ESTTA Tracking number: **ESTTA829740**

Filing date: **06/28/2017**

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

Proceeding	91234098
Party	Defendant DERMAVITA limited partnership
Correspondence Address	TANJA PROEHL GREER BURNS & CRAIN LTD 300 SOUTH WACKER DRIVE, SUITE 2500 CHICAGO, IL 60606 UNITED STATES Email: aziegler@gbc.law, tproehl@gbc.law, tmdocket@gbclaw.net
Submission	Answer and Counterclaim
Filer's Name	Tanja Proehl
Filer's email	tproehl@gbclaw.net
Signature	/Tanja Proehl/
Date	06/28/2017
Attachments	Answer and Counterclaims.pdf(214711 bytes) Exhibit 1.pdf(503028 bytes) Exhibit 2.pdf(490053 bytes) Exhibit 3_Juv Volift specimen.pdf(1445729 bytes) Exhibit 4.pdf(2256134 bytes) Exhibit 4a.pdf(606536 bytes) Exhibit 5_Juv specimen.pdf(231078 bytes) Exhibit 6_Juv Voluma specimen.pdf(168439 bytes) Exhibit 7_Ownership.pdf(418710 bytes)

Registrations Subject to the filing

Registration No.	4380506	Registration date	08/06/2013
Registrant	Allergan, Inc. 2525 Dupont Drive Irvine, CA 92612 UNITED STATES Email: hinchey_susan@allergan.com		

Goods/Services Subject to the filing

Class 005. First Use: 2012/09/13 First Use In Commerce: 2012/09/13 All goods and services in the class are requested, namely: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles			
Registration No.	3706974	Registration date	11/03/2009
Registrant	ALLERGAN, INC. 2525 DUPONT DRIVE IRVINE, CA 92612 UNITED STATES		

Goods/Services Subject to the filing

Class 005. First Use: 2000/12/31 First Use In Commerce: 2004/08/31 All goods and services in the class are requested, namely: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin, all

to be sold andmarketed only to licensed physicians, surgeons, and healthcare professionals

Grounds for Cancellation

Abandonment		Trademark Act Section 14(3)	
Fraud on the USPTO		Trademark Act Section 14(3); In re Bose Corp., 580 F.3d 1240, 91 USPQ2d 1938 (Fed. Cir. 2009)	
Registration No.	4380507	Registration date	08/06/2013
Registrant	Allergan, Inc. 2525 Dupont Drive Irvine, CA 92612 UNITED STATES Email: hinchey_susan@allergan.com		

Goods/Services Subject to the filing

Class 005. First Use: 2013/02/19 First Use In Commerce: 2013/02/19 All goods and services in the class are requested, namely: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles			
Registration No.	4481317	Registration date	02/11/2014
Registrant	Allergan, Inc. 2525 Dupont Drive Irvine, CA 92612 UNITED STATES Email: hinchey_susan@allergan.com		

Goods/Services Subject to the filing

Class 005. First Use: 2013/12/02 First Use In Commerce: 2013/12/02 All goods and services in the class are requested, namely: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles

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

In the matter of Trademark Application Serial Number 79/975,292
Published in the *Official Gazette* on April 11, 2017

ALLERGAN, INC.,	)	
	)	Opposition No.: 91234098
Opposer and Registrant,	)	
	)	
v.	)	Cancellation No.:
	)	Registration Nos.: 4,380,506,
DERMAVITA limited partnership,	)	4,380,507,
	)	3,706,974 and
Applicant and Petitioner.	)	4,481,317
	)	

ANSWER TO NOTICE OF OPPOSTION,
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Box TTAB
Commissioner for Trademarks
P.O. Box 1451
Alexandria, VA 22313-1451

Dear Sir or Madam:

Applicant, DERMAVITA limited partnership, by and through its undersigned counsel hereby answers the Notice of Opposition by addressing each allegation and files affirmative defenses, as well as counterclaims against Opposer's pleaded U.S. Trademark Registration Nos. 4380506, 4380507, 3706974 and 4481317.

ANSWER

1. Opposer is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2525 Dupont Drive, Irvine, California 92612. Opposer is a multi-specialty health care company and has been for many years, engaged in the development

and commercialization of specialty pharmaceutical, biologics, medical devices and over- the-counter products for the ophthalmic, neurological, medical aesthetics, medical dermatology, breast aesthetics, urological and other specialty markets in more than 100 countries around the world. Since at least 2007, Opposer and its subsidiaries and predecessors-in-interest have continuously used JUVÉDERM-formative marks (the "JUVÉDERM Marks") in connection with a line of injectable dermal fillers and related services (the "JUVÉDERM Products").

RESPONSE:

Applicant lacks knowledge or information sufficient to form a belief about the truth of the allegations of this paragraph with regard to the Opposer's business and therefore denies same. Applicant denies that since at least 2007, Opposer and its subsidiaries and predecessors-in-interest have continuously used JUVÉDERM-formative marks in connection with a line of injectable dermal fillers and related services. To the contrary, the records on the USPTO database show that Opposer's pleaded trademark registrations for the marks JUVEDERM VOLIFT, JUVEDERM VOLBELLA and JUVEDERM VOLUMA state a date of first use of September 13, 2012 for the JUVEDERM VOLIFT mark, Reg. No. 4380506; February 19, 2013 for the JUVEDERM VOLBELLA mark, Reg. No. 4380507; and December 2, 2013 for the JUVEDERM VOLUMA mark, Reg. No. 4481317. See **Exhibit 1**. This contradicts Opposer's statement in paragraph 1.

2. Opposer directly, and through its subsidiaries, owns all right, title and interest in and to the JUVÉDERM Marks, as well as the following United States registrations on the Principal Register:

a. Registration No. 3,706,974, granted November 3, 2009, for the mark JUVEDERM in International Class 5 for "pharmaceutical preparations for the treatment

of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin, all to be sold and marketed only to licensed physicians, surgeons, and healthcare professionals."

b. Registration No. 4,380,506, granted August 6, 2013, for the mark JUVEDERM VOLIFT in International Class 5 for "Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles."

c. Registration No. 4,380,507, granted August 6, 2013, for the mark JUVEDERM VOLBELLA in International Class 5 for "Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles."

d. Registration No. 4,481,317, granted February 11,2014, for the mark JUVEDERM VOLUMA in International Class 5 for "Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles."

All of these registrations are valid and subsisting and Registration Nos. 3463915 and 3706974 have become incontestable. Copies of current printouts of information from the electronic database records of the USPTO showing the current status and title of these registrations are attached hereto as Exhibit 1 and are incorporated by reference herein as if set forth in full.

RESPONSE:

Applicant lacks knowledge or information sufficient to form a belief about the truth of the allegations of this paragraph and therefore denies same. Further, Applicant has reason to believe that Opposer's above referenced marks were not in use in the United States at the time of filing the required statements of use and that Opposer knowingly and with an intent to deceive made false use statements. The registrations were obtained based on these fraudulent statements. In addition, Applicant has reason to believe that Opposer is not the rightful owner of the registrations.

3. In addition to using its JUVÉDERM Marks on and in connection with its JUVÉDERM Products, since long prior to the filing of the Application at issue Opposer has been providing advertising services for others under the JUVÉDERM Marks.

RESPONSE:

Applicant lacks knowledge or information sufficient to form a belief about the truth of the allegations of this paragraph and therefore denies same.

4. From a time long prior to the filing of the Application at issue, Opposer has used the JUVÉDERM Marks in commerce in the United States on and in connection with the foregoing goods, for which the mark has become famous. Moreover, by virtue of the excellence of the products sold under the JUVÉDERM Marks, the marks have a valuable reputation.

RESPONSE:

Applicant lacks knowledge or information sufficient to form a belief about the truth of the allegations of this paragraph and therefore denies same.

5. Notwithstanding Opposer's long prior rights in and to the JUVÉDERM Marks, on information and belief, on June 17, 2015, Applicant filed an application for registration of the trademark "JUVEDERM" for goods and services in two International Classes. That application has since been sub-divided into three separate applications. The application at issue, Application Serial No. 79/975,292, seeks registration of the mark "JUVEDERM" ("Applicant's Mark") for "Advertising, marketing and promotion services; commercial trading services in the nature of direct marketing services, promotional marketing and representation services for sales to the public sector; providing consumer product information via the Internet; business management analysis, business research and business information management services" in International Class 35, and the application was published for opposition in the Trademark Official Gazette of April l1, 2017 (the "Opposed Application").

RESPONSE:

Applicant admits that it filed a multiclass application for registration of the trademark "JUVEDERM" and that this application has since been sub-divided into three separate applications. Applicant admits that the application at issue, Application Serial No. 79/975,292, seeks registration of the mark "JUVEDERM" ("Applicant's Mark") for "Advertising, marketing and promotion services; commercial trading services in the nature of direct marketing services, promotional marketing and representation services for sales to the public sector; providing consumer product information via the Internet; business management analysis, business research and business information management services" in International Class 35, and the application was published for opposition in the Trademark Official Gazette of April 11, 2017. Applicant denies that Opposer has long prior rights in and to the JUVÉDERM Marks. To the contrary, Applicant has prior rights with regard to its goods and services covered by International Classes 3 and 35.

FIRST CLAIM FOR RELIEF

(Likelihood of Confusion With Registered Marks)

6. Opposer repeats and realleges the allegations in preceding paragraphs 1 through 5, inclusive, as if fully set forth herein.

RESPONSE:

Applicant repeats and re-alleges its corresponding responses to the allegations in preceding paragraphs 1 through 5, inclusive, as if fully set forth herein.

7. Applicant's Mark shown in the Opposed Application so resembles Opposer's registered JUVÉDERM Marks as to be likely, when used on or in connection with the services in the Opposed Application, to cause confusion, to cause mistake, or to deceive, and Applicant's Mark is thus unregistrable under Section 2(d) of the United States Trademark Act, 15 U.S. C. 1052(d).

RESPONSE:

Applicant denies the allegations of paragraph 7.

8. Opposer will be damaged by registration of the mark shown in the Opposed Application because registration will give Applicant prima facie evidence of its ownership of, and its exclusive nationwide right to use, a mark that is confusingly similar to Opposer's JUVÉDERM Marks.

RESPONSE:

Applicant denies the allegations of paragraph 8.

SECOND CLAIM FOR RELIEF

(Likelihood of Confusion With Previously-Used Trademarks)

9. Opposer repeats and realleges the allegations in preceding paragraphs 1 through 8, inclusive, as if fully set forth herein.

RESPONSE:

Applicant repeats and re-alleges its corresponding responses to the allegations in preceding paragraphs 1 through 8, inclusive, as if fully set forth herein.

10. Applicant's Mark shown in the Opposed Application so resembles Opposer's previously-used and not abandoned JUVÉDERM Marks as to be likely, when used on or in connection with the services identified in the Opposed Application, to cause confusion, to cause mistake, or to deceive, and Applicant's Mark is thus unregistrable under Section 2(d) of the United States Trademark Act, 15 U.S.C. l052(d).

RESPONSE:

Applicant denies the allegations of paragraph 10.

11. Opposer will be damaged by registration of the mark shown in the Opposed Application because registration will give Applicant prima facie evidence of its ownership of, and its exclusive nationwide right to use, a mark that is confusingly similar to Opposer's previously-used and not abandoned JUVÉDERM Marks.

RESPONSE:

Applicant denies the allegations of paragraph 11.

THIRD CLAIM FOR RELIEF

(Likelihood of Dilution With Previously-Registered And Used Trademarks)

12. Opposer repeats and realleges the allegations in preceding paragraphs 1 through 11, inclusive, as if fully set forth herein.

RESPONSE:

Applicant repeats and re-alleges its corresponding responses to the allegations in preceding paragraphs 1 through 11, inclusive, as if fully set forth herein.

13. Opposer's JUVÉDERM Marks are famous and were famous long prior to the filing of the Opposed Application.

RESPONSE:

Applicant denies the allegations of paragraph 13.

14. Applicant's Mark shown in the Opposed Application so resembles Opposer's previously-used, registered and not abandoned JUVÉDERM Marks as to be likely to blur the distinctiveness of Opposer's JUVÉDERM Marks, and Applicant's Mark is thus unregistrable under Section 43(c) of the United States Trademark Act, 15 U.S.C. 1125(c).

RESPONSE:

Applicant denies the allegations of paragraph 14.

15. Opposer will be damaged by registration of the mark shown in the Opposed Application because registration will give Applicant prima facie evidence of its ownership of,

and its exclusive nationwide right to use, a mark that is likely to impair the distinctiveness of Opposer's famous JUVÉDERM Marks.

RESPONSE:

Applicant denies the allegations of paragraph 15.

AFFIRMATIVE DEFENSES

1. The Notice of Opposition fails to state a claim upon which relief can be granted.
2. Opposer lacks standing to assert the claims pled in this proceeding.
3. Opposer's claims for relief are barred by the doctrine of unclean hands.

Applicant reserves the right to assert additional affirmative defenses which may emerge up to and including the time of trial.

COUNTERCLAIMS

Pursuant to 15 U.S.C. § 1064, 37 C.F.R. § 2.111(b) and TBMP § 309.03(b), Applicant believes that it is and will continue to be damaged by the continued registration of Opposer's following pleaded registrations:

Trademark	Reg. No.	Class/Goods
JUVEDERM	3706974	05: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin, all to be sold and marketed only to licensed physicians, surgeons, and healthcare professionals

JUVEDERM VOLIFT	4380506	05: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles
JUVEDERM VOLBELLA	4380507	05: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles
JUVEDERM VOLUMA	4481317	05: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles

The four above-referenced registrations by Allergan are collectively and individually referred to as the "Allergan Registrations".

Applicant hereby petitions to cancel the Allergan Registrations. As grounds for cancellation, Applicant alleges as follows:

1. Applicant and Petitioner, DERMAVITA limited partnership is a limited partnership formed under the laws of Lebanon, having a place of business at Spears str., Al Itihad building, Floor 6, Mussaitbeh, Al Sanayeh Beirut LEBANON (hereinafter "Petitioner" or "Applicant").

2. On information and belief, Opposer and Registrant, Allergan, Inc. is a corporation of Delaware, having an address at 2525 Dupont Drive, Irvine, California 92612 (hereinafter "Registrant" or "Opposer").

3. On June 17, 2015, Applicant designated the U.S. in its International Trademark Registration, IR No. 1266937 for the mark JUVEDERM claiming a priority date of April 30, 2015. The U.S. application was assigned U.S. Application Serial No. 79173350 and initially included the following goods and services: "*Cosmetics for professional use and for use by the end consumer; cosmetic creams, emulsions, lotions, liquids, solutions, milks, gels and oils for the skin (of the face, body, hands, feet, and neck), oils for cosmetic purposes; cosmetic kits, cosmetic products and preparations for skin care; cosmetic masks, cosmetics, cosmetic preparations for slimming purposes, cosmetics for exfoliation, cosmetic peelings, cosmetics for smoothing the skin; cosmetics for hair conditioning and care of the hair and scalp; cosmetic sunscreen products and preparations (emulsions, lotions, milks, gels, oils, liquids); cosmetic preparations for skin whitening, skin whitening creams, bleaching preparations (decolorants) for cosmetic purposes, cosmetics for lightening the skin, cosmetics for perfecting the complexion; anti-wrinkle cosmetics, skin rejuvenation cosmetics, skin lightening cosmetics, cosmetic preparations for skin hydration, cosmetics for toning the skin; essential oils and aromatic extracts; toiletries; cleaning and fragrancing preparations*" in International Class 3, "*Advertising, marketing and promotional services; commercial trading and consumer information services; business analysis, research and*

information services" in International Class 35 and "*Human hygiene and beauty care; hygienic and beauty care; human hygiene and beauty care*" in International Class 44.

