant may comprise at least about 60% w/w of the carrier. Furthermore, a lipophilic additive, such as a lipophilic surfactant or a triglyceride may be included in the fill material. Other additives may also be included, such as antioxidants, bufferants, antifoaming agents, detackifiers, preservatives, chelating agents, viscomodulators, tonicifiers, flavorants, colorants, odorants, opacifiers, stabilizing agents, solubilizers, binders, fillers, plasticizing agents, lubricants, and mixtures thereof. The specific type and amount of additive may be selected by one of ordinary skill in the art, in order to provide a dosage form with particular characteristics.

[0043] 1. Triglycerides

[0044] One specific lipohilic additive that may be combined with the hydrophilic surfactant carrier of the present fill material is a triglyceride. Examples of suitable triglycerides are shown in Table 1. In general, these triglycerides are readily available from commercial sources. For several triglycerides, representative commercial products and/or commercial suppliers are listed.

TABLE 1

Triglycerides

Triglyceride	Commercial Source
Aceituno oil	
Almond oil	Super Refined Almond Oil(Croda)
Arachis oil	
Babassu oil	
Blackcurrant seed oil	
Borage oil	
Buffalo ground oil	
Candlenut oil	
Canola oil	Lipex 108 (Abitec)
Caster oil	
Chinese vegetable tallow oil	
Cocoa butter	
Coconut oil	Pureco 76 (Abitec)
Coffee seed oil	
Corn oil	Super Refined Corn Oil (Croda)
Cottonseed oil	Super Refined Cottonseed Oil(Croda)
Crambe oil	
Cuphea species oil	
Evening primrose oil	
Grapeseed oil	
Groundnut oil	
Hemp seed oil	
Illipe butter	
Kapok seed oil	
Linseed oil	

TABLE 1-continued

Triglycerides	
Triglyceride	Commercial Source
Menhaden oil	Super Refined Menhaden Oil (Croda)
Mowrah butter	
Mustard seed oil	
Oiticica oil	
Olive oil	Super Refined Olive Oil (Croda)
Palm oil	
Palm kernel oil	
Peanut oil	Super Refined Peanut Oil(Croda)
Poppy seed oil	
Rapeseed oil	
Rice bran oil	
Safflower oil	Super Refined Safflower Oil(Croda)
Sal fat	
Sesame oil	Super Refined Sesame Oil(Croda)
Shark liver oil	Super Refined Shark Liver Oil(Croda)
Shea nut oil	
Soybean oil	Super Refined Soybean Oil(Croda)
Stillingia oil	
Sunflower oil	
Tall oil	
Tea seed oil	
Tobacco seed oil	
Tung oil (China wood oil)	
Ucuhuba	
Vernonia oil	
Wheat germ oil	Super Refined Wheat Germ Oil(Croda)
Hydrogenated caster oil	Castorwax
Hydrogenated coconut oil	Pureco 100 (Abitec)
Hydrogenated cottonseed oil	Dritex C (Abitec)
Hydrogenated palm oil	Dritex PST (Abitec); Softisan 154 (Huls)
Hydrogenated soybean oil	Sterotex HM NF (Abitec); Dritex S (Abitec)
Hydrogenated vegetable oil	Sterotex NF (Abitec): Hydrokote M (Abitec)
Hydrogenated cottonseed and caster oil	Sterotex K (Abitec)
Partially hydrogenated soybean oil	Hydrokote AP5 (Abitec)
Partially soy and cottonseed oil	Apex B (Abitec)
Glyceryl tributyrate	(Sigma)
Glyceryl tricaproate	(Sigma)
Glyceryl tricaprylate	(Sigma)
Glyceryl tricaprate	Captex 1000 (Abitec)
Glyceryl trundecanoate	Captex 8227 (Abitec)
Glyceryl trilaurate	(Sigma)
Glyceryl trimyristate	Dynasan 114 (Huls)
Glyceryl tripalmitate	Dynasan 116 (Huls)
Glyceryl tristearate	Dynasan 118 (Huls)
Glyceryl triarcidate	(Sigma)
Glyceryl trimyristoleate	(Sigma)
Glyceryl tripalmitoleate	(Sigma)
Glyceryl trioleate	(Sigma)
Glyceryl trilinoleate	(Sigma)
Glyceryl trilinolenate	(Sigma)
Glyceryl tricaprylate/caprate	Captex 300 (Abitec); Captex 355 (Abitec); Miglyol 810 (Huls); Miglyol 812 (Huls)
Glyceryl tricaprylate/caprate/laurate	Captex 350 (Abitec)
Glyceryl tricaprylate/caprate/linoleate	Captex 810 (Abitec); Miglyol 818 (Huls)
Glyceryl tricaprylate/caprate/stearate	Softisan 378 (Huls); (Larodan)
Glyceryl tricaprylate/laurate/stearate	(Larodan)
Glyceryl 1,2-caprylate-3-linoleate	(Larodan)
Glyceryl 1,2-caprate-3-stearate	(Larodan)
Glyceryl 1,2-laurate-3-myristate	(Larodan)
Glyceryl 1,2-myristate-3-laurate	(Larodan)
Glyceryl 1,3-palmitate-2-butyrate	(Larodan)
Glyceryl 1,3-stearate-2-caprate	(Larodan)
Glyceryl 1,2-linoleate-3-caprylate	(Larodan)

[0045] Fractionated triglycerides, modified triglycerides, synthetic triglycerides, and mixtures of triglycerides are also within the scope of the invention.

[0046] Preferred triglycerides include vegetable oils, fish oils, animal fats, hydrogenated vegetable oils, partially hydrogenated vegetable oils, medium and long-chain triglycerides, and structured triglycerides. It should be appreciated that several commercial surfactant compositions contain small to moderate amounts of triglycerides, typically as a result of incomplete reaction of a triglyceride starting material in, for example, a transesterification reaction. Such commercial surfactant compositions, while nominally referred to as "surfactants", may be suitable to provide a desired triglyceride amount. Examples of commercial surfactant compositions containing triglycerides include some members of the surfactant families Gelucires (Gattefosse), Maisines (Gattefosse), and Imwitors (Huls). Specific examples of these compositions are:

[0047] Gelucire 44/14 (saturated polyglycolized glycerides)

[0048] Gelucire 50/13 (saturated polyglycolized glycerides)

[0049] Gelucire 53/10 (saturated polyglycolized glycerides)

[0050] Gelucire 33/01 (semi-synthetic triglycerides of C<8>-C<18> saturated fatty acids)

[0051] Gelucire 39/01 (semi-synthetic glycerides)

[0052] other Gelucires, such as 37/06, 43/01, 35/10, 37/02, 46/07, 48/09, 50/02, 62/05, etc.

[0053] Maisine 35-I (linoleic glycerides)

[0054] Imwitor 742 (caprylic/capric glycerides)

[0055] Still other commercial surfactant compositions having significant triglyceride content are known to those skilled in the art. It should be appreciated that such compositions, which contain triglycerides as well as surfactants, may be suitable to provide a triglyceride constituent for the purposes of the present invention.

[0056] Among the above-listed triglycerides, preferred triglycerides include: almond oil; babassu oil; borage oil; blackcurrant seed oil; canola oil; castor oil; coconut oil; corn oil; cottonseed oil; evening primrose oil; grapeseed oil; groundnut oil; mustard seed oil; olive oil; palm oil; palm kernel oil; peanut oil; rapeseed oil; safflower oil; sesame oil; shark liver oil; soybean oil; sunflower oil; hydrogenated castor oil; hydrogenated coconut oil; hydrogenated palm oil; hydrogenated soybean oil; hydrogenated vegetable oil; hydrogenated cottonseed and castor oil; partially hydrogenated soybean oil; partially soy and cottonseed oil; glyceryl tricaproate; glyceryl tricaprylate; glyceryl tricaprate; glyceryl triundecanoate; glyceryl trilaurate; glyceryl trioleate; glyceryl trilinoleate; glyceryl trilinolenate; glyceryl tricaprylate/caprate; glyceryl tricaprylate/caprate/laurate; glyceryl tricaprylate/caprate/linoleate; and glyceryl tricaprylate/caprate/stearate. Other preferred triglycerides are saturated polyglycolized glycerides (Gelucire 44/14, Gelucire 50/13 and Gelucire 53/10), linoleic glycerides (Maisine 35-I), and caprylic/capric glycerides (Imwitor 742).

[0057] Among the preferred triglycerides, more preferred triglycerides include: coconut oil; corn oil; olive oil; palm oil; peanut oil; safflower oil; sesame oil; soybean oil; hydrogenated castor oil; hydrogenated coconut oil; partially hydrogenated soybean oil; glyceryl tricaprate; glyceryl trilaurate; glyceryl trioleate; glyceryl trilinoleate; glyceryl tricaprylate/caprate; glyceryl tricaprylate/caprate/laurate; glyceryl tricaprylate/caprate/linoleate; glyceryl tricaprylate/caprate/stearate; saturated polyglycolized glycerides (Gelucire 44/14, Gelucire 14 50/13 and Gelucire 53/10); linoleic glycerides (Maisine 35-I); and caprylic/capric glycerides (Imwitor 742).

[0058] 2. Surfactants

[0059] As is well known in the art, the terms "hydrophilic" and "lipophilic" are relative terms. To function as a surfactant, a compound must necessarily include polar or charged hydrophilic moieties as well as non-polar lipophilic (hydrophobic) moieties. In other words, a surfactant compound must be amphiphilic. An empirical parameter commonly used to characterize the relative hydrophilicity and lipophilicity of non-ionic amphiphilic compounds is the hydrophilic-lipophilic balance ("HLB" value). Surfactants with lower HLB values are more lipophilic, and have greater solubility in oils, while surfactants with higher HLB values are more hydrophilic, and have greater solubility in aqueous solutions.

[0060] Using HLB values as a rough guide, hydrophilic surfactants are generally considered to be those compounds having an HLB value of greater than about 10, as well as anionic, cationic, or zwitterionic compounds for which the HLB scale is not generally applicable. Similarly, lipophilic surfactants are compounds having an HLB value of less than about 10.

[0061] It should be appreciated that the HLB value of a surfactant is merely a rough guide generally used to enable formulation of industrial, pharmaceutical and cosmetic emulsions. For many important surfactants, including several polyethoxylated surfactants, it has been reported that HLB values can differ by as much as about 8 HLB units, depending upon the empirical method chosen to determine the HLB value (Schott, J Pharm. Sciences, 79(1), 87-88 (1990)). Likewise, for certain polypropylene oxide containing block copolymers (PLURONIC® surfactants, BASF Corp.), the HLB values may not accurately reflect the true physical chemical nature of the compounds. Finally, commercial surfactant products are generally not pure compounds, but are complex mixtures of compounds, and the HLB value reported for a particular compound may more accurately be characteristic of the commercial product of which the compound is a major component. Different commercial products having the same primary surfactant component can, and typically do, have different HLB values. In addition, a certain amount of lot-to-lot variability is expected even for a single commercial surfactant product. Keeping these inherent difficulties in mind, and using HLB values as a guide, one skilled in the art can readily identify surfactants having suitable hydrophilicity or lipophilicity for use in the present invention, as described herein.

[0062] The hydrophilic surfactant can be any hydrophilic surfactant suitable for use in pharmaceutical compositions. Such surfactants can be anionic, cationic, zwitterionic or non-ionic, although non-ionic hydrophilic surfactants are

presently preferred. As discussed above, these non-ionic hydrophilic surfactants will generally have HLB values greater than about 10. Mixtures of hydrophilic surfactants are also within the scope of the invention.

[0063] Similarly, the lipophilic surfactant can be any lipophilic surfactant suitable for use in pharmaceutical compositions. In general, suitable lipophilic surfactants will have an HLB value less than about 10. Mixtures of lipophilic surfactants are also within the scope of the invention.

[0064] The choice of specific lipophilic and hydrophilic surfactants should be made keeping in mind the particular therapeutic agent to be used in the composition, and the range of polarity appropriate for the chosen therapeutic agent, as discussed in more detail below. With these general principles in mind, a very broad range of surfactants is suitable for use in the present invention. Such surfactants can be grouped into the following general chemical classes detailed in the Tables below. The HLB values given in the Tables below generally represent the HLB value as reported by the manufacturer of the corresponding commercial product. In cases where more than one commercial product is listed, the HLB value in the Tables is the value as reported for one of the commercial products, a rough average of the reported values, or a value that, in the judgment of the Applicants, is more reliable. It should be emphasized that the invention is not limited to the surfactants in the following Tables, which show representative, but not exclusive, lists of available surfactants.

[0065] 2.1. Polyethoxylated Fatty Acids

[0066] Although polyethylene glycol (PEG) itself does not function as a surfactant, a variety of PEG-fatty acid esters do. Among the PEG-fatty acid monoesters, esters of lauric acid, oleic acid, and stearic acid are most useful. Among the surfactants of Table 1, preferred hydrophilic surfactants include PEG-8 laurate, PEG-8 oleate, PEG-8 stearate, PEG-9 oleate, PEG-10 laurate, PEG-10 oleate, PEG-12 laurate, PEG-12 oleate, PEG-15 oleate, PEG-20 laurate and PEG-20 oleate. Examples of polyethoxylated fatty acid monoester surfactants commercially available are shown in Table 2.

TABLE 2

PEG-Fatty Acid Monoester Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG 4-100 monolaurate	Crodet L series (Croda)	>9
PEG 4-100 monooleate	Crodet O series (Croda)	>8
PEG 4-100 monostearate	Crodet S series (Croda), Myrj Series (Atlas/ICI)	>6
PEG 400 distearate	Cithrol 4DS series (Croda)	>10
PEG 100, 200, 300 monolaurate	Cithrol ML series (Croda)	>10
PEG 100, 200, 300 monooleate	Cithrol MO series (Croda)	>10
PEG 400 dioleate	Cithrol 4DO series (Croda)	>10
PEG 400-1000 monostearate	Cithrol MS series (Croda)	>10
PEG-1 stearate	Nikkol MYS-1EX (Nikko), Coster K1 (Condea)	2
PEG-2 stearate	Nikkol MYS-2 (Nikko)	4
PEG-2 oleate	Nikkol MYO-2 (Nikko)	4.5
PEG-4 laurate	Mapeg ® 200 ML (PPG), Kessco ® PEG 200 ML (Stepan), LIPOPEG 2 L(LIPO Chem.)	9.3
PEG-4 oleate	Mapeg ® 200 MO (PPG), Kessco ® PEG 200 MO (Stepan)	8.3
PEG-4 stearate	Kessco ® PEG 200 MS (Stepan), Hodag 20 S (Calgene), Nikkol MYS-4 (Nikko)	6.5
PEG-5 stearate	Nikkol TMGS-5 (Nikko)	9.5
PEG-5 oleate	Nikkol TMGO-5 (Nikko)	9.5
PEG-6 oleate	Algon OL 60 (Auschem SpA), Kessco ® PEG 300 MO (Stepan), Nikkol MYO-6 (Nikko), Emulgante A6 (Condea)	8.5
PEG-7 oleate	Algon OL 70 (Auschem SpA)	10.4
PEG-6 laurate	Kessco ® PEG300 ML (Stepan)	11.4
PEG-7 laurate	Lauridac 7 (Condea)	13
PEG-6 stearate	Kessco ® PEG300 MS (Stepan)	9.7
PEG-8 laurate	Mapeg ® 400 ML (PPG), LIPOPEG 4DL(Lipo Chem.)	13
PEG-8 oleate	Mapeg ® 400 MO (PPG), Emulgante A8 (Condea)	12
PEG-8 stearate	Mapeg ® 400 MS (PPG), Myrj 45	12
PEG-9 oleate	Emulgante A9 (Condea)	>10
PEG-9 stearate	Cremophor S9 (BASF)	>10
PEG-10 laurate	Nikkol MYL-10 (Nikko), Lauridac 10 (Croda)	13
PEG-10 oleate	Nikkol MYO-10 (Nikko)	11
PEG-12 stearate	Nikkol MYS-10 (Nikko), Coster K100 (Condea)	11
PEG-12 laurate	Kessco ® PEG 600 ML (Stepan)	15
PEG-12 oleate	Kessco ® PEG 600 MO (Stepan)	14
PEG-12 ricinoleate	(CAS #9004-97-1)	>10
PEG-12 stearate	Mapeg ® 600 MS (PPG), Kessco ® PEG 600 MS (Stepan)	14
PEG-15 stearate	Nikkol TMGS-15 (Nikko), Koster K15 (Condea)	14
PEG-15 oleate	Nikkol TMGO-15 (Nikko)	15
PEG-20 laurate	Kessco ® PEG 1000 ML (Stepan)	17
PEG-20 oleate	Kessco ® PEG 1000 MO (Stepan)	15

TABLE 2-continued

PEG-Fatty Acid Monoester Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG-20 stearate	Mapeg ® 1000 MS (PPG), Kessco ® PEG 1000 MS (Stepan), Myrj 49	16
PEG-25 stearate	Nikkol MYS-25 (Nikko)	15
PEG-32 laurate	Kessco ® PEG 1540 ML (Stepan)	16
PEG-32 oleate	Kessco ® PEG 1540 MO (Stepan)	17
PEG-32 stearate	Kessco ® PEG 1540 MS (Stepan)	17
PEG-30 stearate	Myrj 51	>10
PEG-40 laurate	Crodet L40 (Croda)	17.9
PEG-40 oleate	Crodet O40 (Croda)	17.4
PEG-40 stearate	Myrj 52, Emerest ® 2715 (Henkel), Nikkol MYS-40 (Nikko)	>10
PEG-45 stearate	Nikkol MYS-45 (Nikko)	18
PEG-50 stearate	Myrj 53	>10
PEG-55 stearate	Nikkol MYS-55 (Nikko)	18
PEG-100 oleate	Crodet O-100 (Croda)	18.8
PEG-100 stearate	Myrj 59, Ariacel 165 (ICI)	19
PEG-200 oleate	Albunol 200 MO (Taiwan Surf.)	>10
PEG-400 oleate	LACTOMUL (Henkel), Albunol 400 MO (Taiwan Surf.)	>10
PEG-600 oleate	Albunol 600 MO (Taiwan Surf.)	>10

[0067] 2.2 PEG-Fatty Acid Diesters

[0068] Polyethylene glycol fatty acid diesters are also suitable for use as surfactants in the compositions of the present invention. Among the surfactants in Table 2, preferred hydrophilic surfactants include PEG-20 dilaurate, PEG-20 dioleate, PEG-20 distearate, PEG-32 dilaurate and PEG-32 dioleate. Representative PEG-fatty acid diesters are shown in Table 3.

TABLE 3

PEG-Fatty Acid Diester Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG-4 dilaurate	Mapeg ® 200 DL (PPG), Kessco ® PEG 200 DL (Stepan), LIPOPEG 2-DL (Lipo Chem.)	7
PEG-4 dioleate	Mapeg ® 200 DO (PPG),	6
PEG-4 distearate	Kessco ® 200 DS (Stepan)	5
PEG-6 dilaurate	Kessco ® PEG 300 DL (Stepan)	9.8
PEG-6 dioleate	Kessco ® PEG 300 DO (Stepan)	7.2
PEG-6 distearate	Kessco ® PEG 300 DS (Stepan)	6.5
PEG-8 dilaurate	Mapeg ® 400 DL (PPG), Kessco ® PEG 400 DL (Stepan), LIPOPEG 4 DL (Lipo Chem.)	11
PEG-8 dioleate	Mapeg ® 400 DO (PPG), Kessco ® PEG 400 DO (Stepan), LIPOPEG 4 DO (Lipo Chem.)	8.8
PEG-8 distearate	Mapeg ® 400 DS (PPG), CDS 400 (Nikkol)	11
PEG-10 dipalmitate	Polyaldo 2PKFG	>10
PEG-12 dilaurate	Kessco ® PEG 600 DL (Stepan)	11.7
PEG-12 distearate	Kessco ® PEG 600 DS (Stepan)	10.7
PEG-12 dioleate	Mapeg ® 600 DO (PPG), Kessco ® 600 DO (Stepan)	10
PEG-20 dilaurate	Kessco ® PEG 1000 DL (Stepan)	15
PEG-20 dioleate	Kessco ® PEG 1000 DO (Stepan)	13
PEG-20 distearate	Kessco ® PEG 1000 DS (Stepan)	12
PEG-32 dilaurate	Kessco ® PEG 1540 DL (Stepan)	16
PEG-32 dioleate	Kessco ® PEG 1540 DO (Stepan)	15
PEG-32 distearate	Kessco ® PEG 1540 DS (Stepan)	15
PEG-400 dioleate	Cithrol 4DO series (Croda)	>10
PEG-400 distearate	Cithrol 4DS series (Croda)	>10

[0069] 2.3 PEG-Fatty Acid Mono- and Di-ester Mixtures

[0070] In general, mixtures of surfactants are also useful in the present invention, including mixtures of two or more commercial surfactant products. Several PEG-fatty acid esters are marketed commercially as mixtures or mono- and diesters. Representative surfactant mixtures are shown in Table 4.

TABLE 4

PEG-Fatty Acid Mono- and Diester Mixtures

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG 4-150 mono, dilaurate	Kessco ® PEG 200–6000 mono, dilaurate (Stepan)	
PEG 4-150 mono, dioleate	Kessco ® PEG 200–6000 mono, dioleate (Stepan)	
PEG 4-150 mono, distearate	Kessco ® 200–6000 mono, distearate (Stepan)	

[0071] 2.4 Polyethylene Glycol Glycerol Fatty Acid Esters

[0072] Suitable PEG glycerol fatty acid esters are shown in Table 5. Among the surfactants in the Table, preferred hydrophilic surfactants are PEG-20 glyceryl laurate, PEG-30 glyceryl laurate, PEG-40 glyceryl laurate, PEG-20 glyceryl oleate, and PEG-30 glyceryl oleate.

TABLE 5

PEG Glycerol Fatty Acid Esters

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG-20 glyceryl laurate	Tagat ® L (Goldschmidt)	16
PEG-30 glyceryl laurate	Tagat ® L2 (Goldschmidt)	16
PEG-15 glyceryl laurate	Glycerox L series (Croda)	15
PEG-40 glyceryl laurate	Glycerox L series (Croda)	15
PEG-20 glyceryl stearate	Capmul ® EMG (ABITEC), Aldo ® MS-20 KFG (Lonza)	13

TABLE 5-continued

PEG Glycerol Fatty Acid Esters

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG-20 glyceryl oleate	Tagat ® O (Goldschmidt)	>10
PEG-30 glyceryl oleate	Tagat ® O2 (Goldschmidt)	>10

[0073] 2.5. Alcohol-Oil Transesterification Products

[0074] A large number of surfactants of different degrees of lipophilicity or hydrophilicity can be prepared by reaction of alcohols or polyalcohols with a variety of natural and/or hydrogenated oils. Most commonly, the oils used are castor oil or hydrogenated castor oil, or an edible vegetable oil such as corn oil, olive oil, peanut oil, palm kernel oil, apricot kernel oil, or almond oil. Preferred alcohols include glycerol, propylene glycol, ethylene glycol, polyethylene glycol, sorbitol, and pentaerythritol. Among these alcohol-oil transesterified surfactants, preferred hydrophilic surfactants are PEG-35 castor oil (Incrocas-35), PEG-40 hydrogenated castor oil (Cremophor RH 40), PEG-25 trioleate (TAGAT® TO), PEG-60 corn glycerides (Crovol M70), PEG-60 almond oil (Crovol A70), PEG-40 palm kernel oil (Crovol PK70), PEG-50 castor oil (Emalex C-50), PEG-50 hydrogenated castor oil (Emalex HC-50), PEG-8 caprylickcapric glycerides (Labrasol), and PEG-6 caprylic/capric glycerides (Softigen 767). Preferred lipophilic surfactants in this class include PEG-5 hydrogenated castor oil, PEG-7 hydrogenated castor oil, PEG-9 hydrogenated castor oil, PEG-6 corn oil (Labrafil® M 2125 CS), PEG-6 almond oil (Labrafil® M 1966 CS), PEG-6 apricot kernel oil (Labrafil® M 1944 CS), PEG-6 olive oil (Labrafil® M 1980 CS), PEG-6 peanut oil (Labrafil® M 1969 CS), PEG-6 hydrogenated palm kernel oil (Labrafil® 2130 BS), PEG-6 palm kernel oil (Labrafil® M 2130 CS), PEG-6 triolein (Labrafil® M 2735 CS), PEG-8 corn oil (Labrafil® WL 2609 BS), PEG-20 corn glycerides (Crovol M40), and PEG-20 almond glycerides (Crovol A40). The latter two surfactants are reported to have HLB values of 10, which is generally considered to be the approximate border line between hydrophilic and lipophilic surfactants. For purposes of the present invention, these two surfactants are considered to be lipophilic.

[0075] Representative surfactants of this class suitable for use in the present invention are shown in Table 6.

TABLE 6

Transesterification Products of Oils and Alcohols

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG-3 castor oil	Nikkol CO-3 (Nikko)	3
PEG-5, 9, and 16 castor oil	ACCONON CA series (ABITEC)	6–7
PEG-20 castor oil	Emalex C-20 (Nihon Emulsion), Nikkol CO-20 TX (Nikko)	11
PEG-23 castor oil	Emulgante EL23	>10
PEG-30 castor oil	Emalex C-30 (Nihon Emulsion), Alkamuls ® EL 620 (Rhone-Poulenc), Incrocas 30 (Croda)	11
PEG-35 castor oil	Cremophor EL and EL-P (BASF), Emulphor EL, Incrocas-35(Croda), Emulgin RO 35 (Henkel)	
PEG-38 castor oil	Emulgante EL 65 (Condea)	
PEG-40 castor oil	Emalex C-40 (Nihon Emulsion), Alkamuls ® EL 719 (Rhone-Poulenc)	13
PEG-50 castor oil	Emalex C-50 (Nihon Emulsion)	14
PEG-56 castor oil	Eumulgin ® PRT 56 (Pulcra SA)	>10
PEG-60 castor oil	Nikkol CO-60TX (Nikko)	14
PEG-100 castor oil	Thornley	>10
PEG-200 castor oil	Eumulgin ® PRT 200 (Pulcra SA)	>10
PEG-5 hydrogenated castor oil	Nikkol HCO-5 (Nikko)	6
PEG-7 hydrogenated castor oil	Simusol ® 989 (Seppic), Cremophor WO7 (BASF)	6
PEG-10 hydrogenated castor oil	Nikkol HCO-10 (Nikko)	6.5
PEG-20 hydrogenated castor oil	Nikkol HCO-20 (Nikko)	11
PEG-25 hydrogenated castor oil	Simulsol ® 1292 (Seppic), Cerex ELS 250 (Auschem SpA)	11
PEG-30 hydrogenated castor oil	Nikkol HCO-30 (Nikko)	11
PEG-40 hydrogenated castor oil	Cremophor RH 40 (BASF), Croduret (Croda), Emulgin HRE 40 (Henkel)	13
PEG-45 hydrogenated castor oil	Cerex ELS 450 (Auschem Spa)	14
PEG-50 hydrogenated castor oil	Emalex HC-50 (Nihon Emulsion)	14
PEG-60 hydrogenated castor oil	Nikkol HCO-60 (Nikko); Cremophor RH 60 (BASF)	15
PEG-80 hydrogenated castor oil	Nikkol HCO-80 (Nikko)	15
PEG-100 hydrogenated castor oil	Nikkol HCO-100 (Nikko)	17
PEG-6 corn oil	Labrafil ® M 2125 CS (Gattefosse)	4
PEG-6 almond oil	Labrafil ® M 1966 CS (Gattefosse)	4
PEG-6 apricot kernel oil	Labrafil ® M 1944 CS (Gattefosse)	4
PEG-6 olive oil	Labrafil ® M 1980 CS (Gattefosse)	4
PEG-6 peanut oil	Labrafil ® M 1969 CS (Gattefosse)	4
PEG-6 hydrogenated palm kernel oil	Labrafil ® M 2130 BS (Gattefosse)	4
PEG-6 palm kernel oil	Labrafil ® M 2130 CS (Gattefosse)	4

TABLE 6-continued

Transesterification Products of Oils and Alcohols

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG-6 triolein	Labrafil ® M 2735 CS (Gattefosse)	4
PEG-8 corn oil	Labrafil ® WL 2609 BS (Gattefosse)	6–7
PEG-20 corn glycerides	Crovol M40 (Croda)	10
PEG-20 almond glycerides	Crovol A40 (Croda)	10
PEG-25 trioleate	TAGAT ® TO (Goldschmidt)	11
PEG-40 palm kernel oil	Crovol PK-70	>10
PEG-60 corn glycerides	Crovol M70(Croda)	15
PEG-60 almond glycerides	Crovol A70 (Croda)	15
PEG-4 caprylic/capric triglyceride	Labrafac ® Hydro (Gattefosse),	4–5
PEG-8 caprylic/capric glycerides	Labrasol (Gattefosse), Labrafac ® CM 10 (Gattefosse)	>10
PEG-6 caprylic/capric glycerides	SOFTIGEN ® 767 (Huls), Glycerox 767 (Croda)	19
Lauroyl macrogol-32 glyceride	GELUCIRE 44/14 (Gattefosse)	14
Stearoyl macrogol glyceride	GELUCIRE 50/13 (Gattefosse)	13
Mono, di, tri, tetra esters of vegetable oils and sorbitol	SorbitoGlyceride (Gattefosse)	<10
Pentacrythrityl tetraisostearate	Crodamol PTIS (Croda)	<10
Pentaerythrityl distearate	Albunol DS (Taiwan Surf.)	<10
Pentaerythrityl tetraoleate	Liponate PO-4 (Lipo Chem.)	<10
Pentacrythrityl tetrastearate	Liponate PS-4 (Lipo Chem.)	<10
Pentaerythrityl tetracaprylate/ tetracaprate	Liponate PE-810 (Lipo Chem.), Crodamol PTC (Croda)	<10
Pentaerythrityl tetraoctanoate	Nikkol Pentarate 408 (Nikko)	

[0076] Also included as oils in this category of surfactants are oil-soluble vitamins, such as vitamins A, D, E, K, etc. Thus, derivatives of these vitamins, such as tocopheryl PEG-1000 succinate (TPGS, available from Eastman), are also suitable surfactants.