4. On October 8, 2015, an Office Action issued and partially refused registration of the JUVEDERM mark in U.S. Application Serial No. 79173350 for goods and services in International Classes 3 and 44 only based on alleged likelihood of confusion with U.S. Reg. Nos. 4481317, 3463915, 3706974, 4380506 and 4380507. Subsequently, Applicant deleted International Class 44, divided out hair care products from International Class 3 goods, now U.S. Application Serial No. 79975300, and divided out services in International Class 35, now U.S. Application Serial No. 79975292 which has been published and is the subject of the instant opposition by Allergan, Inc.

5. The alleged refusal with regard to Applicant's International Class 3 applications, namely U.S. Application Serial Nos. 79173350 and 79975300, was maintained and the examination of both applications is currently suspended.

6. At least as early as 1999, Applicant adopted the trademark JUVEDERM in Lebanon for at least various cosmetic preparations. Subsequently, Applicant expanded its trademark portfolio for the mark JUVEDERM in many countries of the world, including the U.S. with an intention to use the mark in connection with at least various cosmetic and beauty care items and the services covered by the opposed Application.

7. On information and belief, Registrant only registered the Allergan Registrations in connection with a narrow list of goods in International Class 5, such as "*Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles*."

8. On information and belief, Registrant did not file any U.S. trademark applications in International Class 3 for the mark JUVEDERM.

9. On information and belief, another company called Allergan Holdings France SAS just recently filed U.S. trademark applications in International Class 3 for JUVEDERM VOLUX, Serial No. 87270389 and for the mark JUVÉDERM (stylized), Serial No. 87089516 and JUVÉDERM (word mark), Serial No. 87089435, well after Petitioner had already applied to register its JUVEDERM mark for cosmetic goods in International Class 3. See **Exhibit 2**.

10. On information and belief, Registrant is not the rightful owner of the Allergan Registrations.

11. On information and belief, Registrant's "Allergan Registrations" should have never been registered because an appropriate use specimen was never submitted.

12. On information and belief, Registrant acted in bad faith and with an intent to deceive when submitting the Statements of Use in the Allergan Registrations.

13. Petitioner has been, and continues to be, damaged in that the Allergan Registrations are cited against Petitioner's JUVEDERM application in International Class 3 as a basis for refusal of registration under Trademark Act Section 2(d), 15 U.S.C. § 1052(d) and are pleaded in this opposition proceeding.

Count I – Trademark Act Section 14(3)
Regarding All of the Allergan Registrations

14. Applicant hereby re-alleges paragraphs 1-13 of the Counterclaims section as if fully set forth herein. Applicant further claims that Opposer abandoned the marks that are the subject of the Allegan Registrations with no intent to resume use of these marks under Section 14(3). Each of these registrations is addressed as follows:

a) JUVEDERM VOLIFT, Reg. No. 4380506

15. Upon information and belief, Opposer has abandoned the JUVEDERM VOLIFT mark shown in Reg. No. 4380506 pursuant to Section 14(3) of the Trademark Act, 15 U.S.C. § 1064(3).

16. Upon information and belief, Opposer is not currently using the JUVEDERM VOLIFT mark with the goods listed in Reg. No. 4380506 in commerce in the ordinary course of trade.

17. Upon information and belief, Opposer has discontinued use of the JUVEDERM VOLIFT mark with the goods listed in Reg. No. 4380506 with no intent to resume use of the mark. In fact, it is believed that Opposer never used the JUVEDERM VOLIFT mark in U.S. commerce.

18. Upon information and belief, for at least the last three consecutive years, Opposer has not used the JUVEDERM VOLIFT mark with the goods listed in Reg. No. 4380506 in commerce in the ordinary course of trade, thereby constituting *prima facie* evidence of abandonment of the JUVEDERM VOLIFT mark as shown in Reg. No. 4380506 pursuant to 15 U.SC. § 1127.

19. In view of Opposer's non-use and abandonment of the JUVEDERM VOLIFT mark shown in Reg. No. 4380506, Opposer is not entitled to continued registration of the mark pursuant to Section 14(3) of the Trademark Act, 15 U.S.C. § 1064(3), such that Reg. No. 4380506 should be cancelled.

20. For the reasons set forth above, Petitioner has been, and continues to be, damaged by continued registration of Reg. No. 4380506.

b) JUVEDERM VOLBELLA, Reg. No. 4380507

21. Upon information and belief, Opposer has abandoned the JUVEDERM VOLBELLA mark shown in Reg. No. 4380507 pursuant to Section 14(3) of the Trademark Act, 15 U.S.C. § 1064(3).

22. Upon information and belief, Opposer is not currently using the JUVEDERM VOLBELLA mark as registered with the goods listed in Reg. No. 4380507 in commerce in the ordinary course of trade.

23. Upon information and belief, Opposer never used the JUVEDERM VOLBELLA mark as registered with the goods listed in Reg. No. 4380507 and has no intent to resume use of the mark. Opposer's submitted specimen does not show the mark as applied for. In the instant case, Opposer's specimen shows the mark as "JUVÉDERM VOLBELLA XC" (with the French "e acute" and the additional letters "XC"). See **Exhibit 4.** Opposer's registration, on the other hand, is for the mark "JUVEDERM VOLBELLA" (with the letter "e", not "e acute" and without the letters "XC"). Further, on information and belief, Opposer obtained FDA approval for the product "JUVÉDERM VOLBELLA XC" and not for "JUVEDERM VOLBELLA" as applied for. See **Exhibit 4a**.

24. In view of Opposer's non-use and abandonment of the JUVEDERM VOLBELLA mark shown in Reg. No. 4380507, Opposer is not entitled to continued registration of the mark pursuant to Section 14(3) of the Trademark Act, 15 U.S.C. § 1064(3), such that Reg. No. 4380507 should be cancelled.

25. For the reasons set forth above, Petitioner has been, and continues to be, damaged by continued registration of Reg. No. 4380507.

c) JUVEDERM, Reg. No. 3706974

26. Upon information and belief, Opposer has abandoned the JUVEDERM mark shown in Reg. No. 3706974 pursuant to Section 14(3) of the Trademark Act, 15 U.S.C. § 1064(3).

27. Upon information and belief, Opposer is not currently using the JUVEDERM mark as registered with the goods listed in Reg. No. 3706974 in commerce in the ordinary course of trade.

28. Upon information and belief, Opposer never used the JUVEDERM mark as registered with the goods listed in Reg. No. 3706974 and has no intent to resume use of the mark. Opposer's submitted specimen does not show the mark as applied for. In the instant case, Opposer's specimen shows the mark as "JUVÉDERM ULTRA PLUS" (with the French "e acute" and the additional words "ULTRA PLUS"). See **Exhibit 5.** Opposer's registration, on the other hand, is for the mark "JUVEDERM" (with the letter "e", not "e acute" and without the additional words "ULTRA PLUS"). Further, on information and belief, Opposer obtained FDA approval for the product "JUVÉDERM ULTRA XC AND JUVÉDERM ULTRA PLUS XC" and not for "JUVEDERM" as applied for. See **Exhibit 4a**.

29. In view of Opposer's non-use and abandonment of the JUVEDERM mark shown in Reg. No. 3706974, Opposer is not entitled to continued registration of the mark pursuant to Section 14(3) of the Trademark Act, 15 U.S.C. § 1064(3), such that Reg. No. 3706974 should be cancelled.

30. For the reasons set forth above, Petitioner has been, and continues to be, damaged by continued registration of Reg. No. 3706974.

d) JUVEDERM VOLUMA, Reg. No. 4481317

31. Upon information and belief, Opposer has abandoned the JUVEDERM VOLUMA mark shown in Reg. No. 4481317 pursuant to Section 14(3) of the Trademark Act, 15 U.S.C. § 1064(3).

32. Upon information and belief, Opposer is not currently using the JUVEDERM VOLUMA mark as registered with the goods listed in Reg. No. 4481317 in commerce in the ordinary course of trade.

33. Upon information and belief, Opposer never used the JUVEDERM VOLUMA mark as registered with the goods listed in Reg. No. 4481317 and has no intent to resume use of the mark. Opposer's submitted specimen does not show the mark as applied for. In the instant case, Opposer's specimen shows the mark as "JUVÉDERM VOLUMA XC" (with the French "e acute" and the additional letters "XC"). See **Exhibit 6.** Opposer's registration, on the other hand, is for the mark "JUVEDERM VOLUMA" (with the letter "e", not "e acute" and without the letters "XC"). Further, on information and belief, Opposer obtained FDA approval for the product "JUVÉDERM VOLUMA XC" and not for "JUVEDERM VOLUMA" as applied for. See **Exhibit 4a**.

34. In view of Opposer's non-use and abandonment of the JUVEDERM VOLUMA mark shown in Reg. No. 4481317, Opposer is not entitled to continued registration of the mark pursuant to Section 14(3) of the Trademark Act, 15 U.S.C. § 1064(3), such that Reg. No. 4481317 should be cancelled.

35. For the reasons set forth above, Petitioner has been, and continues to be, damaged by continued registration of Reg. No. 4481317.

COUNT II – Section 1(a) and (c)
Regarding All of the Allergan Registrations

36. Applicant hereby re-alleges paragraphs 1-35 of the Counterclaims section as if fully set forth herein. Applicant further claims that Opposer filed false Statements of Use in connection with all of the Allergan Registrations under Section 1(a) and (c). Each of the Allergan Registrations is addressed as follows:

a) JUVEDERM VOLIFT, Reg. No. 4380506

37. On September 15, 2010, Opposer filed an application for the mark JUVEDERM VOLIFT based on an intent to use for "*Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles*" in International Class 5.

38. On April 05, 2013, Opposer submitted a Statement of Use and declared that the mark JUVEDERM VOLIFT was first used at least as early as September 13, 2012 and first used in commerce at least as early as September 13, 2012, and is now in use in such commerce in connection with *"Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles"* in International Class 5.

39. On information and belief, Opposer's declaration was false in that, as of September 13, 2012, Opposer had not actually offered the recited goods in commerce and therefore had not used the mark in commerce.

40. On information and belief, Opposer never obtained FDA approval of the JUVEDERM VOLIFT product.

41. Further, Opposer's submitted use specimen does not show the mark as applied for. In an intent to use based application, the drawing of the mark must be a substantially exact representation of the mark as used or as intended to be used on or in connection with the goods. This means that the mark as shown in the drawing must be substantially the exact same mark as shown in the specimen of use. In the instant case, Opposer's specimen shows the mark as "JUVÉDERM VOLIFT XC" (with the French "e acute" and the letters "XC"). See **Exhibit 3.** Opposer's registration on the other hand is for the mark "JUVEDERM VOLIFT" (with the letter "e", not "e acute" and without the letters "XC"). Both letters "e acute" and "e" are standard characters according to the Trademark Manual of Examining Procedure (TMEP), and Opposer could have used the "e acute" in its filing. For a specimen to be acceptable the mark shown in the drawing must be substantially the exact same mark as shown in the specimen of use. See § 19:58.50 in 3 McCarthy on Trademarks and Unfair Competition § 19:58.50 (4th ed.). In the instant case, Opposer's application for "JUVEDERM VOLIFT" is not substantially the exact same as "JUVÉDERM VOLIFT XC" (with the French "e acute" and the letters "XC"). For example, the Trademark Trial and Appeal Board found that a drawing of the mark UPPER 90 for clothing was not a substantially exact representation of the mark as used, because the specimen showed the mark as UPPER 90°. See In re Yale Sportswear Corporation, 88 U.S.P.Q.2d 1121, 2008 WL 2675684 (T.T.A.B. 2008). In the instant case, the "e acute" as shown in the specimen is pronounced differently and provides the mark with an overall French look, and the letters "XC" are included in the specimen. Therefore, the mark in the drawing of Opposer's mark is not substantially the exact same mark as shown in the specimen of use.

42. Opposer did not use the mark "JUVEDERM VOLIFT" as shown in the application. Opposer refers to its marks as the "JUVÉDERM MARKS" and its products as the "JUVÉDERM

PRODUCTS" throughout the entire Notice of Opposition. Further, Opposer well understands the differences between the JUVEDERM mark with an "e acute" and without the "e acute", as evidenced by the more recent applications and one registration for "JUVÉDERM" with the e acute on the U.S. Register (*e.g.*, Reg. No. 4933963 by Allergan Holdings France).

43. Opposer's Reg. No. 4380506 was allowed based on a false Statement of Use and is invalid and null and void, ab initio under Section 1 (a) and (c) of the Trademark Act, 15 USC §§1051, 1053 and 1063.

b) JUVEDERM VOLBELLA, Reg. No. 4380507

44. On September 15, 2010, Opposer filed an application for the mark JUVEDERM VOLBELLA based on an intent to use for "*Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles*" in International Class 5.

45. On April 5, 2013, Opposer submitted a Statement of Use and declared that the mark JUVEDERM VOLBELLA was first used in commerce at least as early as February 9, 2013, and is now in use in such commerce in connection with *"Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles"* in International Class 5.

46. On information and belief, Opposer's declaration was false in that Opposer's submitted specimen does not show the mark as applied for. In the instant case, Opposer's specimen shows the mark as "JUVÉDERM VOLBELLA XC" (with the French "e acute" and the additional

letters "XC"). See **Exhibit 4.** Opposer's registration, on the other hand, is for the mark "JUVEDERM VOLBELLA" (with the letter "e", not "e acute" and without the letters "XC"). On information and belief, Opposer obtained FDA approval for the product "JUVÉDERM VOLBELLA XC" and not for "JUVEDERM VOLBELLA" as applied for. See **Exhibit 4a**. Therefore, the mark in the drawing of Opposer's mark is not substantially the exact same mark as shown in the specimen of use. Reference is made to the arguments and citation of case law in paragraph 41 of the Counterclaim Section.

47. Opposer did not use the mark "JUVEDERM VOLBELLA" as shown in the application. Opposer refers to its marks as the "JUVÉDERM MARKS" and its products as the "JUVÉDERM PRODUCTS" throughout the entire Notice of Opposition. Further, Opposer well understands the differences between the JUVEDERM mark with an "e acute" and without the "e acute", as is evidenced by the more recent applications and one registration for "JUVÉDERM" with the e acute on the U.S. Register (*e.g.*, Reg. No. 4933963 by Allergan Holdings France).

48. Opposer's Reg. No. 4380507 was allowed based on a false Statement of Use and is invalid and null and void, ab initio under Section 1 (a) and (c) of the Trademark Act, 15 USC §§1051, 1053 and 1063.

c) JUVEDERM, Reg. No. 3706974

49. On May 19, 2005, a company called Inamed Corporation (listed current owner is the Opposer) filed an application for the mark JUVEDERM based on an intent to use and based on a foreign mark for "Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin, all to be sold and marketed only to licensed physicians, surgeons, and healthcare professionals" in International Class 5.

50. On September 8, 2009, a Statement of Use was submitted and declared that the mark JUVEDERM was first used in commerce at least as early as August 31, 2004, and is now in use in such commerce in connection with "Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin, all to be sold and marketed only to licensed physicians, surgeons, and healthcare professionals" in International Class 5.

51. On information and belief, Opposer's declaration was false in that Opposer did not have any use in commerce on August 31, 2004. On information and belief, Opposer did not even file for FDA approval until well over one year later, in December 2005.

52. In addition, Opposer's submitted specimen does not show the mark as applied for. In the instant case, Opposer's specimen shows the mark as "JUVÉDERM ULTRA PLUS" (with the French "e acute" and the additional words "ULTRA PLUS"). See **Exhibit 5.** Opposer's registration on the other hand is for the mark "JUVEDERM" (with the letter "e", not "e acute" and without the additional words "ULTRA PLUS"). Therefore, the mark in the drawing of Opposer's mark is not substantially the exact same mark as shown in the specimen of use. Reference is made to the arguments and citation of case law in paragraph 41 of the Counterclaim Section.