[0077] 2.6. Polyglycerized Fatty Acids

[0078] Polyglycerol esters of fatty acids are also suitable surfactants for the present invention. Among the polyglyceryl fatty acid esters, preferred lipophilic surfactants include polyglyceryl oleate (Plurol Oleique), polyglyceryl-2 dioleate (Nikkol DGDO), and polyglyceryl-10 trioleate. Preferred hydrophilic surfactants include polyglyceryl-110 laurate (Nikkol Decaglyn 1-L), polyglyceryl-10 oleate (Nikkol Decaglyn 1-O), and polyglyceryl-10 mono, dioleate (Caprol® PEG 860). Polyglyceryl polyricinoleates (Polymuls) are also preferred hydrophilic and lipophilic surfactants. Examples of suitable polyglyceryl esters are shown in Table 7.

TABLE 7

Polyglycerized Fatty Acids

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Polyglyceryl-2 stearate	Nikkol DGMS (Nikko)	5–7
Polyglyceryl-2 oleate	Nikkol DGMO (Nikko)	5–7
Polyglyceryl-2 isostearate	Nikkol DGMIS (Nikko)	5–7
Polyglyceryl-3 oleate	Caprol ® 3GO (ABITEC), Drewpol 3-1-O (Stepan)	6.5
Polyglyceryl-4 oleate	Nikkol Tetraglyn 1-O (Nikko)	5–7
Polyglyceryl-4 stearate	Nikkol Tetraglyn 1-S (Nikko)	5–6
Polyglyceryl-6 oleate	Drewpol 6-1-O (Stepan), Nikkol Hexaglyn 1-O (Nikko)	9
Polyglyceryl-10 laurate	Nikkol Decaglyn 1-L (Nikko)	15
Polyglyceryl-10 oleate	Nikkol Decaglyn 1-O (Nikko)	14
Polyglyceryl-10 stearate	Nikkol Decaglyn 1-S (Nikko)	12
Polyglyceryl-6 ricinolente	Nikkol Hexaglyn PR-15 (Nikko)	>8

TABLE 7-continued

Polyglycerized Fatty Acids

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Polyglyceryl-10 linoleate	Nikkol Decaglyn 1-LN (Nikko)	12
Polyglyceryl-6 pentaoleate	Nikkol Hexaglyn 5-O (Nikko)	<10
Polyglyceryl-3 dioleate	Cremophor GO32 (BASF)	<10
Polyglyceryl-3 distearate	Cremophor GS32 (BASF)	<10
Polyglyceryl-4 pentaoleate	Nikkol Tetraglyn 5-O (Nikko)	<10
Polyglyceryl-6 dioleate	Caprol ® 6G20 (ABITEC); Hodag PGO-62 (Calgene), PLUROL OLEIQUE CC 497 (Gattefosse)	8.5
Polyglyceryl-2 dioleate	Nikkol DGDO (Nikko)	7
Polyglyceryl-10 trioleate	Nikkol Decaglyn 3-O (Nikko)	7
Polyglyceryl-10 pentaoleate	Nikkol Decaglyn 5-O (Nikko)	3.5
Polyglyceryl-10 septaoleate	Nikkol Decaglyn 7-O (Nikko)	3
Polyglyceryl-10 tetraoleate	Caprol ® 10G4O (ABITEC); Hodag PGO-62 (CALGENE), Drewpol 10-4-O (Stepan)	6.2
Polyglyceryl-10 decaisostearate	Nikkol Decaglyn 10-IS (Nikko)	<10
Polyglyceryl-101 decaoleate	Drewpol 10-10-O (Stepan), Caprol 10G10O (ABITEC), Nikkol Decaglyn 10-O	3.5
Polyglyceryl-10 mono, dioleate	Caprol ® PGE 860 (ABITEC)	11
Polyglyceryl polyricinoleate	Polymuls (Henkel)	3–20

[0079] 2.7. Propylene Glycol Fatty Acid Esters

[0080] Esters of propylene glycol and fatty acids are suitable surfactants for use in the present invention. In this surfactant class, preferred lipophilic surfactants include propylene glycol monolaurate (Lauroglycol FCC), propylene glycol ricinoleate (Propymuls), propylene glycol monooleate (Myverol P-O6), propylene glycol dicaprylate/dicaprate (Captex ® 200), and propylene glycol dioctanoate (Captex® 800). Examples of surfactants of this class are given in Table 8.

TABLE 8

Propylene Glycol Fatty Acid Esters

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Propylene glycol monocaprylate	Capryol 90 (Gattefosse), Nikkol Sefsol 218 (Nikko)	<10
Propylene glycol monolaurate	Lauroglycol 90 (Gattefosse), Lauroglycol FCC (Gattefosse)	<10
Propylene glycol oleate	Lutrol OP2000 (BASF)	<10
Propylene glycol myristate	Mirpyl	<10
Propylene glycol monostearate	ADM PGME-03 (ADM), LIPO PGMS (Lipo Chem.), Aldo ® PGHMS (Lonza)	3–4
Propylene glycol hydroxy stearate		<10
Propylene glycol ricinoleate	PROPYMULS (Henkel)	<10
Propylene glycol isostearate		<10
Propylene glycol monooleate	Myverol P-O6 (Eastman)	<10
Propylene glycol dicaprylate/dicaprate	Captex ® 200 (ABITEC), Miglyol ® 840 (Huls), Neobee ® M-20 (Stepan)	>6
Propylene glycol dioctanoate	Captex ® 800 (ABITEC)	>6
Propylene glycol caprylate/caprate	LABRAFAC PG (Gattefosse)	>6
Propylene glycol dilaurate		>6
Propylene glycol distearate	Kessco ® PGDS (Stepan)	>6
Propylene glycol dicaprylate	Nikkol Sefsol 228 (Nikko)	>6
Propylene glycol dicaprate	Nikkol PDD (Nikko)	>6

[0081] 2.8. Mixtures of Propylene Glycol Esters-Glycerol Esters

[0082] In general, mixtures of surfactants are also suitable for use in the present invention. In particular, mixtures of propylene glycol fatty acid esters and glycerol fatty acid esters are suitable and are commercially available. One preferred mixture is composed of the oleic acid esters of propylene glycol and glycerol (Arlacel 186). Examples of these surfactants are shown in Table 9.

TABLE 9

Glycerol/Propylene Glycol Fatty Acid Esters

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Oleic	ATMOS 300, ARLACEL 186 (ICI)	3–4
Stearic	ATMOS 150	3–4

[0083] 2.9. Mono- and Diglycerides

[0084] A particularly important class of surfactants is the class of mono- and diglycerides. These surfactants are generally lipophilic. Preferred lipophilic surfactants in this class of compounds include glyceryl monooleate (Peceol), glyceryl ricinoleate, glyceryl laurate, glyceryl dilaurate (Capmul® GDL), glyceryl dioleate (Capmul® GDO), glyceryl mono/dioleate (Capmul® GMO-K), glyceryl caprylate/caprate (Capmul® MCM), caprylic acid mono/diglycerides (Imwitor® 988), and mono- and diacetylated monoglycerides (Myvacet® 9-45). Examples of these surfactants are given in Table 10.

TABLE 10

Mono- and Diglyceride Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Monopalmitolein (C16:1)	(Larodan)	<10
Monoolaidin (C18:1)	(Larodan)	<10
Monocaproin (C6)	(Larodan)	<10
Monocaprylin	(Larodan)	<10
Monocaprin	(Larodan)	<10
Monolaurin	(Larodan)	<10
Glyceryl monomyristate (C14)	Nikkol MGM (Nikko)	3–4
Glyceryl monooleate (C18:1)	PECEOL (Gattefosse), Hodag GMO-D, Nikkol MGO (Nikko)	3–4
Glyceryl monooleate	RYLO series (Danisco), DIMODAN series (Danisco), EMULDAN (Danisco), ALDO ® MO FG (Lonza), Kessco ® GMO (Stepan), MONOMULS ® series (Henkel), TEGIN O, DREWMULSE GMO (Stepan), Atlas G-695 (ICI), GMOrphic 80 (Eastman), ADM DMG-40, 70, and 100 (ADM), Myverol(Eastman)	3–4

TABLE 10-continued

Mono- and Diglyceride Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Glycerol monooleate/linoleate	OLICINE (Gattefosse)	3–4
Glycerol monolinoleate	Maisine (Gattefosse), MYVEROL 18–92, Myverol 18–06 (Eastman)	3–4
Glyceryl ricinoleate	Softigen ® 701 (Huls), HODAG GMR-D (Calgene), ALDO ® MR (Lonza)	6
Glyceryl monolaurate	ALDO ® MLD (Lonza), Hodag GML (Calgene)	6.8
Glycerol monopalmitate	Emalex GMS-P (Nihon)	4
Glycerol monostearate	Capmul ® GMS (ABITEC), Myvaplex (Eastman), IMWITOR ® 191 (Huls), CUTINA GMS, Aldo ® MS (Lonza), Nikkol MGS series(Nikko)	5–9
Glyceryl mono-, diolate	Capmul ® GMO-K (ABITEC)	<10
Glyceryl palmitic/stearic	CUTINA MD-A, ESTAGEL-G18	<10
Glyceryl acetate	Lamegin ® EE (Grunau GmbH)	<10
Glyceryl laurate	Imwitor ® 312 (Huls), Monomuls ® 90–45 (Grunau GmbH), Aldo ® MLD (Lonza)	4
Glyceryl citrate/lactate/oleate/linoleate	Imwitor ® 375 (Huls)	<10
Glyceryl caprylate	Imwitor ® 308 (Huls), Capmul ® MCMC8 (ABITEC)	5–6
Glyceryl caprylate/caprate	Capmul ® MCM (ABITEC)	5–6
Caprylic acid mono, diglycerides	Imwitor ® 988 (Huls)	5–6
Caprylic/capric glycerides	Imwitor ® 742 (Huls)	<10
Mono- and diacetylated monoglycerides	Myvacet ® 9–45, Myvacet ® 9–40, Myvacet ® 9–08 (Eastman), Lamegin ® (Grunau)	3.8–4
Glyceryl monostearate	Aldo ® MS, Arlacel 129 (ICI), LIPO GMS (Lipo Chem.), Imwitor ® 191 (Huls), Myvaplex (Eastman)	4.4
Lactic acid esters of mono, diglycerides	LAMEGIN GLP (Henkel)	<10
Dicaproin (C6)	(Larodan)	<10
Dicaprin (C10)	(Larodan)	<10
Dioctanoin (C8)	(Larodan)	<10
Dimyristin (C14)	(Larodan)	<10
Dipalmitin (C16)	(Larodan)	<10
Distearin	(Larodan)	<10
Glyceryl dilaurate (C12)	Capmul ® GDL (ABITEC)	3–4
Glyceryl diolate	Capmul ® GDO (ABITEC)	3–4
Glycerol esters of fatty acids	GELUCIRE 39/01 (Gattefosse), GELUCIRE 43/01 (Gattefosse) GELUCIRE 37/06 (Gattefosse)	1 6
Dipalmitolein (C16:1)	(Larodan)	<10
1,2 and 1,3-diolein (C18:1)	(Larodan)	<10
Dielaidin (C18:1)	(Larodan)	<10
Dilinolein (C18:2)	(Larodan)	<10

[0085] 2.10. Sterol and Sterol Derivatives

[0086] Sterols and derivatives of sterols are suitable surfactants for use in the present invention. These surfactants can be hydrophilic or lipophilic. Preferred derivatives include the polyethylene glycol derivatives. A preferred lipophilic surfactant in this class is cholesterol. A preferred hydrophilic surfactant in this class is PEG-24 cholesterol ether Solulan C-24). Examples of surfactants of this class are shown in Table 11.

TABLE 11

Sterol and Sterol Derivative Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Cholesterol, sitosterol, lanosterol		<10
PEG-24 cholesterol ether	Solulan C-24 (Amerchol)	>10
PEG-30 cholestanol	Nikkol DIIC (Nikko)	>10
Phytosterol	GENEROL series (Henkel)	<10
PEG-25 phyto sterol	Nikkol BPSH-25 (Nikko)	>10
PEG-5 soya sterol	Nikkol BPS-5 (Nikko)	<10
PEG-10 soya sterol	Nikkol BPS-10 (Nikko)	<10
PEG-20 soya sterol	Nikkol BPS-20 (Nikko)	<10
PEG-30 soya sterol	Nikkol BPS-30 (Nikko)	>10

[0087] 2.11. Polyethylene Glycol Sorbitan Fatty Acid Esters

[0088] A variety of PEG-sorbitan fatty acid esters are available and are suitable for use as surfactants in the present invention. In general, these surfactants are hydrophilic, although several lipophilic surfactants of this class can be used. Among the PEG-sorbitan fatty acid esters, preferred hydrophilic surfactants include PEG-20 sorbitan monolaurate (Tween-20), PEG-20 sorbitan monopalmitate (Tween-40), PEG-20 sorbitan monostearate (Tween-60), and PEG-20 sorbitan monooleate (Tween-80). Examples of these surfactants are shown in Table 12.

TABLE 12

PEG-Sorbitan Fatty Acid Esters

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG-10 sorbitan laurate	Liposorb L-10 (Lipo Chem.)	>10
PEG-20 sorbitan monolaurate	Tween-20 (Atlas/ICI), Crillet 1 (Croda), DACOL MLS 20 (Condea)	17
PEG-4 sorbitan monolaurate	Tween-21 (Atlas/ICI), Crillet 11 (Croda)	13
PEG-80 sorbitan monolaurate	Hodag PSML-80 (Calgene); T-Maz 28	>10
PEG-6 sorbitan monolaurate	Nikkol GL-1 (Nikko)	16
PEG-20 sorbitan monopalmitate	Tween-40 (Atlas/ICI), Crillet 2 (Croda)	16
PEG-20 sorbitan monostearate	Tween-60 (Atlas/ICI), Crillet 3 (Croda)	15
PEG-4 sorbitan monostearate	Tween-61 (Atlas/ICI), Crillet 31 (Croda)	9.6
PEG-8 sorbitan monostearate	DACOL MSS (Condea)	>10
PEG-6 sorbitan monostearate	Nikkol TS106 (Nikko)	11
PEG-20 sorbitan tristearate	Tween-65 (Atlas/ICI), Crillet 35 (Croda)	11
PEG-6 sorbitan tetrastearate	Nikkol GS-6 (Nikko)	3
PEG-60 sorbitan tetrastearate	Nikkol GS-460 (Nikko)	13
PEG-5 sorbitan monooleate	Tween-81 (Atlas/ICI), Crillet 41 (Croda)	10

TABLE 12-continued

PEG-Sorbitan Fatty Acid Esters

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG-6 sorbitan monooleate	Nikkol TO-106 (Nikko)	10
PEG-20 sorbitan monooleate	Tween-80 (Atlas/ICI), Crillet 4 (Croda)	15
PEG-40 sorbitan oleate	Emalex ET 8040 (Nihon Emulsion)	18
PBG-20 sorbitan trioleate	Tween-85 (Atlas/ICI), Crillet 45 (Croda)	11
PEG-6 sorbitan tetraolcate	Nikkol GO-4 (Nikko)	8.5
PEG-30 sorbitan tetraoleate	Nikkol GO-430 (Nikko)	12
PEG-40 sorbitan tetraoleate	Nikkol GO-440 (Nikko)	13
PEG-20 sorbitan monoisostearate	Tween-120 (Atlas/ICI), Crillet 6 (Croda)	>10
PEG sorbitol hexaoleate	Atlas G-1086 (ICI)	10
PEG-6 sorbitol hexastearate	Nikkol GS-6 (Nikko)	3

[0089] 2.12. Polyethylene Glycol Alkyl Ethers

[0090] Ethers of polyethylene glycol and alkyl alcohols are suitable surfactants for use in the present invention. Preferred lipophilic ethers include PEG-3 oleyl ether (Volpo 3) and PEG-4 lauryl ether (Brij 30). Examples of these surfactants are shown in Table 13.