53. Opposer did not use the mark "JUVEDERM" as shown in the application. Opposer refers to its marks as the "JUVÉDERM MARKS" and its products as the "JUVÉDERM PRODUCTS" throughout the entire Notice of Opposition. Further, Opposer well understands the differences between the JUVEDERM mark with an "e acute" and without the "e acute", as is evidenced by the more recent applications and one registration for "JUVÉDERM" with the e acute on the U.S. Register (*e.g.*, Reg. No. 4933963 by Allergan Holdings France).

54. Opposer's Reg. No. 3706974 was allowed based on a false Statement of Use and is invalid and null and void, ab initio under Section 1 (a) and (c) of the Trademark Act, 15 USC §§1051, 1053 and 1063.

d) JUVEDERM VOLUMA, Reg. No. 4481317

55. On January 10, 2008, Opposer filed an application for the mark JUVEDERM VOLUMA based on an intent to use for "Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles" in International Class 5.

56. On December 3, 2013, Opposer submitted a Statement of Use and declared that the mark JUVEDERM VOLUMA was first used in commerce at least as early as December 2, 2013, and is now in use in such commerce in connection with *"Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles"* in International Class 5.

57. On information and belief, Opposer's declaration was false in that Opposer's submitted specimen does not show the mark as applied for. In the instant case, Opposer's specimen shows the mark as "JUVÉDERM VOLUMA XC" (with the French "e acute" and the additional letters "XC"). See **Exhibit 6.** Opposer's registration, on the other hand, is for the mark "JUVEDERM VOLUMA" (with the letter "e", not "e acute" and without the letters "XC"). On information and belief, Opposer obtained FDA approval for the product "JUVÉDERM VOLUMA XC" and not for "JUVEDERM VOLUMA" as applied for. See **Exhibit 4a**. Therefore, the mark in the drawing of Opposer's mark is not substantially the exact same mark as shown in

the specimen of use. Reference is made to the arguments and citation of case law in paragraph 41 of the Counterclaim Section.

58. Opposer did not use the mark "JUVEDERM VOLUMA" as shown in the application. Opposer refers to its marks as the "JUVÉDERM MARKS" and its products as the "JUVÉDERM PRODUCTS" throughout the entire Notice of Opposition. Further, Opposer well understands the differences between the JUVEDERM mark with an "e acute" and without the "e acute", as evidenced by the more recent applications and one registration for "JUVÉDERM" with the e acute on the U.S. Register (*e.g.*, Reg. No. 4933963 by Allergan Holdings France).

59. Opposer's Reg. No. 4481317 was allowed based on a false Statement of Use and is invalid and null and void, ab initio under Section 1 (a) and (c) of the Trademark Act, 15 USC §§1051, 1053 and 1063.

COUNT III – Fraud
Regarding All of the Allergan Registrations

60. Applicant hereby re-alleges paragraphs 1-59 of the Counterclaims Section as if fully set forth herein.

61. On information and belief, Opposer has not made *bona fide* use of the Allergan Registrations in commerce for any of Opposer's goods, and Opposer knew or at least should have known that its statements to the U.S. Patent and Trademark Office ("USPTO") with regard to all of its pleaded Allergan Registrations were false or misleading and intentionally sought to mislead the USPTO.

62. On information and belief, the Allergan Registrations were allowed based on fraudulent Statements of Use and are invalid and null and void, ab initio.

COUNT IV – Lack of Ownership, Section 1(a)(1)
Regarding All of the Allergan Registrations

63. Applicant hereby re-alleges paragraphs 1-62 of the Counterclaims Section as if fully set forth herein.

64. On information and belief, there are some recent U.S. trademark filings in the name of a third party, Allergan Holdings France SAS, including for example applications for the marks JUVEDERM and JUVÉDERM VOLLURE in International Classes 3 and/or 5. In these applications, Allergan Holdings France SAS explicitly claims ownership of the pleaded Allergan Registrations. For example, in U.S. Serial No. 87228299 for the mark JUVÉDERM VOLLURE in the name of Allergan Holdings France SAS, ownership is claimed of the pleaded Allergan Registrations, for example Reg. No. 3706974 (JUVEDERM) and Reg. No. 4380507 (JUVEDERM VOLBELLA). See **Exhibit 7.**

65. Opposer is Allergan Inc. and the relationship to Allergan Holdings France SAS is unclear. On information and belief, Opposer is not the rightful owner of the JUVÉDERM Marks and, therefore, could not rightfully request registration of the Allergan Registrations. 15 U.S.C. § 1051(a)(1).

Petitioner reserves the right to amend its Counterclaims to allege other claims in the event discovery of other information indicates they are appropriate.

WHEREFORE, Applicant and Petitioner prays that the Notice of Opposition be dismissed, that the Counterclaims for Cancellation be sustained in favor of Petitioner, and that the Allergan Registrations be canceled from the register.

The required fee of $1,600.00 is enclosed in support of the counterclaims for cancellation of the four (4) Allergan Registrations. Any deficiency may be charged to Deposit Account No. 07-2069.

Respectfully submitted,

By *s/_Tanja Proehl*_____

Amy C. Ziegler
Tanja Proehl
GREER, BURNS & CRAIN, LTD.
300 South Wacker Drive
Suite 2500
Chicago, Illinois
Telephone: (312) 360-0080
Facsimile: (312) 360-9315
aziegler@gbc.law
tproehl@gbc.law

Attorneys for APPLICANT and PETITIONER DERMAVITA LIMITED PARTNERSHIP

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and complete copy of this ANSWER TO NOTICE OF OPPOSTION, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS has been served by email and first class mail as follows upon attorneys of record in this proceeding:

KENNETH L WILTON
SEYFARTH SHAW LLP
2029 CENTURY PARK EAST, SUITE 3500
LOS ANGELES, CA 90067

kwilton@seyfarth.com, cprice@seyfarth.com, jgimble@seyfarth.com, ttabdocket@seyfarth.com, hinchey_susan@allergan.com, matthew.brady@allergan.com

Dated: June 28,2017
Chicago, Illinois

s/_Tanja Proehl _____
Tanja Proehl
GREER, BURNS & CRAIN, LTD.
300 South Wacker Drive
Suite 2500
Chicago, Illinois
Telephone: (312) 360-0080
Facsimile: (312) 360-9315

One of the Attorneys for
APPLICANT and PETITIONER
DERMAVITA LIMITED PARTNERSHIP

TESS was last updated on Wed Jun 7 03:33:50 EDT 2017

JUVEDERM VOLBELLA

Word Mark	**JUVEDERM** VOLBELLA
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles. FIRST USE: 20130219. FIRST USE IN COMMERCE: 20130219
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	85130270
Filing Date	September 15, 2010
Current Basis	1A
Original Filing Basis	1B
Published for Opposition	March 8, 2011
Registration Number	4380507
Registration Date	August 6, 2013
Owner	(REGISTRANT) Allergan, Inc. CORPORATION DELAWARE 2525 Dupont Drive Irvine CALIFORNIA 92612
Prior Registrations	3706974
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	**LIVE**

TESS was last updated on Wed Jun 7 03:33:50 EDT 2017

JUVEDERM VOLIFT

Word Mark	**JUVEDERM** VOLIFT
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles. FIRST USE: 20120913. FIRST USE IN COMMERCE: 20120913
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	85130263
Filing Date	September 15, 2010
Current Basis	1A
Original Filing Basis	1B
Published for Opposition	March 8, 2011
Registration Number	4380506
Registration Date	August 6, 2013
Owner	(REGISTRANT) Allergan, Inc. CORPORATION DELAWARE 2525 Dupont Drive Irvine CALIFORNIA 92612
Prior Registrations	3706974
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	**LIVE**

TESS was last updated on Wed Jun 7 03:33:50 EDT 2017

JUVEDERM VOLUMA

Word Mark	**JUVEDERM** VOLUMA
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles. FIRST USE: 20131202. FIRST USE IN COMMERCE: 20131202
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	77368471
Filing Date	January 10, 2008
Current Basis	1A
Original Filing Basis	1B
Published for Opposition	November 16, 2010
Registration Number	4481317
Registration Date	February 11, 2014
Owner	(REGISTRANT) Allergan, Inc. CORPORATION DELAWARE 2525 Dupont Drive Irvine CALIFORNIA 92612
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	**LIVE**

TESS was last updated on Wed Jun 7 03:33:50 EDT 2017

JUVEDERM VOLUX

Word Mark	**JUVEDERM** VOLUX
Goods and Services	IC 003. US 001 004 006 050 051 052. G & S: Cosmetics, namely, preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin, all to be sold and marketed only to licensed physicians, surgeons or healthcare professionals IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin; biological dermal implants, namely, visco-supplementation solutions for filling wrinkles, all to be sold and marketed only to licensed physicians, surgeons or healthcare professionals IC 010. US 026 039 044. G & S: Apparatus for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin, all to be sold and marketed only to licensed physicians, surgeons or healthcare professionals
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	87270389
Filing Date	December 15, 2016
Current Basis	1B
Original Filing Basis	1B
Owner	(APPLICANT) Allergan Holdings France SAS société à responsabilité limitée (sarl) FRANCE 12 place de la defense, 4 eme etage Courbevoie FRANCE 92400
Prior Registrations	3463915;3706974;4933963
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	**LIVE**

TESS was last updated on Wed Jun 7 03:33:50 EDT 2017

JUVÉDERM

Word Mark	**JUVÉDERM**
Goods and Services	IC 003. US 001 004 006 050 051 052. G & S: Cosmetics, namely, preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin, all to be sold and marketed only to licensed physicians, surgeons or healthcare professionals
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	87089435
Filing Date	June 30, 2016
Current Basis	1B
Original Filing Basis	1B
Owner	(APPLICANT) Allergan Holdings France société par actions simplifiée (sas) FRANCE 12 Place de la Defense Courbevoie FRANCE 92400
Prior Registrations	3463915;3706974;4933963
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	**LIVE**

United States Patent and Trademark Office

Home | Site Index | Search | FAQ | Glossary | Guides | Contacts | eBusiness | eBiz alerts | News | Help

Trademarks > Trademark Electronic Search System (TESS)

TESS was last updated on Wed Jun 7 03:33:50 EDT 2017

TESS Home | New User | Structured | Free Form | Browse Dict | SEARCH OG | Bottom | HELP | Prev List | Curr List | Next List | First Doc | Prev Doc | Next Doc | Last Doc

Logout Please logout when you are done to release system resources allocated for you.

Start List At: OR Jump to record: **Record 2 out of 5**

TSDR | ASSIGN Status | TTAB Status *(Use the "Back" button of the Internet Browser to return to TESS)*

Word Mark	**JUVÉDERM**
Goods and Services	IC 003. US 001 004 006 050 051 052. G & S: Cosmetics, namely, preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin, all to be sold and marketed only to licensed physicians, surgeons or healthcare professionals
Mark Drawing Code	(3) DESIGN PLUS WORDS, LETTERS, AND/OR NUMBERS
Design Search Code	26.01.26 - Coils; Spirals; Swirls
Serial Number	87089516
Filing Date	June 30, 2016
Current Basis	1B
Original Filing Basis	1B
Owner	(APPLICANT) Allergan Holdings France société par actions simplifiée (sas) FRANCE 12 Place de la Defense Courbevoie FRANCE 92400
Prior Registrations	3463915;3706974;4933963
Description of Mark	Color is not claimed as a feature of the mark. The mark consists of JUVÉDERM in a stylized font, to the left of which is a swirl comprising three teardrops and which is partially overlapped by the tail of the "J" in JUVÉDERM.
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	**LIVE**

TESS Home | New User | Structured | Free Form | Browse Dict | SEARCH OG | Top | HELP | Prev List | Curr List | Next List | First Doc | Prev Doc | Next Doc | Last Doc

Protocol S17L-001
Directions for Investigational Use
JUVÉDERM VOLIFT™ XC Injectable Gel

For the comparator product refer to the Restylane-L® Instructions For Use for all product information. Restylane-L® should only be injected through the provided 30G ½" needle.

1. DEVICE DESCRIPTION

JUVÉDERM VOLIFT™ XC is a sterile pyrogen-free physiological biodegradable, viscoelastic, clear, colorless, homogenized gel implant. JUVÉDERM VOLIFT™ XC consists of crosslinked hyaluronic acid (HA) produced by *Streptococcus equi* bacteria, formulated to a concentration of 17.5 mg/mL with 0.3% lidocaine, suspended in a physiologic buffer, and provided in a pre-filled, single-use syringe.

2. INTENDED USE/INDICATIONS

JUVÉDERM VOLIFT™ XC is being studied under a U.S. Investigational Device Exemption (IDE) for injection to mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).

3. CONTRAINDICATIONS

- JUVÉDERM VOLIFT™ XC is contraindicated for subjects with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
- JUVÉDERM VOLIFT™ XC contains trace amounts of gram positive bacterial proteins and is contraindicated for subjects with a history of allergies to such material.
- JUVÉDERM VOLIFT™ XC contains lidocaine and is contraindicated for subjects with known hypersensitivity to lidocaine or other amide-type local anesthetics.
- JUVÉDERM VOLIFT™ XC is contraindicated for subjects with untreated epilepsy or porphyria.

4. WARNINGS

- JUVÉDERM VOLIFT™ XC must not be injected into blood vessels. Introduction of HA into the vasculature may occlude the vessels and could cause infarction or embolization.
- Use of JUVÉDERM VOLIFT™ XC at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present, should be deferred until the underlying process has been controlled.
- Injection procedure reactions to similar products have been observed and consist mainly of short-term inflammatory symptoms starting early after treatment and lasting 7 days or less.

5. PRECAUTIONS

- Under Protocol S17L-001, the injection of JUVÉDERM VOLIFT™ XC is limited to Investigators who have received specific training in intradermal injection techniques

with JUVÉDERM VOLIFT™ XC. A thorough knowledge of the anatomy and physiology of the face is required.

- The safety and effectiveness of JUVÉDERM VOLIFT™ XC has not been established in controlled clinical studies.
- Subjects who are using substances that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may, as with any injection, experience increased bruising or bleeding at injection sites.Subjects should be advised to avoid such medications for at least 10 days before treatment and 3 days after treatment.
- The combination of JUVÉDERM VOLIFT™ XC with certain drugs that reduce or inhibit hepatic metabolism (e.g., cimetidine, beta-blockers) is inadvisable.
- JUVÉDERM VOLIFT™ XC should be used with caution in subjects with cardiac conduction disorders.
- HA is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. Therefore, JUVÉDERM VOLIFT™ XC should never be placed in contact with these substances or with medical-surgical instrumentation that has been treated with this type of substance.
- As with all transcutaneous procedures, JUVÉDERM VOLIFT™ XC implantation carries a risk of infection. Standard precautions associated with injectable materials should be followed.
- Based on preclinical studies, subjects should be limited to 20 mL of JUVÉDERM VOLIFT™ XC per 60 kg (130 lbs) body mass per year. The safety of injecting greater amounts has not been established.
- After use, treatment syringes and needles may be potential biohazards. Handle and dispose of these items in accordance with accepted medical practice and applicable local, state, and federal requirements.
- JUVÉDERM VOLIFT™ XC is a clear, colorless gel without particulates. In the event that the content of a syringe shows signs of separation and/or appears cloudy, do not use the syringe.
- JUVÉDERM VOLIFT™ XC is packaged for single subject use. Do not resterilize. Do not use if package is opened or damaged.
- Failure to comply with the needle attachment instructions could result in needle disengagement and/or product leakage at the luer-lock and needle hub connection.

6. TREATMENT PLANNING

The Investigator will evaluate the subject's nasolabial folds using a nasolabial fold severity scale and will discuss the treatment goals with the subject to establish what degree of correction may be anticipated.

After the treatment plan has been discussed, the Investigator will photograph each subject using the provided camera system prior to treatment.

7. INSTRUCTIONS FOR USE

The JUVÉDERM VOLIFT™ XC formulation has been designed to be used without the addition of modifying agents or solutions. Do not add saline, epinephrine, additional

lidocaine, or other solutions/ingredients to the syringe containing JUVÉDERM VOLIFT™ XC.

1. To Attach a Needle to Syringe:
   - To assure proper needle attachment, use the 30G x ½" needles provided.

STEP 1: Remove tip cap
Hold syringe and pull tip cap off the syringe as shown in Figure A.

FIGURE A

STEP 2: Insert needle
Hold the syringe body and firmly insert the hub of the needle (provided in the Juvéderm package) into the luer-lock end of the syringe.

STEP 3: Tighten the needle
Tighten the needle by turning it firmly in a clockwise direction (see Figure B) until it is seated in the proper position as shown in Figure C.

NOTE: If the position of the needle cap is as shown in Figure D, it is not attached correctly. Continue to tighten until the needle is seated in the proper position.

FIGURE B

FIGURE C

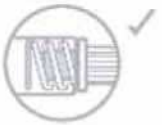
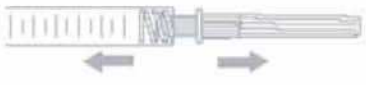


FIGURE D

STEP 4: Remove the needle cap
Hold the syringe body in one hand and the needle cap in the other. Without twisting, pull in opposite directions to remove the needle cap as shown in Figure E.

FIGURE E



2. Investigator Instructions
    a. For use in this study, JUVÉDERM VOLIFT™ XC has been formulated with 0.3% lidocaine. In addition, topical and/or injectable anesthesia may be used to manage pain during and after injection. This includes ice or FDA-approved anesthetic agents such as EMLA® Cream (AstraZeneca), ELAMax® Cream (Ferndale Laboratories), Pliaglis™ Cream (Galderma), Xylocaine® Injection, or Xylocaine® Injection with Epinephrine (AstraZeneca).
    b. Before using JUVÉDERM VOLIFT™ XC or Restylane-L®, verify the expiration date on the packaging. Do not use after the expiration date.
    c. After ensuring that the subject has thoroughly washed the treatment area with soap and water, the area should be swabbed with alcohol or other antiseptic. Prior to injecting JUVÉDERM VOLIFT™ XC, depress the plunger rod until the product visibly flows out of the needle.
    d. The injection technique for JUVÉDERM VOLIFT™ XC may vary with regard to the angle and orientation of the bevel, the depth (mid to deep dermis) of injection, and the quantity administered.
    e. Linear threading injections with antegrade, retrograde, and fanning techniques or serial puncture injections may be used to achieve optimal results. Injecting the product too superficially or in large volumes over a small area may result in visible and persistent lumps and/or discoloration.
    f. Inject JUVÉDERM VOLIFT™ XC applying even pressure on the plunger rod while slowly pulling the needle backward. It is important that the injection be stopped just before the needle is pulled out of the skin to prevent material from leaking out or ending up too superficially in the skin.
    g. If the needle is blocked, do not increase the pressure on the plunger rod. Instead stop the injection and replace the needle.
    h. Determine the appropriate volume to inject to achieve optimal correction of the nasolabial folds based on your clinical experience. Do not exceed a combined volume of 4 mL per NLF for the initial plus touch-up treatments of JUVÉDERM VOLIFT™ XC and Restylane-L® For the optional repeat treatment at Month 18 (± 28 days), do not treat with more than 4 mL of JUVÉDERM VOLIFT™ XC for each NLF.
    i. Correct to 100% of the desired volume effect. Do not overcorrect or undercorrect. The degree and duration of the correction depend on the nature of the defect treated, the tissue stress at the implant site, the depth of the implant in the tissue, and the injection technique.
    j. If immediate blanching occurs at any time during the injection, the injection should be stopped and the area massaged vigorously until it returns to a normal color.
    k. When treatment is completed, the treated site may be gently massaged to assure that the product is evenly distributed and conforms to the contour of the surrounding tissues. Use of a topical lubricant (e.g., ultrasound gel) during massage of the treated area is optional. If overcorrection occurs, massage the area between your fingers or against an underlying superficial bone to obtain optimal results.
    l. With subjects who have localized swelling, the degree of correction is sometimes difficult to judge at the time of treatment. A touch-up treatment at 30 days is allowed under Protocol S17L-001. The touch-up procedure for each individual NLF

is performed using the same device used on that NLF during the initial treatment (i.e., if Restylane-L® was injected for the initial treatment on the designated NLF requiring touch-up, then Restylane-L® will be injected with on that NLF for the touch-up procedure).

m. Subjects may have mild, moderate, or severe injection site responses, which typically resolve in a few days. If the treated area is swollen immediately after the injection, an ice pack may be applied to the site for a short period.
n. For the purposes of this study, the Investigator will document each subject's post-treatment appearance using the provided camera system after each treatment.

To report an adverse reaction or product malfunction, contact the Medical Monitor by the phone number specified in the protocol and specify your participation in Allergan Protocol S17L-001.

8. SUBJECT INSTRUCTIONS

During the informed consent process the Investigator and the subject will discuss the potential injection site responses and other immediate or delayed side effects possible from treatment with JUVÉDERM VOLIFT™ XC. Previous studies with injectable HA gels have shown that injection site responses may include redness, pain, tenderness, firmness, swelling, lumps/bumps, bruising, itching, discoloration, and other less common responses. The Investigator will instruct the subject to promptly report to her/him any evidence of possible problems associated with the use of JUVÉDERM VOLIFT™ XC.

Recommendations to the subject after treatment include the following:

- For the first 24 hours subjects should avoid strenuous exercise, extensive sun or heat exposure, and alcoholic beverages. Exposure to any of the above may cause temporary redness, swelling, and/or itching at the injection sites.
- For the first few days the subject should avoid massaging or putting pressure on the implantation site.
- Subjects should also be advised that supplemental "touch-up" implantations may be required to achieve and maintain optimal correction.
- Athletes should be aware that JUVÉDERM VOLIFT™ XC contains an active ingredient that may produce a positive result in anti-doping tests.

9. HOW SUPPLIED

Each box contains 2 syringes (1 mL each) of JUVÉDERM VOLIFT™ XC and 4 needles (30G ½") along with product and lot number labels for the subject's medical and study records. The carton bears an investigational caution label which includes the study number and manufacturing/distribution addresses:

CAUTION: INVESTIGATIONAL DEVICE. LIMITED BY FEDERAL (UNITED STATES) LAW TO INVESTIGATIONAL USE.

EXCLUSIVELY FOR CLINICAL TRIAL PROTOCOL # S17L-001

MANUFACTURED BY
Allergan
Route de Promery
Zone Artisanale de Pré-Mary
74370 PRINGY
FRANCE

DISTRIBUTED BY
Allergan, Inc.
Goleta, CA 93117

The volume in each syringe is stated on the syringe label. The contents of the syringe are sterile and non-pyrogenic. Do not resterilize. Do not use if package is opened or damaged.

10. STORAGE

JUVÉDERM VOLIFT™ XC should be stored between 2°C and 25°C (36°F - 77ºF). DO NOT FREEZE.

MANUFACTURED BY
Allergan
Route de Promery
Zone Artisanale de Pré-Mary
74370 PRINGY
FRANCE

DISTRIBUTED BY
Allergan, Inc.
Goleta, CA 93117

ALLERGAN

Investigational Directions for Use v1

Date (DD/MMM/YYYY)/Time (PT)	Signed by:	Justification
17-Sep-2012 11:19 GMT-070	Purpura_Joseph	Medical Monitor Approval
17-Sep-2012 13:43 GMT-070	Guillen_Karina	Regulatory Affairs Approval

Protocol VOLBELLA-004
Investigational Directions for Use

JUVÉDERM VOLBELLA™ XC Injectable Gel

1. DEVICE DESCRIPTION

JUVÉDERM VOLBELLA™ XC is a sterile, biodegradable, non-pyrogenic, viscoelastic, clear, colorless, homogenized, HA gel implant (dermal filler). The HA is produced by *Streptococcus equi* bacteria and is mixed with phosphate buffer and crosslinked by adding a minimum amount of BDDE to form a 3-dimensional HA gel. The HA concentration is 15 mg/mL in JUVÉDERM VOLBELLA™ XC suspended in a physiological buffer. JUVÉDERM VOLBELLA™ XC contains 0.3% lidocaine to enhance patient comfort. JUVÉDERM VOLBELLA™ XC is supplied in a pre-filled, single-use syringe.

2. INTENDED USE/INDICATIONS

JUVÉDERM VOLBELLA™ XC is being studied under a U.S. Investigational Device Exemption (IDE) for intra-dermal, subdermal, and intramuscular injection into the lips and perioral area for enhancement of the perioral region including the lip vermilion, wet-dry border, vermilion border, Cupid's bow, philtral columns, perioral lines, and oral commissures in adults age 22 or over.

For investigational use in this study, JUVÉDERM VOLBELLA™ XC and Restylane-L® will be administered using a 30 G x ½" needle. Although Restylane-L® is approved for use with 30 G x ½" needles, they are not part of the marketed configuration. This needle configuration will be used in this study to help reduce differences between treatment and control subjects. Both products will be injected into the vermilion body, oral commissures, perioral lines, vermilion border, Cupid's bow, and philtral columns for lip and perioral enhancement by the Treating Investigator in accordance with the randomization scheme and each product's respective DFU. Both products will be injected into the lips or mid to deep dermis. This investigational DFU is provided for JUVÉDERM VOLBELLA™ XC, and the US commercial DFU will be provided for Restylane-L.

All Treating and Evaluating Investigators will be board-certified plastic surgeons or dermatologists with experience injecting dermal fillers in the lips and perioral area.

3. CONTRAINDICATIONS

- JUVÉDERM VOLBELLA™ XC is contraindicated for subjects with a history of anaphylaxis, atopy, allergy to lidocaine (or any amide-based anesthetics), HA products, or *Streptococcal* protein, or be planning to undergo a desensitization therapy during the term of the study
- JUVÉDERM VOLBELLA™ XC is contraindicated for subjects with a history of streptococcal disease (e.g., strep throat or rheumatic fever with or without heart complications)

- JUVÉDERM VOLBELLA™ XC is contraindicated for subjects with porphyria

4. WARNINGS

- JUVÉDERM VOLBELLA™ XC must not be injected into blood vessels. Introduction of HA into the vasculature may occlude the vessels and could cause infarction or embolization
- JUVÉDERM VOLBELLA™ XC should not be used if there is an active inflammation, infection, cancerous or precancerous lesion, or unhealed wound in the mouth area
- Injection procedure reactions to similar products have been observed and consist mainly of short-term inflammatory symptoms starting early after treatment and lasting 7 days or less

5. PRECAUTIONS

- Based on preclinical studies, patients should be limited to 20 mL of JUVÉDERM VOLBELLA™ XC per 60 kg (130 lbs) body mass per year. The safety of injecting greater amounts has not been established
- In this clinical study, the maximum total volume allowed for an individual subject for the initial and touch-up treatments combined is 6.0 mL, and the maximum volume in each lip (upper and lower) is 1.5 mL at each treatment. For the repeat treatment at Month 12, the Treating Investigator may inject up to 6.0 mL of JUVÉDERM VOLBELLA™ XC
- The safety and effectiveness of JUVÉDERM VOLBELLA™ XC has not been established in pregnant or lactating women
- Subjects on an ongoing regimen of anti-coagulation therapy (e.g., warfarin) or NSAIDs (e.g., aspirin, ibuprofen) or other substances known to increase coagulation time (e.g., herbal supplements with garlic or gingko) within 10 days of undergoing study device injections and 3 days after treatment (study device injections may be delayed as necessary to accommodate this 10-day washout period)
- The combination of JUVÉDERM VOLBELLA™ XC with certain drugs that reduce or inhibit hepatic metabolism (e.g., cimetidine, beta-blockers) is inadvisable
- HA is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. Therfore, JUVÉDERM VOLBELLA™ XC should never be placed in contact with these substances or with medical-surgical instrumentation that has been treated with this type of substance
- JUVÉDERM VOLBELLA™ XC should be used with caution for subjects on a concurrent regimen of lidocaine or structurally related local anesthetics (e.g., bupivacaine)
- JUVÉDERM VOLBELLA™ XC should be used with caution for subjects with impaired cardiac conduction, severely impaired hepatic function, or severe renal dysfunction
- JUVÉDERM VOLBELLA™ XC should be used with caution for subjects with uncontrolled disease or severe cardiovascular disease
- Athletes should be aware that JUVÉDERM VOLBELLA™ XC contains an active ingredient that may produce a positive result in anti-doping tests

6. TREATMENT PLANNING

During the informed consent process the Investigator and the subject will discuss the potential injection site responses and other immediate or delayed side effects possible from treatment with JUVÉDERM VOLBELLA™ XC. Previous studies with injectable HA gels have shown that injection site responses may include redness, pain, tenderness, firmness, swelling, lumps/bumps, bruising, itching, discoloration, and other less common responses. The Investigator will instruct the subject to promptly report to her/him any evidence of possible problems associated with the use of JUVÉDERM VOLBELLA™ XC.

At the screening visit, the Treating Investigator will discuss alternative treatments that may be available with any subject who is interested in participating in the study; s/he will counsel the subject regarding his/her treatment goals and the potential benefit and limitations of study treatment. After counseling, if the subject's expectations are not realistic, the Treating Investigator will not proceed with randomization and will discontinue the subject from the study.

The Treating Investigator will ensure that each subject meets the run-in and washout requirements as well as other eligibility criteria (see Sections 5.3, 5.4, and 6.1). The Treating and Evaluating Investigators will assess the subject's lip fullness using the 5-point LFS2 and the subject's perioral line severity at rest using the 4-point POLSS and agree upon a score for each area and a treatment plan. Subjects who have a LFS2 score of marked or very marked for both lips will be ineligible for the study. All subjects who are eligible for the study may receive treatment in the vermilion body, oral commissures, vermilion border, Cupid's bow, and philtral columns at each treatment. Only subjects who have a POLSS score of moderate or severe will be eligible for treatment in the perioral lines at the initial and touch-up treatments. All subjects may receive treatment in the perioral lines at repeat treatment.

Before treatment, vital signs (systolic and diastolic blood pressure, heart rate, respiration rate, and temperature) will be recorded and facial digital photographs will be captured. Women of childbearing potential will take a urine pregnancy test, and, should the test be positive, the subject will not receive treatment and will be exited from the study.

The Evaluating Investigator will score the subject's perioral line severity at maximal contraction using the 4-point Perioral Lines at Maximal Contraction Scale (POLM), and the subject's oral commissure severity using the 4-point OCSS. The Evaluating Investigator will assess lip sensation. In addition, the Evaluating Investigator will assess functional features by carefully examining inside and around the subject's lips and mouth, in repose (at rest) and in animation (smiling, frowning, etc.), for function, texture, discoloration, firmness, lumpiness, or mucoceles.

The subject will complete the Satisfaction with Lips and Lip Lines modules of the FACE-Q questionnaire, rate lip hydration using an 11-point scale, and read a series of words and phrases while being videorecorded.

7. INSTRUCTIONS FOR USE

All Treating and Evaluating Investigators will be board-certified plastic surgeons or dermatologists with experience injecting dermal fillers in the lips and perioral area. Before the beginning of the study, a formal training for Investigators and study coordinators will be held, in which discussion of study procedures, including product administration, visit schedule, effectiveness assessments, and safety assessments will take place. Since JUVÉDERM VOLBELLA™ XC requires less force to extrude than seen with comparable products, clinical Investigators will be trained on the extrusion ease of JUVÉDERM VOLBELLA™ XC to reduce the risk of unintentional overcorrection.