TABLE 13

Polyethylene Glycol Alkyl Ethers

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG-2 oleyl ether,oleth-2	Brij 92/93 (Atlas/ICI)	4.9
PEG-3 oleyl ether,oleth-3	Volpo 3 (Croda)	<10
PEG-5 oleyl ether,oleth-5	Volpo 5 (Croda)	<10
PEG-10 oleyl ether,oleth-10	Volpo 10 (Croda), Brij 96/97 (Atlas/ICI)	12
PEG-20 oleyl ether,oleth-20	Volpo 20 (Croda), Brij 98/99 (Atlas/ICI)	15
PEG-4 lauryl ether,laureth-4	Brij 30 (Atlas/ICI)	9.7
PEG-9 lauryl ether		>10
PEG-23 lauryl ether,laureth-23	Brij 35 (Atlas/ICI)	17
PEG-2 cetyl ether	Brij 52 (ICI)	5.3
PEG-10 cetyl ether	Brij 56 (ICI)	13
PEG-20 cetyl ether	Brij 58 (ICI)	16
PEG-2 stearyl ether	Brij 72 (ICI)	4.9
PEG-10 stearyl ether	Brij 76 (ICI)	12
PEG-20 stearyl ether	Brij 78 (ICI)	15
PEG-100 stearyl ether	Brij 700 (ICI)	>10

[0091] 2.13. Sugar Esters

[0092] Esters of sugars are suitable surfactants for use in the present invention. Preferred hydrophilic surfactants in this class include sucrose monopalmitate and sucrose monolaurate. Examples of such surfactants are shown in Table 14.

TABLE 14

Sugar Ester Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Sucrose distearate	SUCRO ESTER 7 (Gattefosse), Crodesta F-10 (Croda)	3
Sucrose distearate/monostearate	SUCRO ESTER 11 (Gattefosse), Crodesta F-110 (Croda)	12

TABLE 14-continued

Sugar Ester Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Sucrose dipalmitate		7.4
Sucrose monostearate	Crodesta F-160 (Croda)	15
Sucrose monopalmitate	SUCRO ESTER 15 (Gattefosse)	>10
Sucrose monolaurate	Saccharose monolaurate 1695 (Mitsubishi-Kasei)	15

[0093] 2.14. Polyethylene Glycol Alkyl Phenols

[0094] Several hydrophilic PEG-alkyl phenol surfactants are available, and are suitable for use in the present invention. Examples of these surfactants are shown in Table 15.

TABLE 15

Polyethylene Glycol Alkyl Phenol Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
PEG-10-100 nonyl phenol	Triton X series (Rohm & Haas), Igepal CA series (GAF, USA), Antarox CA series (GAF, UK)	>10
PEG-15-100 octyl phenol ether	Triton N-series (Rohm & Haas), Igepal CO series (GAF, USA), Antarox CO series (GAF, UK)	>10

[0095] 2.15. Polyoxyethylene-Polyoxypropylene Block Copolymers

[0096] The POE-POP block copolymers are a unique class of polymeric surfactants.

[0097] The unique structure of the surfactants, with hydrophilic POE and lipophilic POP moieties in well-defined ratios and positions, provides a wide variety of surfactants suitable for use in the present invention. These surfactants are available under various trade names, including Synperonic PE series (ICI); Pluronic ® series (BASF), Emkalyx, Lutrol (BASF), Supronic, Monolan, Pluracare, and Plurodac. The generic term for these polymers is "poloxamer" (CAS 9003-11-6). These polymers have the formula:

HO(C<2>H<4>O)<a>(C<3>H<6>O)<b>(C<2>H<4>O)<a>H

[0098] where "a" and "b" denote the number of polyoxyethylene and polyoxypropylene units, respectively.

[0099] Preferred hydrophilic surfactants of this class include Poloxamers 108, 188, 217, 238, 288, 338, and 407. Preferred lipophilic surfactants in this class include Poloxamers 124, 182, 183, 212, 331, and 335.

[0100] Examples of suitable surfactants of this class are shown in Table 15. Since the compounds are widely available, commercial sources are not listed in the Table. The compounds are listed by generic name, with the corresponding "a" and "b" values.

TABLE 16

POE-POP Block Copolymers

COMPOUND	a, b values in HO(C<2>H<4>O)<a>(C<3>H<6>O)<b>(C<2>H<4>O)<a>H		HLB
Poloxamer 105	a 11	b 16	8
Poloxamer 108	a 46	b 16	>10
Poloxamer 122	a 5	b 21	3
Poloxamer 123	a 7	b 21	7
Poloxamer 124	a 11	b 21	>7
Poloxamer 181	a 3	b 30	
Poloxamer 182	a 8	b 30	2
Poloxamer 183	a 10	b 30	
Poloxamer 184	a 13	b 30	
Poloxamer 185	a 19	b 30	
Poloxamer 188	a 75	b 30	29
Poloxamer 212	a 8	b 35	
Poloxamer 215	a 24	b 35	
Poloxamer 217	a 52	b 35	
Poloxamer 231	a 16	b 39	
Poloxamer 234	a 22	b 39	
Poloxamer 235	a 27	b 39	
Poloxamer 237	a 62	b 39	24
Poloxamer 238	a 97	b 39	
Poloxamer 282	a 10	b 47	
Poloxamer 284	a 21	b 47	
Poloxamer 288	a 122	b 47	>10
Poloxamer 331	a 7	b 54	0.5
Poloxamer 333	a 20	b 54	
Poloxamer 334	a 31	b 54	
Poloxamer 335	a 38	b 54	
Poloxamer 338	a 128	b 54	
Poloxamer 401	a 6	b 67	
Poloxamer 402	a 13	b 67	
Poloxamer 403	a 21	b 67	
Poloxamer 407	a 98	b 67	

[0101] 2.16. Sorbitan Fatty Acid Esters

[0102] Sorbitan esters of fatty acids are suitable surfactants for use in the present invention. Among these esters, preferred lipophilic surfactants include sorbitan monolaurate (Arlacel 20), sorbitan monopalmitate (Span-40), sorbitan monooleate (Span-80), sorbitan monostearate, and sorbitan tristearate. Examples of these surfactants are shown in Table 17.

TABLE 17

Sorbitan Fatty Acid Ester Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Sorbitan monolaurate	Span-20 (Atlas/ICI), Crill 1 (Croda), Arlacel 20 (ICI)	8.6
Sorbitan monopalmitate	Span-40 (Atlas/ICI), Crill 2 (Croda), Nikkol SP-10 (Nikko)	6.7
Sorbitan monooleate	Span-80 (Atlas/ICI), Crill 4 (Croda), Crill 50 (Croda)	4.3
Sorbitan monostearate	Span-60 (Atlas/ICI), Crill 3 (Croda), Nikkol SS-10 (Nikko)	4.7
Sorbitan trioleate	Span-85 (Atlas/ICI), Crill 45 (Croda), Nikkol SO-30 (Nikko)	4.3
Sorbitan sesquioleate	Arlacel-C (ICI), Crill 43 (Croda), Nikkol SO-15 (Nikko)	3.7
Sorbitan tristearate	Span-65 (Atlas/ICI) Crill 35 (Croda), Nikkol SS-30 (Nikko)	2.1

TABLE 17-continued

Sorbitan Fatty Acid Ester Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Sorbitan monoisostearate	Crill 6 (Croda), Nikkol SI-10 (Nikko)	4.7
Sorbitan sesquistearate	Nikkol SS-15 (Nikko)	4.2

[0103] 2.17. Lower Alcohol Fatty Acid Esters

[0104] Esters of lower alcohols (C<2> to C<4>) and fatty acids (C<8> to C<18>) are suitable surfactants for use in the present invention. Among these esters, preferred lipophilic surfactants include ethyl oleate (Crodamol EO), isopropyl myristate (Crodamol IPM), and isopropyl palmitate (Crodamol IPP). Examples of these surfactants are shown in Table 18.

TABLE 18

Lower Alcohol Fatty Acid Ester Surfactants

COMPOUND	COMMERCIAL PRODUCT (Supplier)	HLB
Ethyl oleate	Crodamol EO (Croda), Nikkol EOO (Nikko)	<10
Isopropyl myristate	Crodamol IPM (Croda)	<10
Isopropyl palmitate	Crodamol IPP (Croda)	<10
Ethyl linoleate	Nikkol VF-E (Nikko)	<10
Isopropyl linoleate	Nikkol VF-IP (Nikko)	<10

[0105] 2.18. Ionic Surfactants

[0106] Ionic surfactants, including cationic, anionic and zwitterionic surfactants, are suitable hydrophilic surfactants for use in the present invention. Preferred anionic surfactants include fatty acid salts and bile salts. Specifically, preferred ionic surfactants include sodium oleate, sodium lauryl sulfate, sodium lauryl sarcosinate, sodium dioctyl sulfosuccinate, sodium cholate, and sodium taurocholate. Examples of such surfactants are shown in Table 18 below. For simplicity, typical counterions are shown in the entries in the Table. It will be appreciated by one skilled in the art, however, that any bioacceptable counterion may be used. For example, although the fatty acids are shown as sodium salts, other cation counterions can also be used, such as alkali metal cations or ammonium. Unlike typical non-ionic surfactants, these ionic surfactants are generally available as pure compounds, rather than commercial (proprietary) mixtures. Because these compounds are readily available from a variety of commercial suppliers, such as Aldrich, Sigma, and the like, commercial sources are not generally listed in Table 19.

TABLE 19

Ionic Surfactants

COMPOUND	HLB
FATTY ACID SALTS	>10
Sodium caproate	
Sodium caprylate	
Sodium caprate	
Sodium laurate	

TABLE 19-continued

Ionic Surfactants

COMPOUND	HLB
Sodium myristate	
Sodium myristolate	
Sodium palmitate	
Sodium palmitoleate	
Sodium oleate	18
Sodium ricinolcate	
Sodium linoleate	
Sodium linolenate	
Sodium stearate	
Sodium lauryl sulfate (dodecyl)	40
Sodium tetradecyl sulfate	
Sodium lauryl sarcosinate	
Sodium dioctyl sulfosuccinate [sodium docusate (Cytec)]	
BILE SALTS	>10
Sodium cholate	
Sodium taurocholate	
Sodium glycocholate	
Sodium deoxycholate	
Sodium taurodeoxycholate	
Sodium glycodeoxycholate	
Sodium ursodeoxycholate	
Sodium chenodeoxycholate	
Sodium taurochenodeoxycholate	
Sodium glyco cheno deoxycholate	
Sodium cholylsarcosinate	
Sodium N-methyl taurocholate	
PHOSPHOLIPIDS	
Egg/Soy lecithin [EpikuronTM (Lucas Meyer), OvothinTM] (Lucas Meyer)]	
Lyso egg/soy lecithin	
Hydroxylated lecithin	
Lysophosphatidylcholine	
Cardiolipin	
Sphingomyelin	
Phosphatidylcholine	
Phosphatidyl ethanolamine	
Phosphatidic acid	
Phosphatidyl glycerol	
Phosphatidyl serine	
PHOSPHORIC ACID ESTERS	
Diethanolammonium polyoxyethylene-10 oleyl ether phosphate	
Esterification products of fatty alcohols or fatty alcohol ethoxylates with phosphoric acid or anhydride	
CARBOXYLATES	
Ether carboxylates (by oxidation of terminal OH group of fatty alcohol ethoxylates)	
Succinylated monoglycerides [LAMEGIN ZB (Henkel)]	
Sodium stearyl fumarate	
Stearoyl propylene glycol hydrogen succinate	
Mono/diacetylated tartaric acid esters of mono- and diglycerides	
Citric acid esters of mono-, diglycerides	
Glyceryl-lacto esters of fatty acids (CFR ref. 172.852)	
Acyl lactylates:	
lactylic esters of fatty acids	
calcium/sodium stearoyl-2-lactylate	
calcium/sodium stearoyl lactylate	
Alginate salts	
Propylene glycol alginate	
SULFATES AND SULFONATES	
Ethoxylated alkyl sulfates	
Alkyl benzene sulfones	
α-olefin sulfonates	
Acyl isethionates	
Acyl taurates	
Alkyl glyceryl ether sulfonates	
Octyl sulfosuccinate disodium	
Disodium undecylenamideo-MEA-sulfosuccinate	
CATIONIC Surfactants	>10
Hexadecyl triammonium bromide	
Decyl trimethyl ammonium bromide	
Cetyl trimethyl ammonium bromide	
Dodecyl ammonium chloride	

TABLE 19-continued

Ionic Surfactants

COMPOUND	HLB
Alkyl benzyldimethylammonium salts	
Diisobutyl phenoxyethoxydimethyl benzylammonium salts	
Alkylpyridinium salts	
Betaines (trialkylglycine)	
Lauryl betaine (N-lauryl,N,N-dimethylglycine)	
Ethoxylated amines:	
Polyoxyethylene-15 coconut amine	

[0107] 2.20 Preferred Surfactants and Surfactant Combinations

[0108] Among the above-listed surfactants, several combinations are preferred. Preferred non-ionic hydrophilic surfactants include alkylglucosides; alkylmaltosides; alkylthioglucosides; lauryl macrogolglycerides; polyoxyethylene alkyl ethers; polyoxyethylene alkylphenols; polyethylene glycol fatty acids esters; polyethylene glycol glycerol fatty acid esters; polyoxyethylene sorbitan fatty acid esters; polyoxyethylene-polyoxypropylene block copolymers; polyglycerol fatty acid esters; polyoxyethylene glycerides; polyoxyethylene sterols, derivatives, and analogues thereof; polyoxyethylene vegetable oils; polyoxyethylene hydrogenated vegetable oils; reaction mixtures of polyols with fatty acids, glycerides, vegetable oils, hydrogenated vegetable oils, and sterols; sugar esters, sugar ethers; sucroglycerides; and mixtures thereof.

[0109] More preferably, the non-ionic hydrophilic surfactant is selected from the group consisting of polyoxyethylene alkylethers; polyethylene glycol fatty acids esters; polyethylene glycol glycerol fatty acid esters; polyoxyethylene sorbitan fatty acid esters; polyoxyethylene-polyoxypropylene block copolymers; polyglyceryl fatty acid esters; polyoxyethylene glycerides; polyoxyethylene vegetable oils; and polyoxyethylene hydrogenated vegetable oils. The glyceride can be a monoglyceride, diglyceride, triglyceride, or a mixture.