The Treating Investigator will ensure the subject meets the inclusion criteria as outlined in the protocol. He/she will also review the patient's medical history in light of the contraindications, warnings, and precautions as listed in this investigational DFU to determine if the subject is eligible to participate in this study. If eligible, the subject will receive treatment. The Treating Investigator will use aseptic skin preparation and will administer injections according the relevant product's DFU (see Section 2) . The Evaluating Investigator will not be present during treatment. To ensure that the subject is blinded to the product used, the Treating Investigator will prepare the syringe in an area screened off from the subject and will mask the syringe to obscure any identifying information (e.g., product name) using the labels provided. The subject will remain blinded to treatment until repeat treatment.

The JUVÉDERM VOLBELLA™ XC formulation has been designed to be used without the addition of modifying agents or solutions. Do not add saline, epinephrine, additional lidocaine, or other solutions/ingredients to the syringe containing JUVÉDERM VOLBELLA™ XC.

Before using JUVÉDERM VOLBELLA™ XC, verify the expiration date on the packaging. Do not use after the expiration date.

Inject to 100% of the desired volume effect. Do not overcorrect.

After using JUVÉDERM VOLBELLA™ XC, treatment syringes and needles may be potential biohazards. Handle and dispose of these items in accordance with accepted medical practice and applicable local, state, and federal requirements.

1. To Attach a Needle to Syringe:
   - To assure proper needle attachment, use the 30G x ½" needles provided.

STEP 1: Remove tip cap
Hold syringe and pull tip cap off the syringe as shown in Figure A.

FIGURE A

STEP 2: Insert needle
Hold the syringe body and firmly insert the hub of the needle (provided in the Juvéderm package) into the luer-lock end of the syringe.

STEP 3: Tighten the needle
Tighten the needle by turning it firmly in a clockwise direction (see Figure B) until it is seated in the proper position as shown in Figure C.

NOTE: If the position of the needle cap is as shown in Figure D, it is not attached correctly. Continue to tighten until the needle is seated in the proper position.

FIGURE B

FIGURE C

FIGURE D

STEP 4: Remove the needle cap
Hold the syringe body in one hand and the needle cap in the other. Without twisting, pull in opposite directions to remove the needle cap as shown in Figure E.

FIGURE E

Prior to injecting JUVÉDERM VOLBELLA™ XC, depress the plunger rod until the project visibly flows out of the needle.

If the needle is blocked during injection, do not increase the pressure on the plunger rod. Instead, stop the injection and replace the needle.

2. Investigator Instructions

The Treating Investigator will inject each device into the lips and perioral area (vermilion body, oral commissures, vermilion border, Cupid's bow, and philtral columns). Each device will be injected into the lips or mid to deep dermis using the supplied 30 G x ½" needle to achieve optimal lip and perioral enhancement. Subjects with moderate to severe perioral lines may also receive treatment in the perioral lines. The Treating Investigator will determine the appropriate volume to inject at each site based on clinical experience. The maximum total volume allowed for an individual subject for the initial and touch-up treatments combined is 6.0 mL, and the maximum volume in each lip (upper and lower) is 1.5 mL at each treatment. Anesthesia will be administered following the standard practice at each clinical investigation site, and anesthesia use should be similar for both devices. The application of ice and topical anesthesia is allowed to reduce injection discomfort. Injectable anesthesia must be limited to the treatment area only. The Investigator will thoroughly review the subject's history to confirm the suitability of the planned anesthetic agent and route.

Following injection, facial digital photographs will be captured. Details regarding anesthesia use, injection procedure, volume injected, device kit numbers, needle gauge, characteristics of the procedure (e.g., subject assessment of procedural pain on an 11-point scale), and characteristics of the product (e.g., Treating Investigator evaluation of injection ease and moldability, each on an 11-point scale) will be recorded on the eCRF.

The subject will receive instructions on how to evaluate the treatment areas and complete a diary to record the presence or absence, severity, and duration of injection site reactions (ISRs) for 30 days after the initial treatment.

Up to 2 treatment sessions approximately 30 days apart are allowed. The Treating Investigator will determine the appropriate volume of JUVÉDERM VOLBELLA™ XC or Restylane-L® to inject at initial and touch-up treatment based on his/her clinical experience and the randomization assignment. The product used for touch-up procedures is the same product used at the initial treatment. The maximum volume allowed for an individual subject for the initial and touch-up treatments combined is 6.0 mL. The maximum volume allowed for an individual subject for repeat treatment is 6.0 mL of JUVÉDERM VOLBELLA™ XC. The maximum volume allowed for each lip is 1.5 mL at each treatment (initial, touch-up and repeat treatment).

At the Month 12 visit, all subjects will undergo repeat treatment with JUVÉDERM VOLBELLA™ XC to restore optimal lip and perioral enhancement. Before repeat treatment, facial digital photographs will be captured, vital signs will be recorded, and women of childbearing potential will complete a urine pregnancy test. If the urine test is positive, the subject will not be eligible for repeat treatment, and the pregnancy will be followed as described in Section 10.3 of the Protocol.

The Evaluating Investigator will assess lip sensation. In addition, the Evaluating Investigator will assess functional features by carefully examining inside and around the subject's lips and mouth, in repose (at rest) and in animation (smiling, frowning, etc.), for function, texture, discoloration, firmness, lumpiness, or mucoceles.

The subject will read series of words and phrases while being videorecorded.

The Treating Investigator will use aseptic skin preparation and injection techniques to administer JUVÉDERM VOLBELLA™ XC in the lips and perioral area (vermilion body, perioral lines, oral commissures, vermilion border, Cupid's bow, and philtral columns). Each device will be injected into the lips or mid to deep dermis using the supplied 30 G x ½" needle to achieve optimal lip and perioral enhancement. At repeat treatment, perioral lines rated as mild, moderate, or severe using the POLSS may be treated. The Treating Investigator may inject up to 6.0 mL of JUVÉDERM VOLBELLA™ XC at repeat treatment. Anesthesia will be administered following the standard practice of each clinical investigation site. The application of ice and topical anesthesia are allowed to reduce injection discomfort. Injectable anesthesia must be limited to the area of injection only.

Following injection, facial digital photographs will be captured. Details regarding anesthesia use, injection procedure, volume injected, device kit numbers, needle gauge, characteristics of the procedure (e.g., subject assessment of procedural pain on an 11-point scale), and characteristics of the product (e.g., Treating Investigator evaluation of injection ease and moldability, each on an 11-point scale) will be recorded on the eCRF.

To report an adverse reaction or product malfunction, contact the Medical Monitor by the phone number specified in the protocol and specify your participation in Allergan Protocol VOLBELLA-004.

8. SUBJECT INSTRUCTIONS

Potential Adverse Effects and Complications

As with any skin or lip injection, there are risks with the injection procedure itself, the anesthetic agent, and the type of injection (in this case an HA facial injection). Risks related to the injection procedure and/or device include redness, pain, tenderness, swelling, itching, firmness, lumps and bumps, and delayed AEs. These risks are common to all dermal filler injection procedures, with most being self-limiting. Risks associated with the anesthetic agent include allergic reactions that may manifest as an anaphylactic reaction, skin rash, redness, itching, hives, burning, stinging, swelling, tenderness, and transient loss of skin color. The use of a small gauge needle to deliver both devices used in this clinical study is intended to minimize tissue trauma. The inclusion of 0.3% lidocaine in JUVÉDERM VOLBELLA™ XC is meant to reduce pain during the injection and during the hours following injection as well as to provide consistency in anesthetic dosing. Restylane-L® also contains 0.3% lidocaine. It is advisable to carefully weigh the potential risks against the expected benefits of the product and placement procedure. Furthermore, the literature analysis and medical device reporting from FDA-approved dermal filler products reveal that pre-existing pathological conditions of patients along with contraindications and precautions for use as written in this investigational Directions for Use should be carefully reviewed.

Subjects will avoid anti-coagulation, antiplatelet, or thrombolytic medications (such as warfarin), anti-inflammatory drugs (oral corticosteroids or NSAIDs such as aspirin or

ibuprofen), or vitamins or herbs (such as Vitamin E, garlic, or gingko biloba) from 10 days before to 3 days after the treatment injections to reduce the risk of post-treatment bleeding or bruising.

Subjects will avoid strenuous exercise, consumption of alcoholic beverages, and extended exposure to sun or heat for at least 24 hours to reduce the risk of post-treatment redness, swelling, and/or itching.

Study-related Requirements

During each study visit, subjects will be required to remove all make-up and lipstick from, and will not have facial hair in, the perioral area to avoid interference with the digital photographs.

Subjects should not use any make up for at least 12 hours.

Subjects will also be instructed to contact the Evaluating Investigator or his/her research staff to report any unexpected symptoms or to ask questions about the study.

9. HOW SUPPLIED

Each box of JUVÉDERM VOLBELLA™ XC contains 1 syringe filled to 1.0 mL with 2 single-use 30 G x ½" needles. Each box of Restylane-L® contains 1 syringe filled to 1.0 mL. Single-use 30 G x ½" needles for use with Restylane-L® will be provided. Although Restylane-L® is approved for use with 30 G x ½" needles, they are not part of the marketed configuration. Both products will be provided sterile, and sterile notation will be marked on syringes and supplied needles. An investigation caution label, such as the following, will appear on the outer box:

CAUTION: Investigational Device
Limited By U.S. (Federal) Law to Investigational Use

Protocol #VOLBELLA-004

MANUFACTURED BY
Allergan
Route de Promery
Zone Artisanale de Pré-Mary
74370 PRINGY
FRANCE

DISTRIBUTED BY
Allergan
Goleta, CA 93117

10. STORAGE

JUVÉDERM VOLBELLA™ XC and Restylane-L® should be stored at 2°C to 25°C, not frozen or exposed to extreme heat, and not used if the package is open or damaged or if the product is not clear. The study devices must be stored in a secure area accessible to delegated study personnel only and administered only to subjects entered into the clinical study, at no cost to the subject, in accordance with the conditions specified in this protocol.

MANUFACTURED BY
Allergan
Route de Promery
Zone Artisanale de Pré-Mary
74370 PRINGY
FRANCE

DISTRIBUTED BY
Allergan
Goleta, CA 93117

ALLERGAN

Volbella-004 Investigational DFU v1

Date (DD/MMM/YYYY)/Time (PT)	Signed by:	Justification
08-May-2013 17:29 GMT-07	Pathmajeyan_Melissa	Regulatory Affairs Approval
17-May-2013 08:42 GMT-07	Purpura_Joseph	Medical Monitor Approval

w10-tproehl.gbclaw.local - Remote Desktop Connection Manager v2.2

File Edit Session View Remote Desktops Tools Help

RDC
w10-
PC-T

308219711_FULL (1).pdf | Thomson CompuMark - | CompuMark | Dermal Fillers (Soft Tissu

Secure | https://www.fda.gov/medicaldevices/productsandmedicalprocedures/cosmeticdevices/wrinklefillers/ucm227749.htm#approved

Apps | Lexis Advance® Hom | Lexis Advance® Hom | WIPO | Marking Requirement | Trademarks | Other bookmarks

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Medical Devices

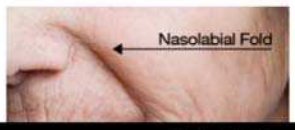
Home > Medical Devices > Products and Medical Procedures > Cosmetic Devices > Dermal Fillers (Soft Tissue Fillers)

Dermal Fillers (Soft Tissue Fillers)

Dermal Fillers Approved by the Center for Devices and Radiological Health

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

- Materials
- Unapproved Dermal Fillers
- Approved Dermal Fillers



FDA approval is based on the review of data collected from controlled clinical studies that evaluated the safe and

4:59 AM 6/28/2017

w10-tproehl.gbclaw.local - Remote Desktop Connection Manager v2.2

File Edit Session View Remote Desktops Tools Help

RDC
w10-
PC-T

308219711_FULL (1).pdf | Thomson CompuMark - | CompuMark | Dermal Fillers (Soft Tissu

Secure | https://www.fda.gov/medicaldevices/productsandmedicalprocedures/cosmeticdevices/wrinklefillers/ucm227749.htm#approved

Apps | Lexis Advance® Hom | Lexis Advance® Hom | WIPO | Marking Requirement | Trademarks | Other bookmarks

FDA approval is based on the review of data collected from controlled clinical studies that evaluated the safe and effective use of the wrinkle fillers when injected into specified areas of facial tissue.

More information about the FDA approval is based on the review of data collected from controlled clinical studies that evaluated the safe and effective use of the dermal fillers when injected into specified areas of facial tissue.

Materials

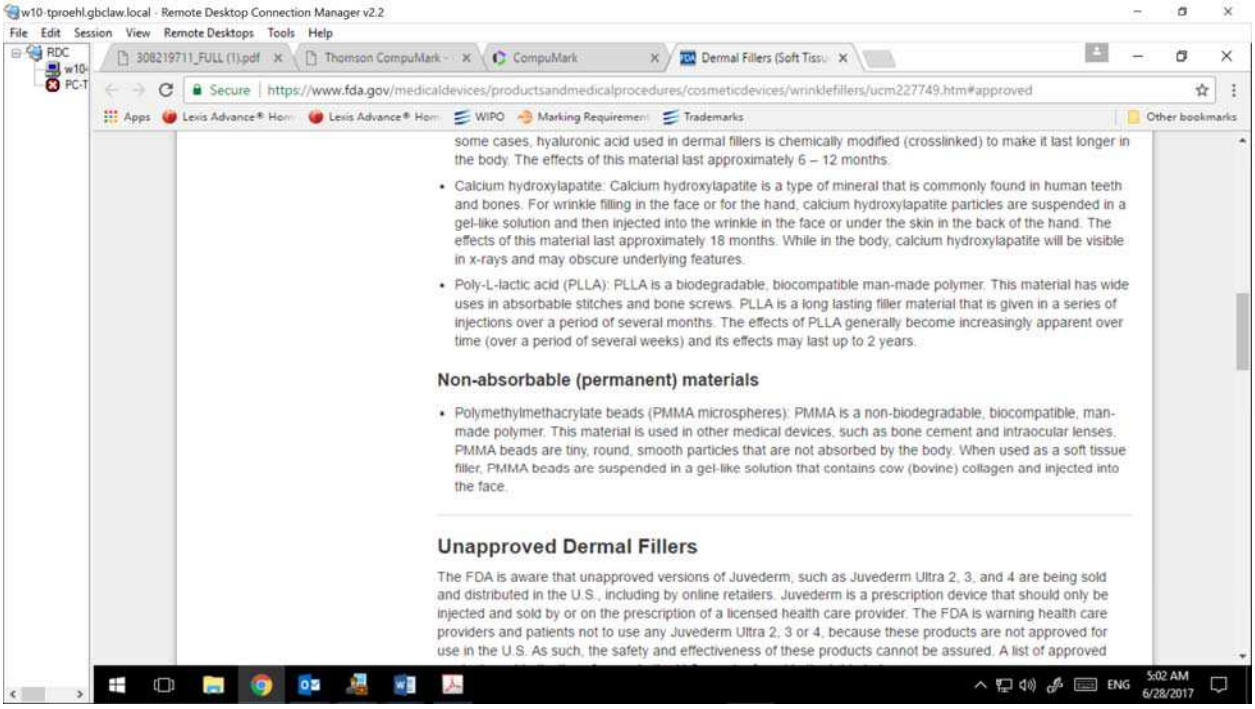
Most dermal fillers have a temporary effect, because they contain materials that are absorbed by the body over time. The FDA has approved only one product made from a material that remains in the body and is not absorbed. Some dermal fillers also contain lidocaine, which is intended to decrease pain or discomfort related to the injection.

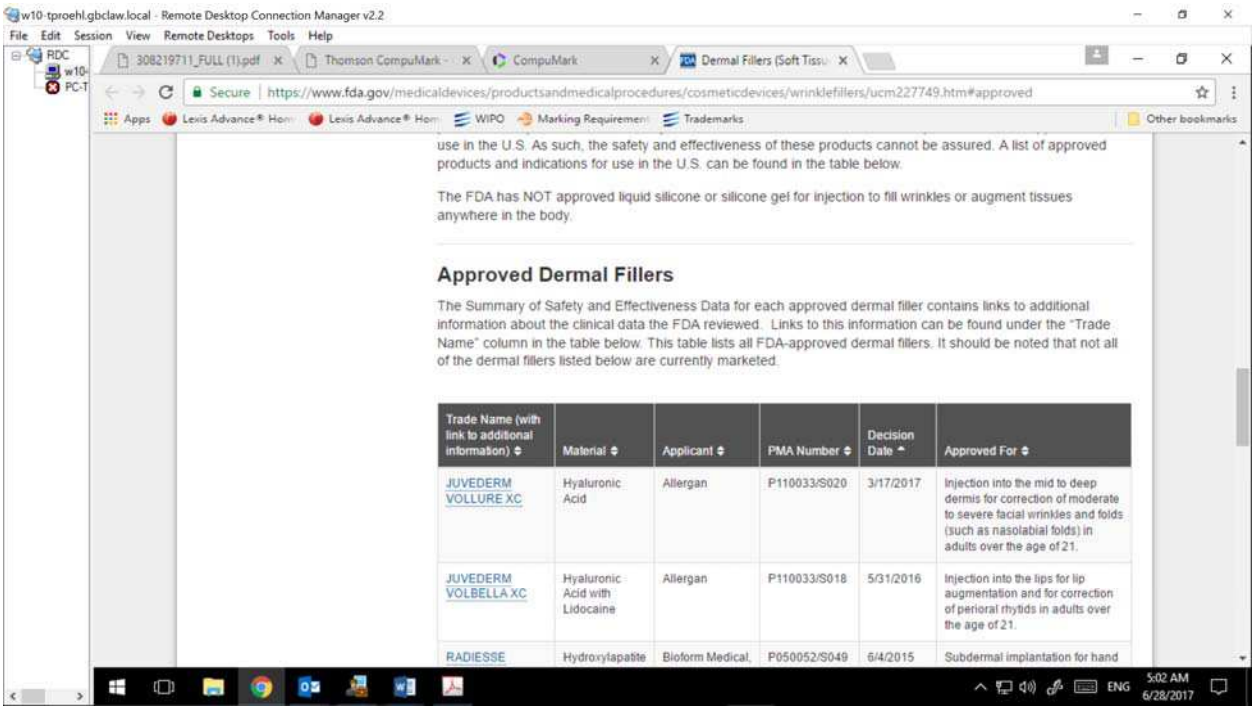
The materials used in dermal fillers include:

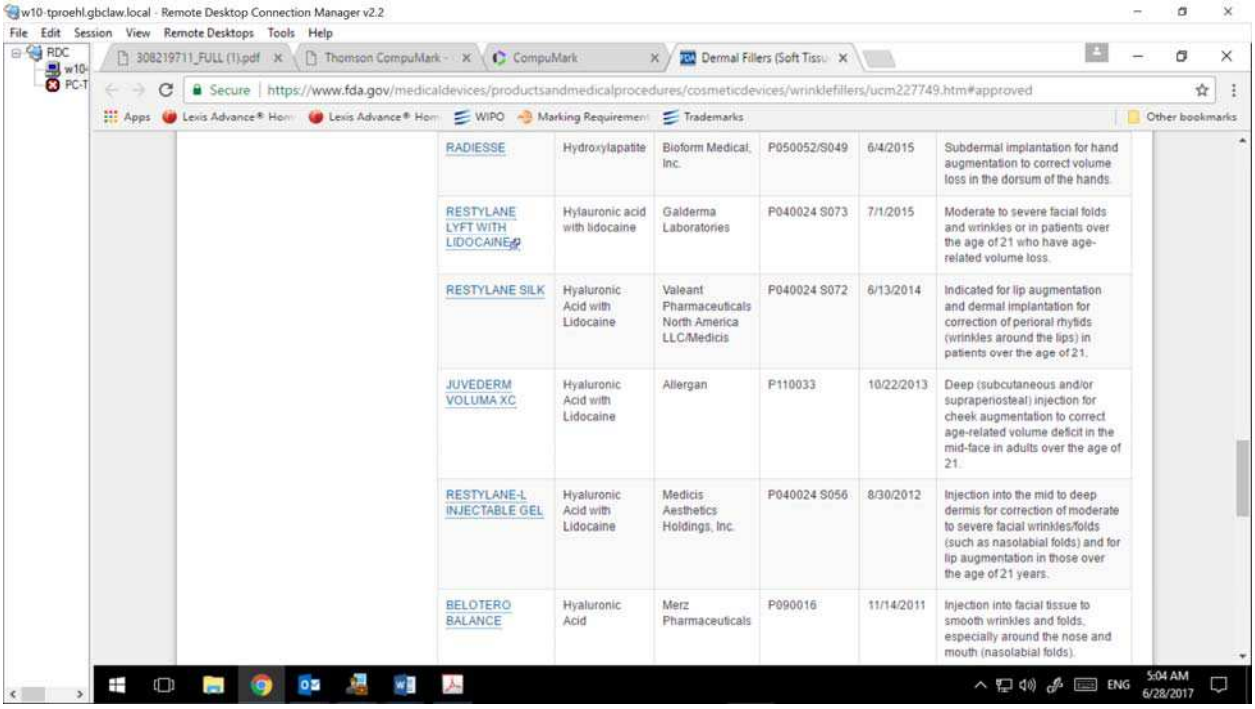
Absorbable (temporary) materials

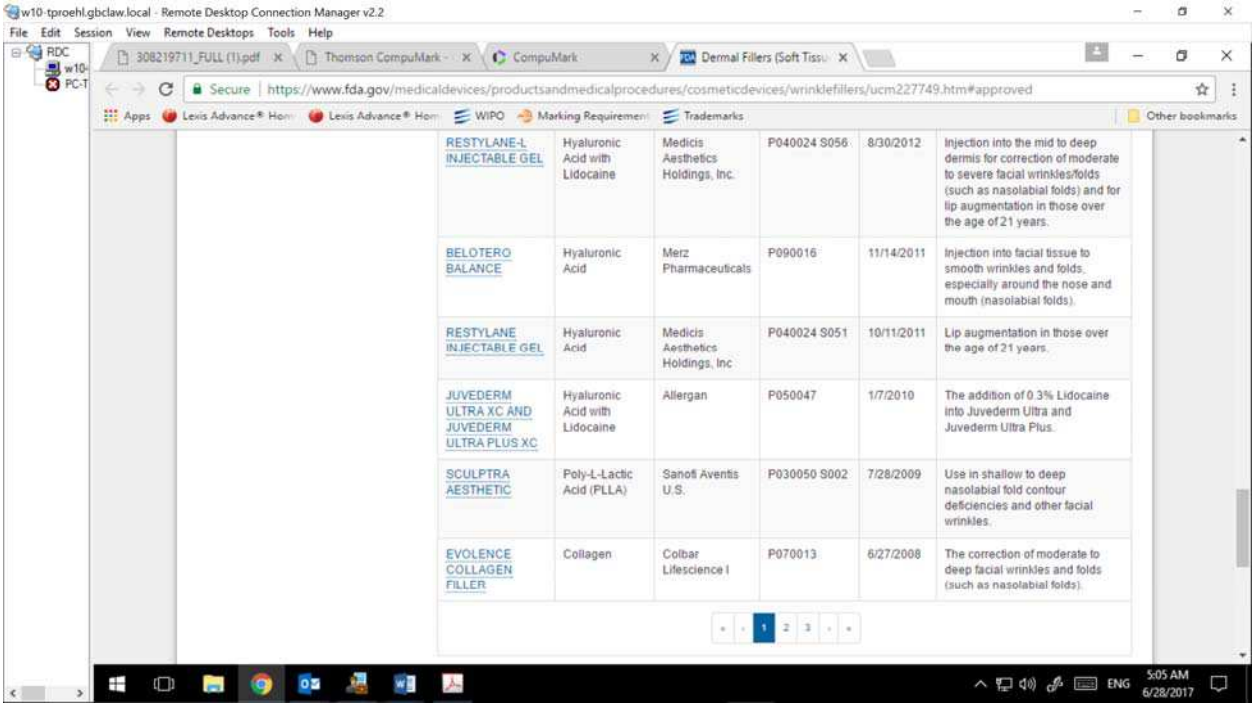
- Collagen: Collagen is a type of protein that is a major part of skin and other tissues in the body. Sources of purified collagen used in soft tissue fillers can be from cow (bovine) or human cells. The effects of collagen fillers generally last for 3-4 months. They are the shortest lasting of injectable filler materials.
- Hyaluronic acid: Hyaluronic acid is a type of sugar (polysaccharide) that is present in body tissues, such as in skin and cartilage. It is able to combine with water and swell when in gel form, causing a smoothing/filling effect. Sources of hyaluronic acid used in dermal fillers can be from bacteria or rooster combs (avian). In some cases, hyaluronic acid used in dermal fillers is chemically modified (crosslinked) to make it last longer in

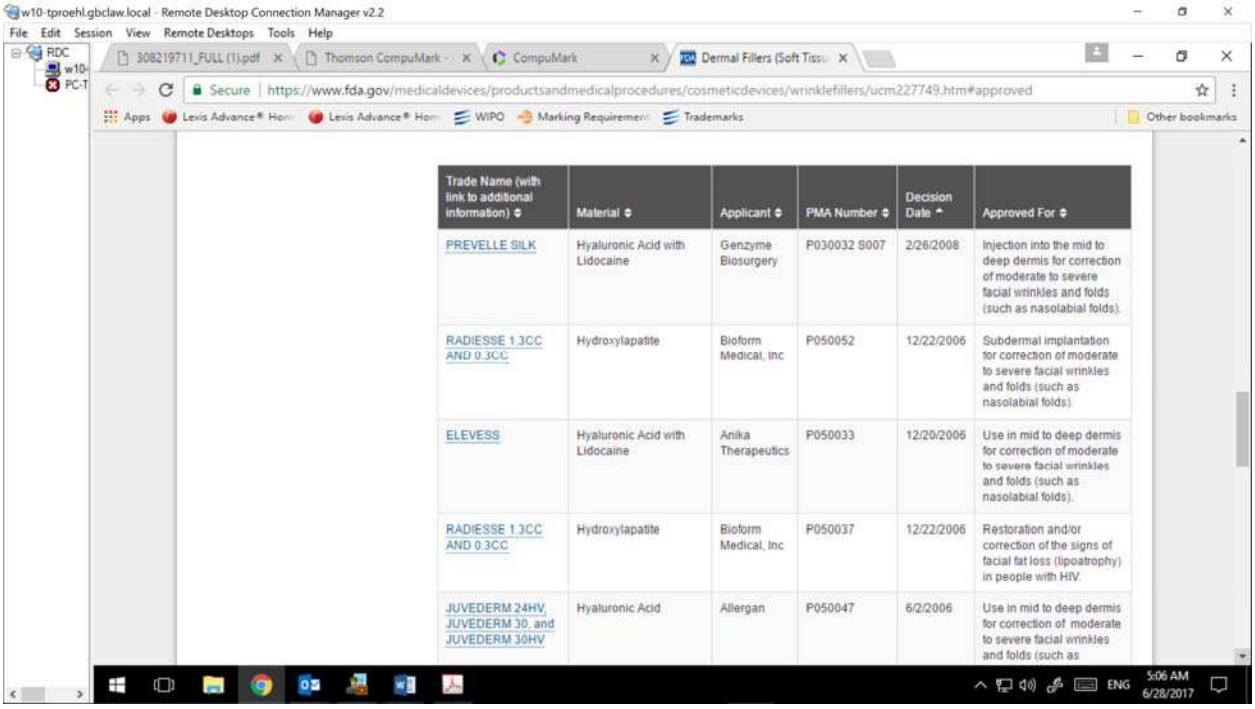
5:00 AM 6/28/2017


w10-tproehl.gbclaw.local - Remote Desktop Connection Manager v2.2
File Edit Session View Remote Desktops Tools Help
308219711_FULL (1).pdf
Thomson CompuMark
CompuMark
Dermal Fillers (Soft Tissu
Secure | https://www.fda.gov/medicaldevices/productsandmedicalprocedures/cosmeticdevices/wrinklefillers/ucm227749.htm#approved
Apps
WIPO
Marking Requirement
Trademarks
Other bookmarks
some cases, hyaluronic acid used in dermal fillers is chemically modified (crosslinked) to make it last longer in the body. The effects of this material last approximately 6 – 12 months.
Calcium hydroxylapatite: Calcium hydroxylapatite is a type of mineral that is commonly found in human teeth and bones. For wrinkle filling in the face or for the hand, calcium hydroxylapatite particles are suspended in a gel-like solution and then injected into the wrinkle in the face or under the skin in the back of the hand. The effects of this material last approximately 18 months. While in the body, calcium hydroxylapatite will be visible in x-rays and may obscure underlying features.
Poly-L-lactic acid (PLLA): PLLA is a biodegradable, biocompatible man-made polymer. This material has wide uses in absorbable stitches and bone screws. PLLA is a long lasting filler material that is given in a series of injections over a period of several months. The effects of PLLA generally become increasingly apparent over time (over a period of several weeks) and its effects may last up to 2 years.
Non-absorbable (permanent) materials
Polymethylmethacrylate beads (PMMA microspheres): PMMA is a non-biodegradable, biocompatible, man-made polymer. This material is used in other medical devices, such as bone cement and intraocular lenses. PMMA beads are tiny, round, smooth particles that are not absorbed by the body. When used as a soft tissue filler, PMMA beads are suspended in a gel-like solution that contains cow (bovine) collagen and injected into the face.
Unapproved Dermal Fillers
The FDA is aware that unapproved versions of Juvederm, such as Juvederm Ultra 2, 3, and 4 are being sold and distributed in the U.S., including by online retailers. Juvederm is a prescription device that should only be injected and sold by or on the prescription of a licensed health care provider. The FDA is warning health care providers and patients not to use any Juvederm Ultra 2, 3 or 4, because these products are not approved for use in the U.S. As such, the safety and effectiveness of these products cannot be assured. A list of approved
ENG
5:02 AM
6/28/2017