[0110] Also preferred are non-ionic hydrophilic surfactants that are reaction mixtures of polyols and fatty acids, glycerides, vegetable oils, hydrogenated vegetable oils or sterols. These reaction mixtures are largely composed of the transesterification products of the reaction, along with often complex mixtures of other reaction products. The polyol is preferably glycerol, ethylene glycol, polyethylene glycol, sorbitol, propylene glycol, pentaerythritol, or a saccharide.

[0111] Several particularly preferred carrier compositions are those which include as a non-ionic hydrophilic surfactant PEG-10 laurate, PEG-12 laurate, HEG-20 laurate, PEG-32 laurate, PEG-32 dilaurate, PEG-12 oleate, PEG-15 oleate, PEG-20 oleate, PEG-20 dioleate, PEG-32 oleate, PEG-200 oleate, PEG-400 oleate, PEG-15 stearate, PEG-32 distearate, PEG-40 stearate, PEG-100 stearate, PEG-20 dilaurate, PEG-25 glyceryl trioleate, PEG-32 dioleate, PEG-20 glyceryl laurate, PEG-30 glyceryl laurate, PEG-20 glyceryl stearate, PEG-glyceryl oleate, PEG-30 glyceryl oleate, PEG-30 glyceryl laurate, PEG-40 glyceryl laurate, PEG-40 palm kernel oil, PEG-50 hydrogenated castor oil, PEG-40 castor oil, PEG-35 castor oil, PEG-60 castor oil, PEG-40 hydrogenated castor oil, PEG-60 hydrogenated castor oil, PEG-60 corn oil, PEG-6 caprate/caprylate glycerides, PEG-8 caprate/caprylate glycerides, polyglyceryl-10 laurate, PEG-30 cholesterol, PEG-25 phyto sterol, PEG-30 soya sterol, PEG-20 triolcate, PEG-40 sorbitan oleate, PEG-80 sorbitan laurate, polysorbate 20, polysorbate 80, POE-9 lauryl ether, POE-23 lauryl ether, POE-10 oleyl ether, POE-20 oleyl ether, POE-20 stearyl ether, tocopheryl PEG-100 succinate, PEG-24 cholesterol, polyglyceryl-10 oleate, Tween 40, Tween 60, sucrose monostearate, sucrose monolaurate, sucrose monopalmitate, PEG 10-100 nonyl phenol series, PEG 15-100 octyl phenol series, or a poloxamer.

[0112] Among these preferred surfactants, more preferred are PEG-20 laurate, PEG-20 oleate, PEG-35 castor oil, PEG-40 palm kernel oil, PEG-40 hydrogenated castor oil, PEG-60 corn oil, PEG-25 glyceryl trioleate, polyglyceryl-10 laurate, PEG-6 caprate/caprylate glycerides, PEG-8 caprate/caprylate glycerides, PEG-30 cholesterol, polysorbate 20 polysorbate 80, POE-9 lauryl ether, POE-23 lauryl ether, POE-10 oleyl ether, PEG-24 cholesterol, sucrose monostearate, sucrose monolaurate and poloxamers. Most preferred are PEG-35 castor oil, PEG-40 hydrogenated castor oil, PEG-60 corn oil, PEG-25 glyceryl trioleate, PEG-6 caprate/caprylate glycerides, PEG-8 caprate/caprylate glycerides, polysorbate 20, polysorbate 80, tocopheryl PEG-1000 succinate, PEG-24 cholesterol, and hydrophilic poloxamers.

[0113] The hydrophilic surfactant can also be, or include as a component, an ionic surfactant. Preferred ionic surfactants include alkyl ammonium salts; bile acids and salts, analogues, and derivatives thereof; fusidic acid and derivatives thereof; fatty acid derivatives of amino acids, oligopeptides, and polypeptides; glyceride derivatives of amino acids oligopeptides, and polypeptides; acyl lactylates; mono-diacetylated tartaric acid esters of mono-diglycerides; succinylated monoglycerides; citric acid esters of mono-diglycerides; alginate salts; propylene glycol alginate; lecithins and hydrogenated lecithins; lysolecithin and hydrogenated lysolecithins; lysophospholipids and derivatives thereof; phospholipids and derivatives thereof; salts of alkylsulfates; salts of fatty acids; sodium docusate; carnitines; and mixtures thereof. More preferable ionic surfactants include bile acids and salts, analogues, and derivatives thereof; lecithins, lysolecithin, phospholipids, lysophospholipids and derivatives thereof; salts of alkylsulfates; salts of fatty acids; sodium docusate; acyl lactylates; mono-diacetylated tartaril acid esters of mono-diglycerides; succinylated monoglycerides; citric acid esters of mono-diglycerides; carnitines; and mixtures thereof.

[0114] More specifically, preferred ionic surfactants are lecithin, lysolecithin, phosphatidylcholine, phosphatidylethanolamine, phosphatidylglycerol, phosphatidic acid, phosphatidylserine, lysophosphatidylcholine, lysophosphatidylethanolamine, lysophosphatidylglycerol, lysophosphatidic acid, lysophosphatidylserine, PEG-phosphatidylethanolamine, PVP-phosphatidylethanolamine, lactylic esters of fatty acids, stearoyl-2-lactylate, stearoyl lactylate, succinylated monoglycerides, mono/diacetylated tartaric acid esters of mono/diglycerides, citric acid esters of mono/diglycerides, cholate, taurocholate, glycocholate, deoxycholate, taurodeoxycholate, chenodeoxycholate, glycodeoxycholate, glycochenodeoxycholate, taurochenodeoxycholate, ursodeoxycholate, tauroursodeoxycholate, glycoursodeoxycholate, cholylsarcosine, N-methyl taurocholate, caproate, caprylate, caprate, laurate, myristate, palmitate, oleate, ricinoleate,

linoleate, linolenate, stearate, lauryl sulfate, teracecyl sulfate, docusate, lauroyl camitines, palmitoyl camitines, myristoyl carnitines, and salts and mixtures thereof.

[0115] Particularly preferred ionic surfactants are lecithin, lysolecithin, phosphatidylcholine, phosphatidylethanolamine, phosphatidylglycerol, lysophosphatidylcholine, PEG-phosphatidylethanolamine, lactylic esters of fatty acids, stearoyl-2-lactylate, stearoyl lactylate, succinylated monoglycerides, mono/diacetylated tartaric acid esters of mono/diglycerides, citric acid esters of mono/diglycerides cholate, taurocholate glycocholate, deoxycholate, taurodeoxycholate, glycodeoxycholate, cholylsarcosine, caproate, caprylate, caprate, laurate, oleate, lauryl sulfate, docusate, and salts and mixtures thereof, with the most preferred ionic surfactants being lecithin, lactylic esters of fatty acids, stearoyl-2-lactylate, stearoyl lactylate, succinylated monoglycerides, mono/diacetylated tartaric acid esters of mono/diglycerides, citric acid esters of mono/diglycerides, taurocholate, caprylate, caprate, oleate, lauryl sulfate, docusate, and salts and mixtures thereof.

[0116] The carrier of the present compositions may include a combination of at least two surfactants, at least one of which is hydrophilic. In one embodiment, the present invention includes at two surfactants that are hydrophilic, and preferred hydrophilic surfactants are listed above. In another embodiment, the carrier includes at least one hydrophilic surfactant and at least one lipophilic surfactant. In this embodiment, preferred lipophilic surfactants are alcohols; polyoxyethylene alkylethers; fatty acids; glycerol fatty acid esters; acetylated glycerol fatty acid esters; lower alcohol fatty acids esters; polyethylene glycol fatty acids esters; polyethylene glycol glycerol fatty acid esters; polypropylene glycol fatty acid esters; polyoxyethylene glycerides; lactic acid derivatives of mono/diglycerides; propylene glycol diglycerides; sorbitan fatty acid esters; polyoxyethylene sorbitan fatty acid esters; polyoxyethylene-polyoxypropylene block copolymers; transesterified vegetable oils; sterols; sterol derivatives; sugar esters; sugar ethers; sucroglycerides; polyoxyethylene vegetable oils; and polyoxyethylene hydrogenated vegetable oils.

[0117] As with the hydrophilic surfactants, lipophilic surfactants can be reaction mixtures of polyols and fatty acids, glycerides, vegetable oils, hydrogenated vegetable oils, and sterols.

[0118] Preferably, the lipophilic surfactant is selected from the group consisting of fatty acids; lower alcohol fatty acid esters; polyethylene glycol glycerol fatty acid esters; polypropylene glycol fatty acid esters; polyoxyethylene glycerides; glycerol fatty acid esters; acetylated glycerol fatty acid esters; lactic acid derivatives of mono/diglycerides; sorbitan fatty acid esters; polyoxyethylene sorbitan fatty acid esters; polyoxyethylene-polyoxypropylene block copolymers; polyoxyethylene vegetable oils; polyoxyethylene hydrogenated vegetable oils; and reaction mixtures of polyols and fatty acids, glycerides, vegetable oils, hydrogenated vegetable oils, and sterols.

[0119] More preferred are lower alcohol fatty acids esters; polypropylene glycol fatty acid esters; propylene glycol fatty acid esters; glycerol fatty acid esters; acetylated glycerol fatty acid esters; lactic acid derivatives of mono/diglycerides; sorbitan fatty acid esters; polyoxyethylene vegetable oils; and mixtures thereof, with glycerol fatty acid esters and acetylated glycerol fatty acid esters being most preferred. Among the glycerol fatty acid esters, the esters are preferably mono- or diglycerides, or mixtures of mono- and diglycerides, where the fatty acid moiety is a C<6> to C<22> fatty acid. Also preferred are lipophilic surfactants which are the reaction mixture of polyols and fatty acids, glycerides, vegetable oils, hydrogenated vegetable oils, and sterols. Preferred polyols are polyethylene glycol, sorbitol, propylene glycol, and pentaerythritol.

[0120] Specifically preferred lipophilic surfactants include myristic acid; oleic acid; lauric acid; stearic acid; palmitic acid; PEG 1-4 stearate; PEG 2-4 oleate; PEG-4 dilaurate; PEG-4 dioleate; PEG-4 distearate; PEG-6 dioleate; PEG-6 distearate; PEG-8 dioleate; PEG 3-16 castor oil; PEG 5-10 hydrogenated castor oil; PEG 6-20 corn oil; PEG 6-20 almond oil; PEG-6 olive oil; PEG-6 peanut oil; PEG-6 palm kernel oil; PEG-6 hydrogenated palm kernel oil; PEG-4 capric/caprylic triglyceride, mono, di, tri, tetra esters of vegetable oil and sorbitol; pentaerythrityl di, tetra stearate, isostearate, oleate, caprylate, or caprate, polyglyceryl 2-4 oleate, stearate, or isostearate; polyglyceryl 4-10 pentaoleate; polyglyceryl-3 dioleate; polyglyceryl-6 dioleate; polyglyceryl-10 trioleate; polyglyceryl-3 distearate; propylene glycol mono- or diesters of a C<6> to C<20> fatty acid; monoglycerides of C<6> to C<20> fatty acids; acetylated monoglycerides of C<6> to C<20> fatty acids; diglycerides of C<6> to C<20> fatty acids; lactic acid derivatives of monoglycerides; lactic acid derivatives of diglycerides; cholesterol; phytosterol; PEG 5-20 soya sterol; PEG-6 sorbitan tetra, hexastearate; PEG-6 sorbitan tetraoleate; sorbitan monolaurate; sorbitan monopalmitate; sorbitan mono, trioleate; sorbitan mono, tristearate; sorbitan monoisostearate; sorbitan sesquioleate; sorbitan sesquistearate; PEG 2-5 oleyl ether; POE 2-4 lauryl ether; PEG-2 cetyl ether; PEG-2 stearyl ether; sucrose distearate; sucrose dipalmitate; ethyl oleate; isopropyl myristate; isopropyl palmitate; ethyl linoleate; isopropyl linoleate; and poloxamers.

[0121] Among the specifically preferred lipophilic surfactants, most preferred are oleic acid; lauric acid; glyceryl monocaprate; glyceryl monocaprylate; glyceryl monolaurate; glyceryl monooleate; glyceryl dicaprate; glyceryl dicaprylate; glyceryl dilaurate; glyceryl dioleate; acetylated monoglycerides; propylene glycol oleate; propylene glycol laurate; polyglyceryl-3 oleate; polyglyceryl-6 dioleate; PEG-6 corn oil; PEG-20 corn oil; PEG-20 almond oil; sorbitan monooleate; sorbitan monolaurate; POE-4 lauryl ether; POE-3 oleyl ether; ethyl oleate; and poloxamers.

[0122] 3. Therapeutic Agents

[0123] As a general matter, the carrier used in the fill material of the present invention will have at least one therapeutic, or pharmaceutically active agent dissolved, disbursed, or otherwise incorporated therein. Any particular active agent may be administered in the form of a salt, ester, amide, prodrug, active metabolite, isomer, analog, fragment, or the like, provided that the salt, ester, amide, prodrug, active metabolite, isomer, analog or fragment, is pharmaceutically acceptable and pharmacologically active in the present context. Salts, esters, amides, prodrugs, metabolites, analogs, fragments, and other derivatives of the active agents may be prepared using standard procedures known to those skilled in the art of synthetic organic chemistry and described, for example, by J. March, Advanced Organic Chemistry: Reactions, Mechanisms and Structure, 4th Edition (New York: Wiley-Interscience, 1992).

[0124] For example, acid addition salts are prepared from a drug in the form of a free base using conventional methodology involving reaction of the free base with an acid. Suitable acids for preparing acid addition salts include both organic acids, e.g., acetic acid, propionic acid, glycolic acid, pyruvic acid, oxalic acid, malic acid, malonic acid, succinic acid, maleic acid, fumaric acid, tartaric acid, citric acid, benzoic acid, cinnamic acid, mandelic acid, methanesulfonic acid, ethanesulfonic acid, p-toluenesulfonic acid, salicylic acid, and the like, as well as inorganic acids, e.g., hydrochloric acid, hydrobromic acid, sulfuric acid, nitric acid, phosphoric acid, and the like. An acid addition salt may be reconverted to the free base by treatment with a suitable base. Conversely, preparation of basic salts of acid moieties that may be present on an active agent may be carried out in a similar manner using a pharmaceutically acceptable base such as sodium hydroxide, potassium hydroxide, ammonium hydroxide, calcium hydroxide, trimethylamine, or the like. Preparation of esters involves transformation of a carboxylic acid group via a conventional esterification reaction involving nucleophilic attack of an RO^- moiety at the carbonyl carbon. Esterification may also be carried out by reaction of a hydroxyl group with an esterification reagent such as an acid chloride. Esters can be reconverted to the free acids, if desired, by using conventional hydrogenolysis or hydrolysis procedures. Amides may be prepared from esters, using suitable amine reactants, or they may be prepared from an anhydride or an acid chloride by reaction with ammonia or a lower alkyl amine. Prodrugs and active metabolites may also be prepared using techniques known to those skilled in the art or described in the pertinent literature. prodrugs are typically prepared by covalent attachment of a moiety that results in a compound that is therapeutically inactive until modified by an individual's metabolic system.

[0125] Other derivatives and analogs of the active agents may be prepared using standard techniques known to those skilled in the art of synthetic organic chemistry, or may be deduced by reference to the pertinent literature. In addition, chiral active agents may be in isomerically pure form, or they may be administered as a racemic mixture of isomers.

[0126] The pharmaceutically active agent is dissolved or disbursed (i.e. suspended) in the fill material. No particular limitation is placed on the specific pharmaceutically active agent that can be included. Rather, the carrier materials recited herein are capable of solubilizing or suspending, and delivering a wide variety of therapeutic agents. The therapeutic agents can be hydrophilic, amphiphilic, or lipophilic. Optionally, the therapeutic agent can be present in a first, solubilized amount, and a second, non-solubilized (suspended) amount. Such therapeutic agents can be any agents having therapeutic or other value when administered to an animal, particularly to a mammal, such as drugs, nutrients, and cosmetics (cosmeceuticals). It should be understood that while the invention is described with particular reference to its value in the form of aqueous dispersions, the invention is not so limited. Thus, drugs, diagnostics, nutrients or cosmetics which derive their therapeutic or other value from, for example, topical or transdermal administration, are still considered to be suitable for use in the present invention.

[0127] A wide variety of active agents may be administered using the dosage forms of the present invention. No limitation is perceived thereon, except to the extent that a particular active agent prevents or hinders the functioning of the present dosage forms to the extent that they become unsuitable for use. However, as the dosage forms of the present invention allow a significant latitude for adjustment, it is expected that attunement of one or more specific parameters will be sufficient to accommodate virtually any active agent desired to be delivered. Examples of active agent contemplated for administration with the dosage forms of the present invention include without limitation various classes of active agents such as, analgesic agents, anesthetic agents, anti-anginal agents, antiarthritic agents, anti-arrhythmic agents, antiasthmatic agents, antibacterial agents, anti-BPH agents, anticancer agents, anticholinergic agents, anticoagulants, anticonvulsants, antidepressants, antidiabetic agents, antidiarrheals, anti-epileptic agents, antifungal agents, antigout agents, antihelminthic agents, antihistamines, antihypertensive agents, antiinflammatory agents, antimalarial agents, antimigraine agents, antimuscarinic agents, antinauseants, antineoplastic agents, anti-obesity agents, antiosteoporosis agents, antiparkinsonism agents, antiprotozoal agents, antipruritics, antipsychotic agents, antipyretics, antispasmodics, antithyroid agents, antituberecular agents, antiulcer agents, anti-urinary incontinence agents, antiviral agents, anxiolytics, appetite suppressants, attention deficit disorder (ADD) and attention deficit hyperactivity disorder (ADHD) drugs, calcium channel blockers, cardiac inotropic agents, beta-blockers, central nervous system stimulants, cognition enhancers, corticosteroids, COX-2 inhibitors, decongestants, diuretics, gastrointestinal agents, genetic materials, histamine receptor antagonists, hormonolytics, hypnotics, hypoglycemic agents, immunosuppressants, keratolytics, leukotriene inhibitors, lipid-regulating agents, macrolides, mitotic inhibitors, muscle relaxants, narcotic antagonists, neuroleptic agents, nicotine, nutritional oils, parasympatholytic agents, sedatives, sex hormones, sympathomimetic agents, tranquilizers, vasodilators, vitamins, and combinations thereof. Active agents that may be administered according to the invention also include nutrients, cosmeceuticals, diagnostic agents, and nutritional agents. Some agents, as will be appreciated by those of ordinary skill in the art, and as may be deduced from the discussion below, are encompassed by two or more of the aforementioned groups or other uses that may be found appropriate.

[0128] Among the various active agent categories, preferred classes of active agents for administration using the present method and formulations are lipid regulating agents, sex hormones, anti-hypertensive agents, anti-diabetic agents, anti-viral agents (including protease inhibitors), gastrointestinal agents, agents for treating neurodegenerative diseases (including anti-parkinson's and anti-Alzheimer's), anxiolytics, sedatives, hypnotics, agents for treating headaches (including anti-migraine agents), neuroleptic drugs (including anti-depressants, anti-manics, anti-psychotics) and combinations of any of the foregoing:

[0129] Lipid-regulating agents that are generally classified as hydrophobic include HMG CoA reductase inhibitors such as atorvastatin, simvastatin, fluvastatin, pravastatin, lovastatin, cerivastatin, rosuvastatin, and pitavastatin, as well as other lipid-lowering ("antihyperlipidemic") agents such as bezafibrate, beclobrate, binifibrate, ciprofibrate, clinofibrate, clofibrate, clofibric acid, ezetimibe, etofibrate, fenofibrate, fenofibric acid, gemfibrozil, lifibrol, nicofibrate, pirifibrate,

probucol, ronifibrate, simfibrate, and theofibrate. A particularly preferred lipid-regulating agent that may be administered using the methods and formulations of the invention is fenofibrate.

[0130] Sex hormones that are preferred for administration according to the invention include progestins (progestogens), estrogens, and combinations thereof. Progestins include acetoxypregnenolone, allylestrenol, anagestone acetate, chlormadinone acetate, cyproterone, cyproterone acetate, desogestrel, dihydrogesterone, dimethisterone, ethisterone (17α-ethinyltestosterone), ethynodiol diacetate, flurogestone acetate, gestadene, hydroxyprogesterone, hydroxyprogesterone acetate, hydroxyprogesterone caproate, hydroxymethylprogesterone, hydroxymethylprogesterone acetate, 3-ketodesogestrel, levonorgestrel, lynestrenol, medrogestone, medroxyprogesterone acetate, megestrol, megestrol acetate, melengestrol acetate, norethindrone, norethindrone acetate, norethisterone, norethisterone acetate, norethynodrel, norgestimate, norgestrel, norgestrienone, normethisterone, progesterone, and trimegestone. Also included within this general class are estrogens, e.g.: estradiol (i.e., 1,3,5-estratriene-3,17β-diol, or "17β-estradiol") and its esters, including estradiol benzoate, valerate, cypionate, heptanoate, decanoate, acetate and diacetate; 17α-estradiol; ethinylestradiol (i.e., 17α-ethinylestradiol) and esters and ethers thereof, including ethinylestradiol 3-acetate and ethinylestradiol 3-benzoate; estriol and estriol succinate; polyestrol phosphate; estrone and its esters and derivatives, including estrone acetate, estrone sulfate, and piperazine estrone sulfate; quinestrol; mestranol; and conjugated equine estrogens. In many contexts, e.g., in female contraception and in hormone replacement therapy (HRT), a combination of a progestin and estrogen is used, e.g., progesterone and 17 β-estradiol. For HRT, an androgenic agent may be advantageously included as well. Androgenic agents for this purpose include, for example, dehydroepiandrosterone (DHEA; also termed "prasterone"), sodium dehydroepiandrosterone sulfate, 4-dihydrotestosterone (DHT; also termed "stanolone"), and testosterone, and pharmaceutically acceptable esters of testosterone and 4-dihydrotestosterone, typically esters formed from the hydroxyl group present at the C-17 position, including, but not limited to, the enanthate, propionate, cypionate, phenylacetate, acetate, isobutyrate, buciclate, heptanoate, decanoate, undecanoate, caprate and isocaprate esters.

[0131] Androgenic agents may also be administered for other purposes well known in the art. In addition to the androgenic agents enumerated above, other androgenic agents include, but are not limited to, androsterone, androsterone acetate, androsterone propionate, androsterone benzoate, androstenediol, androstenediol-3-acetate, androstenediol-17-acetate, androstenediol-3, 17-diacetate, androstenediol-17-benzoate, androstenediol-3-acetate-17-benzoate, androstenedione, ethylestrenol, oxandrolone, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, stanozolol, dromostanolone, and dromostanolone propionate.

[0132] Antihypertensive agents include, without limitation, amlodipine, benazepril, benidipine, candesartan, captopril, carvedilol, darodipine, dilitazem, diazoxide, doxazosin, enalapril, epleronone, eposartan, felodipine, fenoldopam, fosinopril, guanabenz, iloprost, imidapril, irbesartan, isradipine, lercardinipine, lisinopril, losartan, mibefradil, minoxidil, nebivolol, nicardipine, nifedipine, nimodipine, nisoldipine, olmesartan, omapatrilat, phenoxybenzamine, pindolol, prazosin, quinapril, reserpine, semotiadil, sitaxsentan, terazosin, telmisartan, trandolapril, and valsartan.

[0133] Anti-diabetic agents include, by way of example, acetohexamide, chlorpropamide, ciglitazone, farglitazar, glibenclamide, gliclazide, glipizide, glucagon, glyburide, glymepiride, miglitol, pioglitazone, nateglinide, pimagedine, repaglinide, rosiglitazone, tolazamide, tolbutamide, triampterine, and troglitazone.

[0134] Antiviral agents that can be delivered using the present methods and dosage forms include the antiherpes agents acyclovir, famciclovir, foscamet, ganciclovir, idoxuridine, sorivudine, trifluridine, valacyclovir, and vidarabine, and other antiviral agents such as abacavir, amantadine, amprenavir, cidofovir, delviridine, didanosine, efavirenz, indinavir, interferon alpha, lamivudine, lobucavir, lopinavir, nelfinavir, nevirapine, oseltamivir, ribavirin, rimantadine, ritonavir, saquinavir, stavudine, tipranavir, valganciclovir, zanamivir, zalcitabine, and zidovudine; and other antiviral agents such as abacavir, indinavir, interferon alpha, nelfmavir, ribavirin, rimantadine, tipranavir, ursodeoxycholic acid, and valganciclovir.

[0135] Gastrointestinal agnts, such as alosetron, basalazide, bisacodyl, budesonide, cilansetron, cimetidine, cisapride, diphenoxylate, domperidone, esomeprazole, famotidine, granisetron, lafutidine, lansoprazole, leminoprazole, loperamide, merropenum, mesalazine, mesalamine, nitisonone, nizatidine, olsalazine, omeprazole, ondansetron, pantoprazole, palonosetron, pariprazole, rabeprazole sodium, ransoprazole, ranitidine, risperidone, sulphasalazine, and tegaserod;

[0136] Neuroleptic drugs, including antidepressant drugs, antimanic drugs, and antipsychotic agents, wherein antidepressant drugs include (a) the tricyclic antidepressants such as amoxapine, amitriptyline, clomipramine, desipramine, doxepin, imipramine, maprotiline, nortriptyline, protriptyline, and trimipramine, (b) the serotonin reuptake inhibitors citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, and venlafaxine, (c) monoamine oxidase inhibitors such as phenelzine, tranylcypromine, and (−)-selegiline, and (d) other antidepressants such as aprepitant, bupropion, duloxetine, gepirone, igmesine, lamotrigine, maprotiline, mianserin, mirtazapine, nefazodone, rabalzotan, sunepitron, trazodone and venlafaxine, and wherein antimanic and antipsychotic agents include (a) phenothiazines such as acetophenazine, acetophenazine maleate, chlorpromazine, chlorpromazine hydrochloride, fluphenazine, fluphenazine hydrochloride, fluphenazine enanthate, fluphenazine decanoate, mesoridazine, mesoridazine besylate, perphenazine, thioridazine, thioridazine hydrochloride, trifluoperazine, and trifluoperazine hydrochloride, (b) thioxanthenes such as chlorprothixene, thiothixene, and thiothixene hydrochloride, and (c) other heterocyclic drugs such as carbamazepine, clozapine, droperidol, haloperidol, haloperidol decanoate, loxapine succinate, molindone, molindone hydrochloride, olanzapine, perospirone, pimozide, quetiapine, risperidone, sertindole, and ziprasidone.

[0137] Agents for treating headaches, including anti-migraine agents, such as almotriptan, butorphanol, dihydroergotamine, dihydroergotamine mesylate, eletriptan, ergotamine, frovatriptan, methysergide, naratriptan, pizotyline, rizatriptan, sumatriptan, tonaberstat, and zolmitriptan;

[0138] Agents to treat neurodegenerative diseases, including active agents for treating Alzheimer's disease such as akatinol, donezepil, donepezil hydrochloride, dronabinol, galantamine, ipidracine, neotrofin, rasagiline, physostigmine, physostigmine salicylate, propentoffyline, quetiapine, rivastigmine, tacrine, tacrine hydrochloride, thalidomide, and xaliproden; active agents for treating Huntington's Disease, such as fluoxetine and carbamazepine; anti-parkinsonism drugs useful herein include amantadine, apomorphine, bromocriptine, entacapone, levodopa (particularly a levodopa/carbidopa combination), lysuride, pergolide, pramipexole, rasagiline, riluzole, ropinirole, selegiline, sumanirole, tolcapone, trihexyphenidyl, and trihexyphenidyl hydrochloride; and active agents for treating ALS such as the anti-spastic agents baclofen, diazemine, riluzole, and tizanidine; and active agents for multiple sclerosis such as glatiramer.