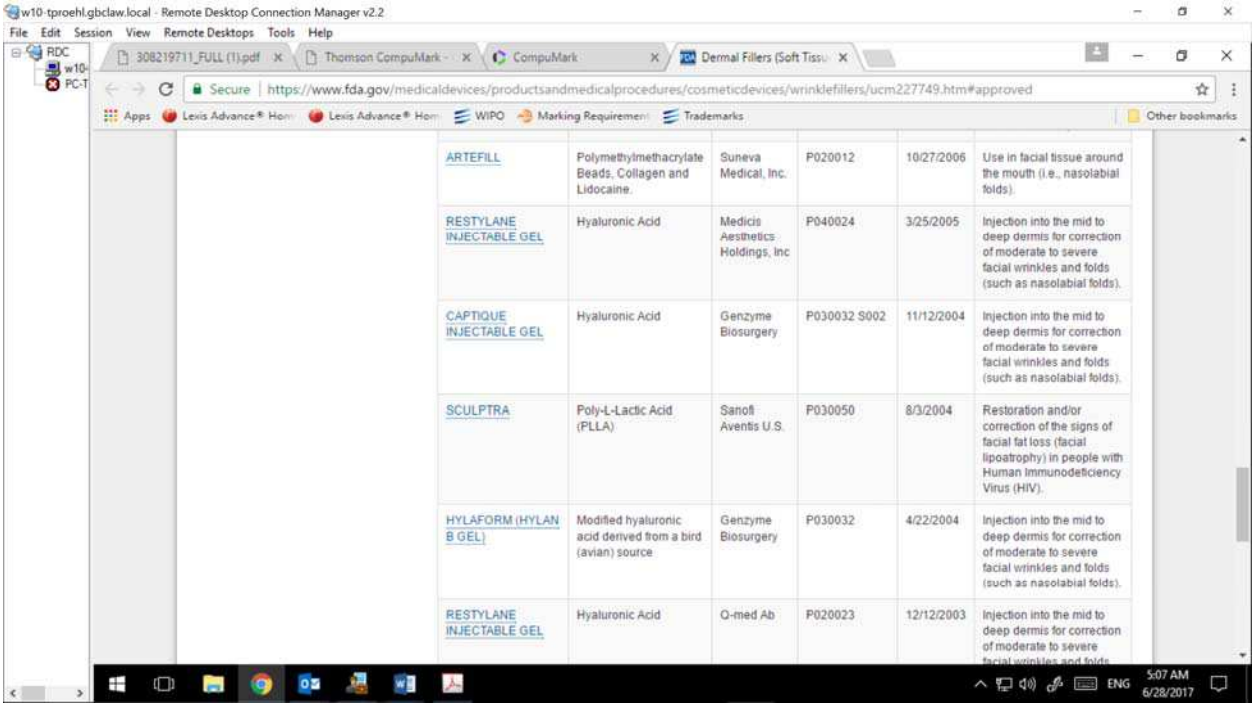

w10-tproehl.gbclaw.local - Remote Desktop Connection Manager v2.2
File Edit Session View Remote Desktops Tools Help
308219711_FULL (1).pdf
Thomson CompuMark
CompuMark
Dermal Fillers (Soft Tissu
Secure | https://www.fda.gov/medicaldevices/productsandmedicalprocedures/cosmeticdevices/wrinklefillers/ucm227749.htm#approved
Apps
WIPO
Marking Requirement
Trademarks
Other bookmarks
use in the U.S. As such, the safety and effectiveness of these products cannot be assured. A list of approved products and indications for use in the U.S. can be found in the table below.
The FDA has NOT approved liquid silicone or silicone gel for injection to fill wrinkles or augment tissues anywhere in the body.
Approved Dermal Fillers
The Summary of Safety and Effectiveness Data for each approved dermal filler contains links to additional information about the clinical data the FDA reviewed. Links to this information can be found under the "Trade Name" column in the table below. This table lists all FDA-approved dermal fillers. It should be noted that not all of the dermal fillers listed below are currently marketed.
Trade Name (with link to additional information)
Material
Applicant
PMA Number
Decision Date
Approved For
JUVEDERM VOLLURE XC
Hyaluronic Acid
Allergan
P110033/S020
3/17/2017
Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds) in adults over the age of 21.
JUVEDERM VOLBELLA XC
Hyaluronic Acid with Lidocaine
Allergan
P110033/S018
5/31/2016
Injection into the lips for lip augmentation and for correction of perioral rhytids in adults over the age of 21.
RADIESSE
Hydroxylapatite
Bioform Medical,
P050052/S049
6/4/2015
Subdermal implantation for hand
ENG
5:02 AM
6/28/2017


w10-tproehl.gbclaw.local - Remote Desktop Connection Manager v2.2
File Edit Session View Remote Desktops Tools Help
308219711_FULL (1).pdf
Thomson CompuMark
CompuMark
Dermal Fillers (Soft Tissu
Secure | https://www.fda.gov/medicaldevices/productsandmedicalprocedures/cosmeticdevices/wrinklefillers/ucm227749.htm#approved
Apps Lexis Advance® Hom Lexis Advance® Hom WIPO Marking Requirement Trademarks Other bookmarks
RADIESSE | Hydroxylapatite | Bioform Medical, Inc. | P050052/S049 | 6/4/2015 | Subdermal implantation for hand augmentation to correct volume loss in the dorsum of the hands.
RESTYLANE LYFT WITH LIDOCAINE | Hylauronic acid with lidocaine | Galderma Laboratories | P040024 S073 | 7/1/2015 | Moderate to severe facial folds and wrinkles or in patients over the age of 21 who have age-related volume loss.
RESTYLANE SILK | Hyaluronic Acid with Lidocaine | Valeant Pharmaceuticals North America LLC/Medicis | P040024 S072 | 6/13/2014 | Indicated for lip augmentation and dermal implantation for correction of perioral rhytids (wrinkles around the lips) in patients over the age of 21.
JUVEDERM VOLUMA XC | Hyaluronic Acid with Lidocaine | Allergan | P110033 | 10/22/2013 | Deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21.
RESTYLANE-L INJECTABLE GEL | Hyaluronic Acid with Lidocaine | Medicis Aesthetics Holdings, Inc. | P040024 S056 | 8/30/2012 | Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles/folds (such as nasolabial folds) and for lip augmentation in those over the age of 21 years.
BELOTERO BALANCE | Hyaluronic Acid | Merz Pharmaceuticals | P090016 | 11/14/2011 | Injection into facial tissue to smooth wrinkles and folds, especially around the nose and mouth (nasolabial folds).
ENG 5:04 AM 6/28/2017

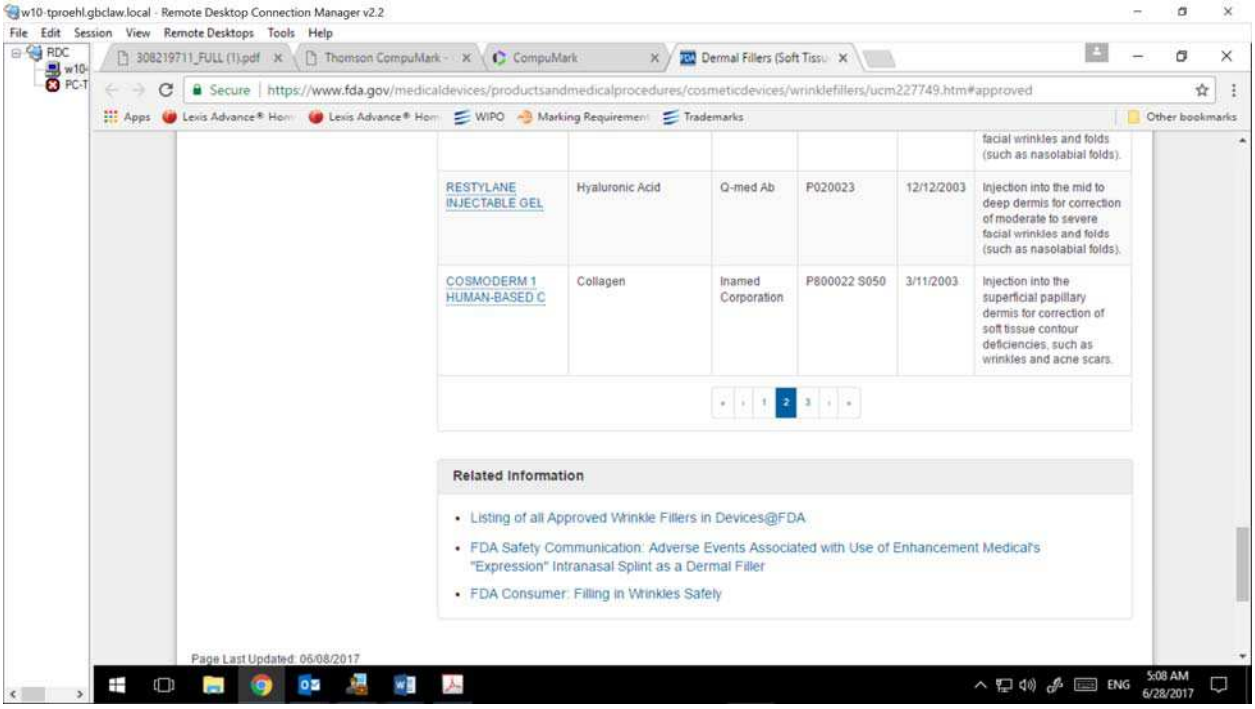

w10-tproehl.gbclaw.local - Remote Desktop Connection Manager v2.2
File Edit Session View Remote Desktops Tools Help
308219711_FULL (1).pdf
Thomson CompuMark
CompuMark
Dermal Fillers (Soft Tissu
Secure | https://www.fda.gov/medicaldevices/productsandmedicalprocedures/cosmeticdevices/wrinklefillers/ucm227749.htm#approved
Apps Lexis Advance® Hom Lexis Advance® Hom WIPO Marking Requirement Trademarks Other bookmarks
RESTYLANE-L INJECTABLE GEL | Hyaluronic Acid with Lidocaine | Medicis Aesthetics Holdings, Inc. | P040024 S056 | 8/30/2012 | Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles/folds (such as nasolabial folds) and for lip augmentation in those over the age of 21 years.
BELOTERO BALANCE | Hyaluronic Acid | Merz Pharmaceuticals | P090016 | 11/14/2011 | Injection into facial tissue to smooth wrinkles and folds, especially around the nose and mouth (nasolabial folds).
RESTYLANE INJECTABLE GEL | Hyaluronic Acid | Medicis Aesthetics Holdings, Inc | P040024 S051 | 10/11/2011 | Lip augmentation in those over the age of 21 years.
JUVEDERM ULTRA XC AND JUVEDERM ULTRA PLUS XC | Hyaluronic Acid with Lidocaine | Allergan | P050047 | 1/7/2010 | The addition of 0.3% Lidocaine into Juvederm Ultra and Juvederm Ultra Plus.
SCULPTRA AESTHETIC | Poly-L-Lactic Acid (PLLA) | Sanofi Aventis U.S. | P030050 S002 | 7/28/2009 | Use in shallow to deep nasolabial fold contour deficiencies and other facial wrinkles.
EVOLENCE COLLAGEN FILLER | Collagen | Colbar Lifescience I | P070013 | 6/27/2008 | The correction of moderate to deep facial wrinkles and folds (such as nasolabial folds).
« 1 2 3 »
ENG 5:05 AM 6/28/2017

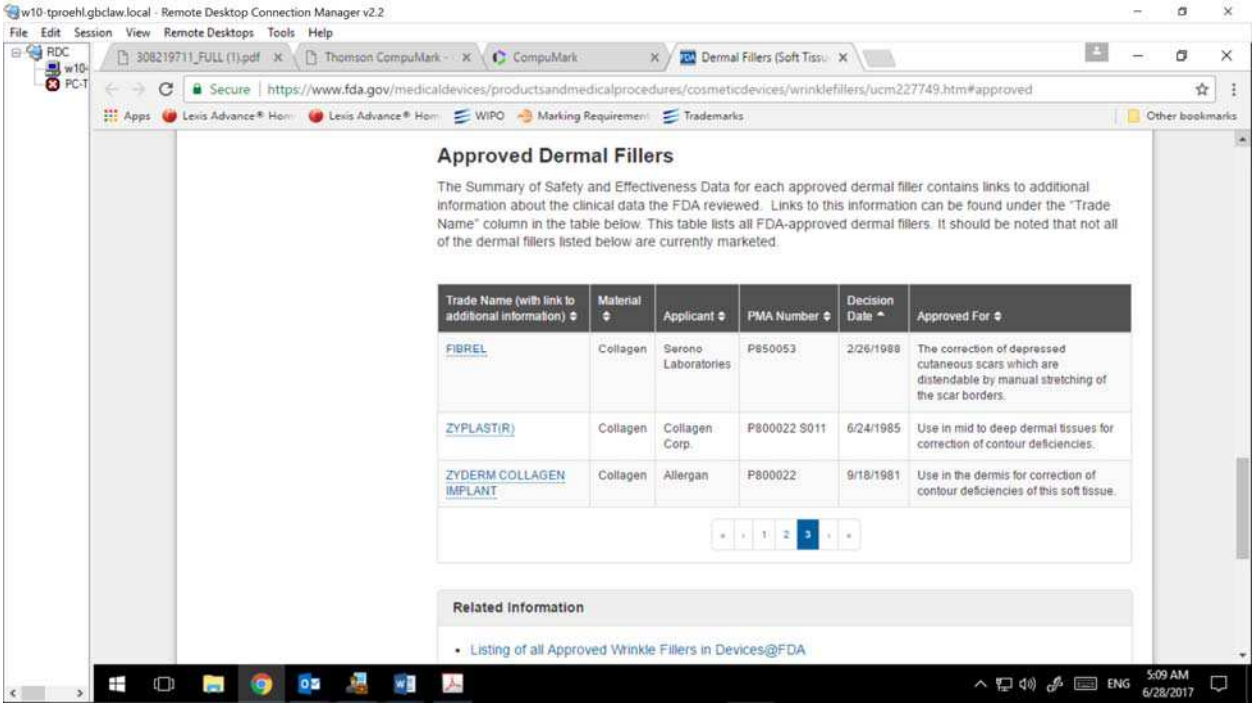


Trade Name (with link to additional information)	Material	Applicant	PMA Number	Decision Date	Approved For
PREVELLE SILK	Hyaluronic Acid with Lidocaine	Genzyme Biosurgery	P030032 S007	2/26/2008	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
RADIESSE 1.3CC AND 0.3CC	Hydroxylapatite	Bioform Medical, Inc	P050052	12/22/2006	Subdermal implantation for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
ELEVESS	Hyaluronic Acid with Lidocaine	Anika Therapeutics	P050033	12/20/2006	Use in mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
RADIESSE 1.3CC AND 0.3CC	Hydroxylapatite	Bioform Medical, Inc	P050037	12/22/2006	Restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with HIV.
JUVEDERM 24HV, JUVEDERM 30, and JUVEDERM 30HV	Hyaluronic Acid	Allergan	P050047	6/2/2006	Use in mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as



ARTEFILL	Polymethylmethacrylate Beads, Collagen and Lidocaine.	Suneva Medical, Inc.	P020012	10/27/2006	Use in facial tissue around the mouth (i.e., nasolabial folds).
RESTYLANE INJECTABLE GEL	Hyaluronic Acid	Medicis Aesthetics Holdings, Inc	P040024	3/25/2005	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
CAPTIQUE INJECTABLE GEL	Hyaluronic Acid	Genzyme Biosurgery	P030032 S002	11/12/2004	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
SCULPTRA	Poly-L-Lactic Acid (PLLA)	Sanofi Aventis U.S.	P030050	8/3/2004	Restoration and/or correction of the signs of facial fat loss (facial lipoatrophy) in people with Human Immunodeficiency Virus (HIV).
HYLAFORM (HYLAN B GEL)	Modified hyaluronic acid derived from a bird (avian) source	Genzyme Biosurgery	P030032	4/22/2004	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
RESTYLANE INJECTABLE GEL	Hyaluronic Acid	Q-med Ab	P020023	12/12/2003	Injection into the mid to deep dermis for correction of moderate to severe


w10-tproehl.gbclaw.local - Remote Desktop Connection Manager v2.2
File Edit Session View Remote Desktops Tools Help
308219711_FULL (1).pdf
Thomson CompuMark
CompuMark
Dermal Fillers (Soft Tissu
https://www.fda.gov/medicaldevices/productsandmedicalprocedures/cosmeticdevices/wrinklefillers/ucm227749.htm#approved
Apps
Lexis Advance® Hom
WIPO
Marking Requirement
Trademarks
Other bookmarks
facial wrinkles and folds (such as nasolabial folds).
RESTYLANE INJECTABLE GEL
Hyaluronic Acid
Q-med Ab
P020023
12/12/2003
Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
COSMODERM 1 HUMAN-BASED C
Collagen
Inamed Corporation
P800022 S050
3/11/2003
Injection into the superficial papillary dermis for correction of soft tissue contour deficiencies, such as wrinkles and acne scars.
Related Information
Listing of all Approved Wrinkle Fillers in Devices@FDA
FDA Safety Communication: Adverse Events Associated with Use of Enhancement Medical's "Expression" Intranasal Splint as a Dermal Filler
FDA Consumer: Filling in Wrinkles Safely
Page Last Updated: 06/08/2017
ENG
5:08 AM
6/28/2017


w10-tproehl.gbclaw.local - Remote Desktop Connection Manager v2.2
File Edit Session View Remote Desktops Tools Help
308219711_FULL (1).pdf
Thomson CompuMark
CompuMark
Dermal Fillers (Soft Tissu
https://www.fda.gov/medicaldevices/productsandmedicalprocedures/cosmeticdevices/wrinklefillers/ucm227749.htm#approved
Apps
Lexis Advance® Hom
WIPO
Marking Requirement
Trademarks
Other bookmarks
Approved Dermal Fillers
The Summary of Safety and Effectiveness Data for each approved dermal filler contains links to additional information about the clinical data the FDA reviewed. Links to this information can be found under the "Trade Name" column in the table below. This table lists all FDA-approved dermal fillers. It should be noted that not all of the dermal fillers listed below are currently marketed.
Trade Name (with link to additional information)
Material
Applicant
PMA Number
Decision Date
Approved For
FIBREL
Collagen
Serono Laboratories
P850053
2/26/1988
The correction of depressed cutaneous scars which are distendable by manual stretching of the scar borders.
ZYPLAST(R)
Collagen
Collagen Corp.
P800022 S011
6/24/1985
Use in mid to deep dermal tissues for correction of contour deficiencies.
ZYDERM COLLAGEN IMPLANT
Collagen
Allergan
P800022
9/18/1981
Use in the dermis for correction of contour deficiencies of this soft tissue.
Related Information
Listing of all Approved Wrinkle Fillers in Devices@FDA
ENG
5:09 AM
6/28/2017


Juvéderm™
ULTRA PLUS
INJECTABLE GEL

About JUVÉDERM VOLUMA® XC

Juvéderm VOLUMA® XC

Before beginning your treatments, please review this important information.