[0139] Anxiolytics sedatives, and hypnotics, such as alprazolam, amylobarbitone, barbitone, bentazepam, bromazepam, bromperidol, brotizolam, butobarbitone, carbromal, chlordiazepoxide, chlormethiazole, chlorpromazine, chlorprothixene, clonazepam, clobazam, clotiazepam, clozapine, dexmethylphenidate (d-threomethylphenidate) diazepam, droperidol, ethinamate, flunanisone, flunitrazepam, triflupromazine, flupenthixol decanoate, fluphenazine, flurazepam, gabapentin, gaboxadol, γ-hydroxybutyrate, haloperidol, lamotrigine, lorazepam, lormetazepam, medazepam, meprobamate, mesoridazine, methaqualone, methylphenidate, midazolam, modafinil, molindone, nitrazepam, olanzapine, oxazepam, pentobarbitone, perphenazine pimozide, pregabalin, prochlorperazine, pseudoephedrine, quetiapine, rispiridone, rohypnol, sertindole, siramesine, sulpiride, sunepitron, temazepam, thioridazine, triazolam, zaleplon, zolpidem, and zopiclone;

[0140] Other therapeutic agents that can be delivered using the present methods and formulations include the following representative compounds:

[0141] Anti-inflammatory agents and non-opioid analgesics, such as aloxiprin, amiprilose, auranofin, azapropazone, azathioprine, benorylate, boswellic acid, butorphenol, capsaicin, celecoxib, diclofenac, diflunisal, esonarimod, etodolac, fenbufen, fenoprofen calcium, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, leflunomide, meclofenamic acid, mefenamic acid, nabumetone, naproxen, novantrone, oxaprozin, oxyphenbutazone, parecoxib, phenylbutazone, piclamilast, piroxicam, rofecoxib, ropivacaine, sulindac, tetrahydrocannabinol, tramadol, tromethamine, valdecoxib, and ziconotide, as well as the urinary analgesics phenazopyridine and tolterodine;

[0142] Anti-angina agents, such as mibefradil, refludan, nalmefene, carvedilol, cromafiban, lamifiban, fasudil, ranolazine, tedisamil, nisoldipine, and tizanidine;

[0143] Antihelminthics, such as albendazole, bephenium hydroxynaphthoate, cambendazole, dichlorophen, ivermectin, mebendazole, oxamniquine, oxfendazole, oxantel embonate, praziquantel, pyrantel embonate and thiabendazole;

[0144] Anti-arrhythmic agents, such as amiodarone, disopyramide, flecainide acetate and quinidine sulfate;

[0145] Anti-asthma agents, such as fudosteine, zileuton, zafirlukast, terbutaline sulfate, montelukast, pranlukast, levalbuterol, ramatroban, suplatast, and albuterol;

[0146] Anti-bacterial agents, such as alatrofloxacin, azithromycin, baclofen, benethamine penicillin, cinoxacin, ciprofloxacin, cefoselis, ceftibuten, clarithromycin, clofazimine, cloxacillin, dalfopristine, demeclocycline, dirithromycin, doxycycline, ecenofloxacin, erythromycin, ethionamide, furazolidone, grepafloxacin, imipenem, levofloxacin, linezolid, loreffoxacin, moxifloxacin, nalidixic acid, nitrofurantoin, norfloxacin, ofloxacin, quinupritin, rifampicin, rifabutine, rifapentine, ritipenem, sparfloxacin, spiramycin, sulphabenzamide, sulphadoxine, sulphamerazine, sulphacetamide, sulphadiazine, sulphafurazole, sulphamethoxazole, sulphapyridine, tazobactum, tetracycline, tosufloxacin, trimethoprim, trovafloxacin, and vancomycin;

[0147] Anti-cancer agents and immunosuppressants, such as alitretinoin, aminoglutethimide, amsacrine, anastrozole, azathioprine, bexarotene, bicalutamide, biricodar, bisantrene, busulfan, camptothecin, candoxatril, capecitabine, cisplatin, cytarabine, chlorambucil, cyclosporin, dacarbazine, decitabine, ellipticine, estramustine, etoposide, examorelin, examestane, fludarabine, gemcitabine, imatinib, irinotecan, lasofoxifene, letrozole, lomustine, melphalan, mercaptopurine, methotrexate, mitomycin, mitotane, mitoxantrone, mofetil, mycophenolate, nebivolol, nilutamide, oxaliplatin, paclitaxel, palonosetron, procarbazine, ramipril, rubitecan, sirolimus, tacrolimus, tamoxifen, teniposide, testolactone, thalidomide, tirapazamine, topotecan, toremifene citrate, vitamin A, vitamin A derivatives, venorelbine, and zacopride;

[0148] Anti-coagulants and other agents for preventing and treating stroke, such agatroban, cilostazol, citicoline, clopidogrel, cromafiban, dexanabinol, dicumarol, dipyridamole, nicoumalone, oprelvekin, ozagrel, perindopril erbumine, phenindione, ramipril, repinotan, ticlopidine, tirofiban, and heparin, including heparin salts formed with organic or inorganic bases, and low molecular weight heparin, i.e., heparin fragments generally having a weight average molecular weight in the range of about 1000 to about 10,000 D and exemplified by enoxaparin, dalteparin, danaproid, gammaparin, nadroparin, ardeparin, tinzaparin, certoparin, and reviparin;

[0149] Anti-diabetics, such as acetohexamide, chlorpropamide, farglitazar, glibenclamide, gliclazide, glipizide, glimepiride, miglitol, nateglinide, pimagedine, pioglitazone, repaglinide, rosiglitazone, tolazamide, tolbutamide, troglitazone, and voglibose;

[0150] Anti-epileptics, such as beclamide, carbamazepine, carbatrol, clobazam, clonazepam, divalproex sodium, ethotoin, felbamate, fosphenytoin, levetriacetam, lamotrigine, methoin, methsuximide, methylphenobarbitone, oxcarbazepine, paramethadione, phenacemide, phenobarbitone, phenytoin, phensuximide, primidone, sulthiame, tiagabine, tolcapone, topiramate, valproic acid, vigabatrin, and zonisamide;

[0151] Anti-fungal agents, such as anidulafungin, amphotericin, butenafine, butoconazole nitrate, clotrimazole, econazole nitrate, fluconazole, flucytosine, griseofulvin, itraconazole, ketoconazole, liranaftate, miconazole, natamycin, nystatin, sulconazole nitrate, oxiconazole, terbinafine, terconazole, tioconazole and undecenoic acid;

[0152] Anti-gout agents, such as allopurinol, probenecid and sulphin-pyrazone;

[0153] Antihistamines and allergy medications, such as acrivastine, astemizole, chlorpheniramine, cinnarizine, cetirizine, clemastine, cyclizine, cyproheptadine, desloratadine, dexchlorpheniramine, dimenhydrinate, diphenhydramine, epinastine, fexofenadine, flunarizine, loratadine, meclizine, mizolastine, oxatomide, and terfenadine;

[0154] Anti-malarials, such as amodiaquine, chloroquine, chlorproguanil, halofantrine, mefloquine, proguanil, pyrimethamine and quinine sulfate;

[0155] Anti-muscarinic agents, such as atropine, benzhexol, biperiden, ethopropazine, hyoscyamine, mepenzolate bromide, oxyphencyclimine, scopolamine, and tropicamide;

[0156] Anti-protozoal agents, such as atovaquone, benznidazole, clioquinol, decoquinate, diiodohydroxyquinoline, diloxanide furoate, dinitolmide, furazolidone, metronidazole, nimorazole, nitrofurazone, omidazole and tinidazole;

[0157] Anti-thyroid agents, such as carbimazole, paricalcitol, and propylthiouracil;

[0158] Anti-tussives, such as benzonatate;

[0159] Appetite suppressants, anti-obesity drugs and drugs for treatment of eating disorders, such as amphetamine, bromocriptine, dextroamphetamine, diethylpropion, ghrelin, lintitript, mazindol, methamphetamine, orlistat, phentermine, and topiramate;

[0160] Cardiovascular drugs, including: angiotensin converting enzyme (ACE) inhibitors such as enalapril, ramipril, perindopril erbumine, 1-carboxymethyl-3-1-carboxy-3-phenyl-(1S)-propylamino-2,3,4,5-tetrahydro-1H-(3S)-11-benzazepine-2-one, 3-(5-amino-1-carboxy-1S-pentyl)amino-2,3,4,5-tetrahydro-2-oxo-3 S-1H-1-benzazepine-1-acetic acid or 3-(1-ethoxycarbonyl-3-phenyl-(1S)-propylamino)-2,3,4,5-tetrahydro-2-oxo-(3S)-benzazepine-1-acetic acid monohydrochloride; cardiac glycosides and cardiac inotropes such as amrinone, digoxin, digitoxin, enoximone, lanatoside C, medigoxin, and milrinone; calcium channel blockers such as verapamil, nifedipine, nicardipene, felodipine, isradipine, nimodipine, amlodipine and diltiazem; beta-blockers such as acebutolol, alprenolol, atenolol, labetalol, metoprolol, nadolol, oxyprenolol, pindolol, propafenone, propranolol, esmolol, sotalol, timolol, and acebutolol; antiarrhythmics such as mexiletene, moricizine, dofetilide, ibutilide, nesiritide, procainamide, quinidine, disopyramide, lidocaine, phenytoin, tocainide, mexiletine, flecainide, encainide, bretylium and amiodarone; cardioprotective agents such as dexrazoxane and leucovorin; vasodilators such as nitroglycerin; diuretic agents such as azetazolamide, amiloride, bendroflumethiazide, bumetanide, chlorothiazide, chlorthalidone, ethacrynic acid, furosemide, hydrochlorothiazide, metolazone, nesiritide, spironolactone, and triamterine; and miscellaneous cardiovascular drugs such as dopradil, midodrine, monatepil, monteplase, nexopamil, ranolazine, and pilsicainide;

[0161] Corticosteroids, such as beclomethasone, betamethasone, budesonide, cortisone, desoxymethasone, dexamethasone, fludrocortisone, flunisolide, fluocortolone, fluticasone propionate, hydrocortisone, methylprednisolone, prednisolone, prednisone and triamcinolone;

[0162] Cytoprotectant/Antioxidant, such as dosmalfate, curcumin, edavarone;

[0163] Erectile dysfunction drugs, such as apomorphine, phentolamine, and vardenafil;

[0164] Keratolytics such as such as acetretin, calcipotriene, calcifediol, calcitriol, cholecalciferol, ergocalciferol, etretinate, retinoids, targretin, and tazarotene;

[0165] Muscle relaxants, such as cyclobenzaprine, dantrolene sodium, mexilitene, and tizanidine HCl;

[0166] Nitrates and other anti-anginal agents, such as amyl nitrate, glyceryl trinitrate, isosorbide dinitrate, isosorbide mononitrate and pentaerythritol tetranitrate;

[0167] Nutritional agents, such as calcitriol, carotenes, dihydrotachysterol, essential fatty acids, non-essential fatty acids, phytonadiol, vitamin A, vitamin B_2, vitamin D, vitamin E and vitamin K.

[0168] Opioid analgesics, such as alfentanil, apomorphine, buprenorphine, butorphanol, codeine, dextropropoxyphene, diamorphine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, meptazinol, methadone, morphine, nalbuphine, oxycodone, oxymorphone, pentazocine, propoxyphene, sufentanil, and tramadol;

[0169] Stimulants, including active agents for treating narcolepsy, attention deficit disorder (ADD) and attention deficit hyperactivity disorder (ADHD), such as amphetamine, dexamphetamine, dexfenfluramine, fenfluramine, mazindol, methylphenidate (including d-threo-methylphenidate, or "dexmethylphenidate," as well as racemic d,1-threo-methylphenidate), modafinil, pemoline, and sibutramine.

[0170] Peptidyl drugs include therapeutic peptides and proteins per se, whether naturally occurring, chemically

synthesized, recombinantly produced, and/or produced by biochemical (e.g., enzymatic) fragmentation of larger molecules, and may contain the native sequence or an active fragment thereof. Specific peptidyl drugs include, without limitation, the peptidyl hormones activin, amylin, angiotensin, atrial natriuretic peptide (ANP), calcitonin, calcitonin gene-related peptide, calcitonin N-terminal flanking peptide, ciliary neurotrophic factor (CNTF), corticotropin (adrenocorticotropin hormone, ACTH), corticotropin-releasing factor (CRF or CRH), epidermal growth factor (EGF), follicle-stimulating hormone (FSH), gastrin, gastrin inhibitory peptide (GIP), gastrin-releasing peptide, gonadotropin-releasing factor (GnRF or GNRH), growth hormone releasing factor (GRF, GRH), human chorionic gonadotropin (hCH), inhibin A, inhibin B, insulin, luteinizing hormone (LH), luteinizing hormone-releasing hormone (LHRH), α-melanocyte-stimulating hormone, β-melanocyte-stimulating hormone, γ-melanocyte-stimulating hormone, melatonin, motilin, oxytocin (pitocin), pancreatic polypeptide, parathyroid hormone (PTH), placental lactogen, prolactin (PRL), prolactin-release inhibiting factor (PIF), prolactin-releasing factor (PRF), secretin, somatotropin (growth hormone, GH), somatostatin (SIF, growth hormone-release inhibiting factor, GIF), thyrotropin (thyroid-stimulating hormone, TSH), thyrotropin-releasing factor (TRH or TRF), thyroxine, vasoactive intestinal peptide (VIP),and vasopressin. Other peptidyl drugs are the cytokines, e.g., colony stimulating factor 4, heparin binding neurotrophic factor (HBNF), interferon-α, interferon α-2a, interferon α-2b, interferon α-n3, interferon -β, etc., interleukin-1, interleukin-2, interleukin-3, interleukin-4, interleukin-5, interleukin-6, etc., tumor necrosis factor, tumor necrosis factor-α, granuloycte colony-stimulating factor (G-CSF), granulocyte-macrophage

[0171] colony-stimulating factor (GM-CSF), macrophage colony-stimulating factor, midkine (MD), and thymopoietin. Still other peptidyl drugs that can be advantageously delivered using the methodology and formulations of the present invention include endorphins (e.g., dermorphin, dynorphin, α-endorphin, β-endorphin, γ-endorphin, σ-endorphin, [Leu^5]enkephalin, [Met^5]enkephalin, substance P), kinins (e.g., bradykinin, potentiator B, bradykinin potentiator C, kallidin), LHRH analogues (e.g., buserelin, deslorelin, fertirelin, goserelin, histrelin, leuprolide, lutrelin, nafarelin, tryptorelin), and the coagulation factors, such as α_1-antitrypsin, α_2-macroglobulin, antithrombin III, factor I (fibrinogen), factor II (prothrombin), factor III (tissue prothrombin), factor V (proaccelerin), factor VII (proconvertin), factor VIII (antihemophilic globulin or AHG), factor IX (Christmas factor, plasma thromboplastin component or PTC), factor X (Stuart-Power factor), factor XI (plasma thromboplastin antecedent or PTA), factor XII (Hageman factor), heparin cofactor II, kallikrein, plasmin, plasminogen, prekallikrein, protein C, protein S, and thrombomodulin and combinations thereof.

[0172] Genetic material may also be delivered using the present methods and formulations, including, for example, nucleic acids, RNA, DNA, recombinant RNA, recombinant DNA, antisense RNA, antisense DNA, ribozymes, ribooligonucleotides, deoxyribonucleotides, antisense ribooligonucleotides, and antisense deoxyribooligonucleotides. Representative genes include those encoding for vascular endothelial growth factor, fibroblast growth factor, Bcl-2, cystic fibrosis transmembrane regulator, nerve growth factor, human growth factor, erythropoietin, tumor necrosis factor, and interleukin-2, as well as histocompatibility genes such as HLA-B7.

[0173] Other actives: dutasetride for hair loss, granelix acetate for female infertility, incadronic acid for cancer or osteoporosis, pergolide for dopamine agonist activity, ritapentine, perenzepine, telenzepine, titanicene, limaprost, olopatidine, falecalcitriol, caldiribine, piapenum, farapenum, piracetam, tianeptine, adrafinil, vinpocetine, idebenone, oxiracetam, aniracetam, ketamine, ertapenum, cabergoline, acamprostate, nevibulol;

[0174] The active agent of the present invention can be hydrophobic, amphiphilic, or hydrophilic. The intrinsic water solubility of those active agents referred to as "hydrophobic" herein, i.e., the aqueous solubility of the active agent in electronically neutral, non-ionized form, is generally less than 1% by weight, and typically less than 0.1% or 0.01% by weight. Hydrophilic and amphiphilic active agents herein (which, unless otherwise indicated, are collectively referred to herein as "hydrophilic" active agents) have apparent water solubilities of at least 0.1% by weight, and typically at least 1% by weight. Both hydrophobic active agents and hydrophilic active agents may be selected from any of the active agent classes enumerated earlier in this section.

[0175] Further, it should be appreciated that the categorization of an active ingredient as hydrophobic or hydrophilic may change, depending upon the particular salts, isomers, analogs and derivatives used. For example, certain active agents indicated as hydrophobic may be readily converted to and commercially available in hydrophilic form, e.g., by ionizing a non-ionized active agent so as to form a pharmaceutically acceptable, pharmacologically active salt. Conversely, certain active agents indicated as hydrophilic may be readily converted to and commercially available in hydrophobic form, e.g., by neutralization, esterification, or the like. Thus, it should be understood that the above categorization of certain active agents as hydrophilic or hydrophobic is not intended to be limiting.

[0176] Specific, non-limiting examples of suitable hydrophobic active ingredients are: acetretin, acetyl coenzyme Q, albendazole, albuterol, aminoglutethimide, amiodarone, amlodipine, amphetamine, amphotericin B, atorvastatin, atovaquone, azithromycin, baclofen, beclomethasone, benezepril, benzonatate, betamethasone, bicalutanide, budesonide, bupropion, busulfan, butenafine, calcifediol, calcipotriene, calcitriol, camptothecin, candesartan, capsaicin, carbamezepine, carotenes, celecoxib, cerivastatin, cetirizine, chlorpheniramine, cholecalciferol, cilostazol, cimetidine, cinnarizine, ciprofloxacin, cisapride, clarithromycin, clemastine, clomiphene, clomipramine, clopidogrel, codeine, coenzyme Q10, cyclobenzaprine, cyclosporin, danazol, dantrolene, dexchlorpheniramine, diclofenac, dicoumarol, digoxin, dehydroepiandrosterone, dihydroergotamine, dihydrotachysterol, dirithromycin, donezepil, efavirenz, eposartan, ergocalciferol, ergotamine, essential fatty acid sources, esomeprazole, estradiol, etodolac, etoposide, famotidine, fenofibrate, fentanyl, fexofenadine, finasteride, fluconazole, flurbiprofen, fluvastatin, fosphenytoin, frovatriptan, furazolidone, gabapentin, gemfibrozil, glibenclamide, glipizide, glyburide, glimepiride, griseofulvin, halofantrine, ibuprofen, irbesartan, irinotecan, isosorbide dinitrate, isotretinoin,

itraconazole, ivermectin, ketoconazole, ketorolac, lamotrigine, lansoprazole, leflunomide, lisinopril, loperamide, loratadine, lovastatin, L-thryroxine, lutein, lycopene, medroxyprogesterone, mifepristone, mefloquine, megestrol acetate, methadone, methoxsalen, metronidazole, miconazole, midazolam, miglitol, minoxidil, mitoxantrone, montelukast, nabumetone, nalbuphine, naratriptan, nelfinavir, nifedipine, nisoldipine, nilutanide, nitrofurantoin, nizatidine, omeprazole, oprevelkin, oxaprozin, paclitaxel, pantoprazole, paracalcitol, paroxetine, pentazocine, pioglitazone, pizofetin, pravastatin, prednisolone, probucol, progesterone, pseudoephedrine, pyridostigmine, rabeprazole, raloxifene, repaglinide, rifabutine, rifapentine, rimexolone, ritanovir, rizatriptan, rofecoxib, rosiglitazone, saquinavir, sertraline, sibutramine, sildenafil citrate, simvastatin, sirolimus, spironolactone, sumatriptan, tacrine, tacrolimus, tamoxifen, tamsulosin, targretin, tazarotene, telmisartan, teniposide, terbinafine, terazosin, tetrahydrocannabinol, tiagabine, ticlopidine, tirofibran, tizanidine, topiramate, topotecan, toremifene, tramadol, tretinoin, troglitazone, trovafloxacin, ubidecarenone, valsartan, venlafaxine, verteporfin, vigabatrin, vitamin A, vitamin D, vitamin E, vitamin K, zafirlukast, zileuton, ziprasidone, zolmitriptan, zolpidem, and zopiclone. Of course, salts, isomers and derivatives of the above-listed hydrophobic active ingredients may also be used, as well as mixtures therof.

[0177] Specific, non-limiting examples of suitable hydrophilic active ingredients include: acarbose; acyclovir; acetyl cysteine; acetylcholine chloride; alatrofloxacin; alendronate; alglucerase; amantadine hydrochloride; ambenomium; amifostine; amiloride hydrochloride; aminocaproic acid; amphotericin B; antihemophilic factor (human); antihemophilic factor (porcine); antihemophilic factor (recombinant); aprotinin; asparaginase; atenolol; atracurium besylate; atropine; azithromycin; aztreonam; BCG vaccine; bacitracin; becalermin; belladona; bepridil hydrochloride; bleomycin sulfate; calcitonin human; calcitonin salmon; carboplatin; capecitabine; capreomycin sulfate; cefamandole nafate; cefazolin sodium; cefepime hydrochloride; cefixime; cefonicid sodium; cefoperazone; cefotetan disodium; cefotaxime; cefoxitin sodium; ceftizoxime; ceftriaxone; cefuroxime axetil; cephalexin; cephapirin sodium; cholera vaccine; chorionic gonadotropin; cidofovir; cisplatin; cladribine; clidinium bromide; clindamycin and clindamycin derivatives; ciprofloxacin; clodronate; colistimethate sodium; colistin sulfate; corticotropin; cosyntropin; cromolyn sodium; cytarabine; dalteparin sodium; danaparoid; desferrioxamine; denileukin diftitox; desmopressin; diatrizoate meglumine and diatrizoate sodium; dicyclomine; didanosine; dirithromycin; dopamine hydrochloride; dornase alpha; doxacurium chloride; doxorubicin; etidronate disodium; enalaprilat; enkephalin; enoxaparin; enoxaparin sodium; ephedrine; epinephrine; epoetin alpha; erythromycin; esmolol hydrochloride; factor IX; famciclovir; fludarabine; fluoxetine; foscarnet sodium; ganciclovir; granulocyte colony stimulating factor; granulocyte-macrophage stimulating factor; recombinant human growth hormones; bovine growth hormone; gentamycin; glucagon; glycopyrolate; gonadotropin releasing hormone and synthetic analogs thereof; GnRH; gonadorelin; grepafloxacin; haemophilus B conjugate vaccine; Hepatitis A virus vaccine inactivated; Hepatitis B virus vaccine inactivated; heparin sodium; indinavir sulfate; influenza virus vaccine; interleukin-2; interleukin-3; insulin-human; insulin lispro; insulin procine; insulin NPH; insulin aspart; insulin glargine; insulin detemir; interferon alpha; interferon beta; ipratropium bromide; ifosfamide; Japanese encephalitis virus vaccine; lamivudine; leucovorin calcium; leuprolide acetate; levofloxacin; lincomycin and lincomycin derivatives; lobucavir; lomefloxacin; loracarbef; mannitol; measles virus vaccine; meningococcal vaccine; menotropins; mepenzolate bromide; mesalamine; methenamine; methotrexate; methscopolamine; metformin hydrochloride; metoprolol; mezocillin sodium; mivacurium chloride; mumps viral vaccine; nedocromil sodium; neostigmine bromide; neostigmine methyl sulfate; neurontin; norfloxacin; octreotide acetate; ofloxacin; olpadronate; oxytocin; pamidronate disodium; pancuronium bromide; paroxetine; perfloxacin; pentamidine isethionate; pentostatin; pentoxifylline; periciclovir; pentagastrin; phentolamine mesylate; phenylalanine; physostigmine salicylate; plague vaccine; piperacillin sodium; platelet derived growth factor; pneumococcal vaccine polyvalent; poliovirus vaccine (inactivated); poliovirus vaccine live (OPV); polymyxin B sulfate; pralidoxime chloride; pramlintide; pregabalin; propafenone; propantheline bromide; pyridostigmine bromide; rabies vaccine; residronate; ribavarin; rimantadine hydrochloride; rotavirus vaccine; salmeterol xinafoate; sincalide; small pox vaccine; solatol; somatostatin; sparfloxacin; spectinomycin; stavudine; streptokinase; streptozocin; suxamethonium chloride; tacrine hydrochloride; terbutaline sulfate; thiopeta; ticarcillin; tiludronate; timolol; tissue type plasminogen activator; TNFR:Fc; TNK-tPA; trandolapril; trimetrexate gluconate; trospectinomycin; trovafloxacin; tubocurarine chloride; tumor necrosis factor; typhoid vaccine live; urea; urokinase; vancomycin; valacyclovir; valsartan; varicella virus vaccine live; vasopressin and vasopressin derivatives; vecoronium bromide; vinblastine; vincristine; vinorelbine; vitamin B12; warfarin sodium; yellow fever vaccine; zalcitabine; zanamivir; zolendronate; zidovudine; pharmaceutically acceptable salts, isomers and derivatives thereof; and mixtures thereof.

[0178] The active ingredient can also be administered in combination with one or more additional active ingredients. Any of the aforementioned active agents may also be administered in combination using the present formulations. Active agents administered in combination may be from the same therapeutic class (e.g., lipid-regulating agents or anticoagulants) or from different therapeutic classes (e.g., a lipid-regulating agent and an anticoagulant). Examples of particularly important drug combination products include, but are not limited to:

[0179] female contraceptive compositions containing both a progestogen and an estrogen;

[0180] female HRT compositions containing a progestogen, an estrogen, and an androgen;

[0181] combinations of lipid-regulating agents, e.g., (a) a fibrate and a statin, such as fenofibrate and atorvastatin, fenofibrate and simvastatin, fenofibrate and lovastatin, or fenofibrate and pravastatin; (b) a fibrate and nicotinic acid, such fenofibrate and niacin; and (c) a statin and a nicotinic acid, such as lovastatin and niacin;

[0182] combinations of a lipid-regulating agent and an antiviral agent, e.g., a fibrate and a protease inhibitor, such as fenofibrate and ritonavir;

[0183] combinations of a lipid-regulating agent and an anticoagulant, e.g., (a) a fibrate and a salicylate, such as fenofibrate and aspirin, (b) a fibrate and another anticoagulant, such as fenofibrate and clopidogrel, (c) a statin and a salicylate, such as simvastatin and aspirin, and (d) a statin and another anticoagulant such as pravastatin and clopidogrel;

[0184] combinations of a lipid-regulating agent and an antidiabetic agent, including (a) a fibrate and a insulin sensitizer such as a thiazolidinedione, e.g., fenofibrate and pioglitazone, or fenofibrate and rosiglitazone, (b) a fibrate and an insulin stimulant such as a sulfonylurea, e.g., fenofibrate and glimepiride, or fenofibrate and glipizide, a statin and and insulin sensitizer such as a thiazolidinedione, e.g., lovastatin and pioglitazone, simvastatin and rosiglitazone, pravastatin and pioglitazone, or the like;

[0185] combinations of a lipid regulating agent and a cardiovascular drug, e.g., (a) a fibrate and a calcium channel blocker, such as fenofibrate and amlodipine, or fenofibrate and irbesartan, or (b) a statin and a calcium channel blocker, such as fosinopril and pravastatin;

[0186] combinations of anticoagulants, e.g., (a) a salicylate and a platelet receptor binding inhibitor, such as aspirin and clopidogrel, (b) a salicylate and a low molecular weight heparin, such as aspirin and dalteparin, and (c) a platelet receptor binding inhibitor and a low molecular weight heparin, such as clopidogrel and enoxaparin;

[0187] combinations of antidiabetics, e.g., (a) an insulin sensitizer and an insulin stimulant, such as (i) a thiazolidinedione such as glitazone or pioglitazone and a sulfonylurea such as glimepiride, and (ii) a biguanide such as metformin and a meglitinide such as repaglinide, (b) an insulin sensitizer and an α-glucosidase inhibitor, such as metformin and acarbose, (c) an insulin stimulant and an α-glucosidase inhibitor, such as (i) a sulfonylurea such as glyburide combined with acarbose, (ii) acarbose and a meglitinide such as repaglinide, (iii) miglitol and a sulfonylurea such as glipizide, or (iv) acarbose and a thiazolidinedione such as pioglitazone;

[0188] combinations of cardiovascular drugs, such as combinations of ACE inhibitors, e.g., lisinopril and candesartan; a combination of an ACE inhibitor with a diuretic agent such as losartan and hydrochlorothiazide; a combination of a calcium channel blocker and a β-blocker such as nifedipine and atenolol; and a combination of a calcium channel blocker and an ACE inhibitor such as felodipine and ramipril;

[0189] combinations of an antihypertensive agent and an antidiabetic agent, such as an ACE inhibitor and a sulfonylurea, e.g., irbesartan and glipizide;

[0190] combinations of antihistamines and antiasthmatic agents, e.g., an antihistamine and a leukotriene receptor antagonist such as loratadine and zafirlukast, desloratidine and zafirlukast, and cetirazine and montelukast;

[0191] combinations of antiinflammatory agents and analgesics, e.g., a COX-2 inhibitor and a nonsteroidal antiinflammatory agent (NSAID) such as rofecoxib and naproxen, or a COX-2 inhibitor and a salicylate such as celecoxib and aspirin;

[0192] combinations of an anti-obesity drug and an antidiabetic agent, e.g., a lipase inhibitor such as orlistat in combination with metformin;

[0193] combinations of a lipid-regulating agent and a drug for treating coronary artery disease, e.g., fenofibrate and ezetimibe, or lovastatin and ezetimibe; and

[0194] other combinations, such as docetaxel and cisplatin, tirapazamine and cisplatin, metoclopramide and naproxen sodium, an opioid analgesic such as oxycodone and an anti-inflammatory agent, an agent for treating erectile dysfunction, such as alprostadil, with an antihypertensive/vasodilator such as prazosin.

[0195] 4. Concentrations

[0196] The components of the pharmaceutical compositions of the present invention in amounts such that upon dilution with an aqueous solution, the composition forms a clear, aqueous dispersion. The determining concentrations of components to form clear aqueous dispersions are the concentrations of triglyceride and surfactants, with the amount of the therapeutic agent, if present, being chosen as described below. The relative amounts of triglycerides and surfactants are readily determined by observing the properties of the resultant dispersion; i.e., when the relative amounts of these components are within a suitable range, the resultant aqueous dispersion is optically clear. When the relative amounts are outside the suitable range, the resulting dispersion is visibly "cloudy", resembling a conventional emulsion or multiple-phase system. Although a visibly cloudy solution may be potentially useful for some applications, such a system would suffer from many of the same disadvantages as conventional prior art formulations, as described above.

[0197] A convenient method of determining the appropriate relative concentrations for any particular triglyceride is as follows. A convenient working amount of a hydrophilic surfactant is provided, and a known amount of the triglyceride is added. The mixture is stirred, with the aid of gentle heating if desired, then is diluted with purified water to prepare an aqueous dispersion. Any dilution amount can be chosen, but convenient dilutions are those within the range expected in vivo, about a 10 to 250-fold dilution. In the Examples herein, a convenient dilution of 100-fold was chosen. The aqueous dispersion is then assessed qualitatively for optical clarity. The procedure can be repeated with incremental variations in the relative amount of triglyceride added, to determine the maximum relative amount of triglyceride that can be present to form a clear aqueous dispersion with a given hydrophilic surfactant. I.e., when the relative amount of triglyceride is too great, a hazy or cloudy dispersion is formed.

[0198] The amount of triglyceride that can be solubilized in a clear aqueous dispersion is increased by repeating the above procedure, but substituting a second hydrophilic surfactant, or a hydrophobic surfactant, for part of the originally-used hydrophilic surfactant, thus keeping the total surfactant concentration constant. Of course, this procedure is merely exemplary, and the amounts of the components can be chosen using other methods, as desired.