1. GLOSSARY

(Note that terms in the glossary are in bold throughout this document.)

***Anesthetic*—**a compound that reduces sensitivity to pain

***Hyaluronic acid (HA)*—**a polysaccharide (sugar) that is naturally in the body. It keeps skin moisturized and soft. HA fillers, including the JUVÉDERM® XC range of products, are a modified form of the HA that is naturally in your body.

***Lidocaine*—**a synthetic compound used as a local anesthetic to decrease pain

***Pigmentation disorder*—**a medical condition that results in a change in skin color

***Repeat injection*—**an additional treatment with dermal filler that is given after the effects of the initial treatment have worn off, in order to maintain the desired result

***Topical*—**a cream or ointment applied on top of the skin and affecting only the area to which it is applied

***Touch-up*—**an additional injection of a small amount of dermal filler, usually given about 2 weeks to 1 month after the initial injection. A touch-up treatment may be necessary to achieve the desired result

***VYCROSS® technology*—**a unique manufacturing process that provides a high concentration of crosslinked HA for long-lasting results. It creates a smooth, consistency gel that flows easily into the skin and provides a smooth, natural look and feel

2. PRODUCT DESCRIPTION

What is it?

JUVÉDERM VOLUMA® XC injectable gel is a smooth, cohesive **hyaluronic acid (HA)** gel that contains a small quantity of local **anesthetic (lidocaine)**. **HA** is a naturally occurring sugar found in the human body. The role of **HA** in the skin is to deliver nutrients and help the skin retain its natural moisture and softness. The addition of **lidocaine** helps to minimize the discomfort of the injection. JUVÉDERM VOLUMA® XC injectable gel is manufactured using **VYCROSS® technology** to give a specialized smooth-gel filler that produces long-lasting results at the treatment site. JUVÉDERM VOLUMA® XC is delivered by an injection into the cheek and surrounding area of the mid-face to correct volume and fullness.

3. INDICATION/INTENDED USE

What is it for?

JUVÉDERM VOLUMA® XC is indicated for deep (subcutaneous and/or submuscular) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21.

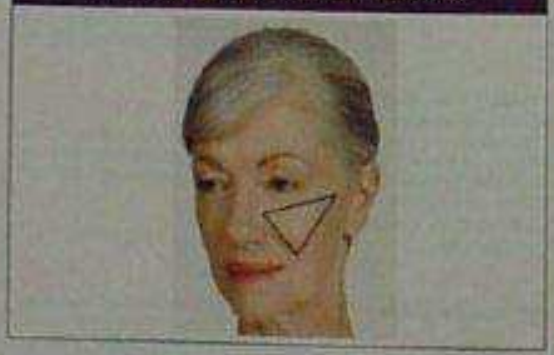
What does it do?

As you age, the cheek area loses its youthful shape. The cheeks flatten out and the skin may begin to sag. JUVÉDERM VOLUMA® XC injectable gel is designed to temporarily reverse these signs of aging. It is a gel that is injected into the cheek area to lift the skin. It temporarily adds volume to the cheek area and results in a smoother contour and more youthful appearance to the face. Figure 1 shows the treatment areas for JUVÉDERM VOLUMA® XC.

How is it used?

It is injected into the cheek area using a small needle. It temporarily corrects volume in the cheek area and gives the appearance of a more youthful, smoother skin surface.

Figure 1: Treatment Area for JUVÉDERM VOLUMA® XC



4. CONTRAINDICATIONS

Are there any reasons why I should not receive JUVÉDERM VOLUMA® XC injectable gel?

Your doctor will ask about your medical history to determine if you are an appropriate candidate for treatment.

- You should not use the product if you have severe allergies with a history of severe reactions (as appropriate). Use may result in an allergic reaction.
- You should not use the product if you are allergic to **lidocaine** or to the proteins used to make the **HA** in JUVÉDERM VOLUMA® XC (gram positive bacteria proteins). Use may result in an allergic reaction.

5. PRECAUTIONS

What precautions should my doctor advise me about?

The following are important treatment considerations for you to discuss with your doctor and understand in order to help avoid unsatisfactory results and complications.

- Minimize strenuous exercise and exposure to extensive sun or heat within the first 24 hours following treatment. Exposure to any of these may cause temporary redness, swelling, and/or itching at the injection site.
- Tell your doctor if you are pregnant or breastfeeding. The safety of JUVÉDERM VOLUMA® XC injectable gel for use during pregnancy, or in patients who are breastfeeding, has not been studied.
- Tell your doctor your age and discuss how your age may influence your decision to use this product. The safety of JUVÉDERM VOLUMA® XC has not been studied in patients under 35 years or over 65 years.
- Tell your doctor which areas of your face you would like to have treated. This product is intended for use in the cheek area, as shown in the highlighted regions in Figure 1, found in Section 3. The safety and effectiveness for treatment in other areas have not been established in controlled, clinical studies.
- Tell your doctor if you have a history of excessive scarring (thick, hard scars). The safety of JUVÉDERM VOLUMA® XC injectable gel in patients with a history of excessive scarring has not been studied and may result in additional scars.
- Tell your doctor if you have a history of **pigmentation disorders**. The safety of JUVÉDERM VOLUMA® XC in patients with a history of **pigmentation disorders** has not been studied. Use in these patients may result in changes in pigmentation.
- Tell your doctor if you are on therapy used to decrease the body's immune response (immunosuppressive therapy). Use may result in an increased risk of infection.
- Tell your doctor before treatment if you are taking substances that can prolong bleeding such as aspirin, ibuprofen, or other blood thinners. As with any injection, this may result in increased bruising or bleeding at the injection site.
- Patients who experience skin injury near the site of JUVÉDERM VOLUMA® XC implantation may be at a higher risk for adverse events.

6. RISKS

What are possible side effects?

In the clinical study, most side effects were moderate (uncomfortable) in nature, and generally lasted 2 to 4 weeks. The most common side effects include temporary reactions at the treatment site such as tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching. These side effects are consistent with other facial injection procedures. See Section 14 for additional information on side effects seen in the clinical study.

Although most side effects will resolve with time, some with effects may persist longer than 30 days. Your doctor may choose to treat them with medications, such as antibiotics, steroids, or hyaluronidase (an enzyme that breaks down **HA**).

As with all skin injection procedures, there is a risk of infection.

Rarely, vision abnormalities have been reported after treatment with JUVÉDERM VOLUMA® XC.

7. BENEFITS

What will it accomplish?

It will temporarily correct volume in the cheeks and cheek area that has been lost due to aging and will provide a smoother contour and more youthful appearance to the face.

8. BEFORE PROCEDURE INFORMATION

What happens in the office before the injection?

Note that each doctor may have a unique process for assessing and treating patients.

(Continued on reverse side.)

The following is an example of what you would experience with a typical procedure. Before the injection procedure, your doctor will ask you questions about your medical history, as well as your treatment goals. Your doctor will discuss whether you are an appropriate candidate for JUVÉDERM VOLUMA™ XC and review what to expect during and after treatment, including possible side effects. Your doctor will also examine your skin in and around the treatment area, and may take photos. Different options for pain management will be discussed, and if pretreatment numbing is desired, a **topical** such as **lidocaine** cream, or other **anesthetic** agent may be used. The treatment area will be cleaned and then prepared with alcohol or other antiseptic. Your doctor may use a pen to mark your face, identifying the planned areas of injection.

9. PROCEDURE DESCRIPTION

What happens during the procedure?

After the first injection into the cheek, your doctor will wait a few seconds to allow the **lidocaine** to take effect before moving forward with the rest of the treatment. JUVÉDERM VOLUMA™ XC will be injected in small amounts over the treatment area until the desired aesthetic outcome is achieved. Your doctor may massage the treatment area gently to assure that the product is evenly distributed. An ice pack may be applied for a brief period following treatment to minimize swelling and reduce pain.

Do the injections hurt?

Injections may cause some discomfort during and after the procedure. In the JUVÉDERM VOLUMA™ XC injectable gel clinical study, immediately after injection, subjects rated injection pain, on average, as a 3 on an 11-point scale where 0 is no pain and 10 is worst pain imaginable. JUVÉDERM VOLUMA™ XC injectable gel contains **lidocaine** to reduce injection site pain. Your doctor may also choose to numb (anesthetize) the treatment area with a **topical** or injected numbing agent to further minimize discomfort.

10. AFTER PROCEDURE INFORMATION

What should I expect following the procedure?

In the clinical trial the most common side effects were temporary reactions at the treatment site such as tenderness, swelling, firmness, and lumps/bumps. These side effects generally lasted 2 to 4 weeks. See Section 14 for additional information on side effects seen in the clinical study.

Your doctor will also tell you what to expect following treatment with JUVÉDERM VOLUMA™ XC injectable gel. Within the first 24 hours, you should minimize strenuous exercise and exposure to extensive sun or heat. Exposure to any of the above may increase temporary redness, swelling, and/or itching at the injection site. If there is swelling, you may place an ice pack over the swollen area. You should ask your doctor when makeup may be applied after your treatment.

Will I need more than one treatment to achieve my desired result?

You should discuss your treatment goals and plan with your doctor. In the clinical study, 55% of subjects received a **touch-up** treatment 1 month after initial treatment in order to achieve the desired result.

Does the correction last forever?

No. While individual results may vary, in the clinical study, the results lasted up to 2 years in a majority of subjects treated with JUVÉDERM VOLUMA™ XC. After this, **repeat injections** are usually needed to maintain your desired result.

11. ALTERNATIVE PROCEDURES

What other treatments are available to me?

Alternative treatments that are available to you to correct lost facial volume include surgical implants or injections of your own fat. You may discuss these treatment options with your doctor.

12. WHEN TO CALL YOUR DOCTOR

When should I call my doctor?

Be sure to call your doctor if you have: 1) significant pain away from the injection site, 2) any redness and/or visible swelling that lasts for more than a few days, 3) any side effect that occurs weeks or months after treatment, or 4) any other symptoms that cause you concern.

13. CLINICAL STUDIES

How was the product studied?

To establish the safety and effectiveness of JUVÉDERM VOLUMA™ XC injectable gel, 270 subjects (82% female and 18% male) were treated. To achieve subjects' desired results, a **touch-up** treatment was allowed 1 month after initial treatment. After 2 years or after correction had been lost, whichever was first, subjects were offered an optional repeat treatment.

The amount of JUVÉDERM VOLUMA™ XC injectable gel used in the clinical study to achieve optimal outcomes ranged from 1.0 mL to 13.0 mL, with a median volume of 6.6 mL. In general, the amount of JUVÉDERM VOLUMA™ XC used for the **touch-up** and repeat treatment was significantly less than the first treatment. For each patient the volume used was based on volume deficit and treatment goals.

To evaluate the safety of JUVÉDERM VOLUMA™ XC injectable gel, subjects noted common side effects in daily diaries. Side effects were also reported by doctors based on interviews with each subject. These interviews included discussing any symptoms or complaints with the subjects and assessing their appearance. To evaluate the effectiveness of the product in restoring fullness to the cheek area, a 6-point scale ranging from 0 to 5 was used.

What did the clinical study show?

JUVÉDERM VOLUMA™ XC injectable gel was found to effectively correct cheek shape and fullness.

- 86% of subjects had at least a 1-point improvement in mid-cheek fullness 6 months after treatment
- Subjects rated themselves as looking an average of 5 years younger 6 months after their last treatment
- More than 75% of subjects reported an improvement in their overall satisfaction with their facial appearance at 2 years after their last treatment

The clinical study showed that JUVÉDERM VOLUMA™ XC injectable gel lasts up to 2 years in the majority of subjects.

14. ADVERSE EFFECTS

What side effects were seen in the clinical study?

Most subjects in the clinical study experienced tenderness, swelling, firmness and/or lumps/bumps at the injection site as reported in their 30-day daily diary. These side effects were usually moderate in severity, did not require treatment, and generally lasted 2 to 4 weeks. Based on the clinical study, the likelihood of experiencing side effects after initial treatment with JUVÉDERM VOLUMA™ XC is shown below in Table 1. These events were reported less often after repeat treatment.

Table 1. Side Effects After Initial Treatment*,**

Side Effects	Likelihood of Experiencing Side Effects
Any Side Effect	98 out of 100 people (98%)
Tenderness	92 out of 100 people (92%)
Swelling	86 out of 100 people (86%)
Firmness	82 out of 100 people (82%)
Lumps/Bumps	81 out of 100 people (81%)
Bruising	78 out of 100 people (78%)
Pain	66 out of 100 people (66%)
Redness	66 out of 100 people (66%)
Discoloration	41 out of 100 people (41%)
Itching	39 out of 100 people (39%)

*Occurring in ≥ 5% of subjects

**Based on 265 subjects who provided information about side effects after initial treatment

What adverse events were seen in the clinical study?

Adverse events (any side effects to JUVÉDERM VOLUMA™ XC that lasted longer than the 30-day daily diary, or side effects that occurred after 30 days) were recorded over the course of the study. The most common adverse events were the same as those reported as side effects in the daily diary, such as lumps/bumps, firmness, swelling, and pain. Adverse events were seen more frequently in subjects who received a large volume of product and subjects who were older. Rarely, adverse events occurred weeks to months after the injection procedure.

15. ADDITIONAL INFORMATION

What if I experience a problem?

If you believe that you have experienced a serious problem related to JUVÉDERM VOLUMA™ XC injectable gel, you should call your doctor. You may also contact the Allergan Product Surveillance line during normal business hours at 1-877-345-5372 to report any side effects.

What should I do if I have additional questions?

For further questions and information, please call Allergan at 1-800-766-0171.

ALLERGAN

©2013 Allergan, Inc. ® and ™ marks owned by Allergan, Inc. JUVÉDERM® mark owned by Allergan Industrie, SAS.
Patented. See www.allergan.com/products/patent_notices
[illegible] Rev. [illegible] 10/2013

TSDR now includes a Post Registration Maintenance Tab. When viewing a Registered mark, users will now find a new 3rd tab providing Post Registration information next to the "Status" and "Document" tabs, below the search text box. The tab will not appear if the mark is not registered.

STATUS DOCUMENTS Back to Search Print

Generated on: This page was generated by TSDR on 2017-06-07 15:30:23 EDT

Mark: JUVÉDERM VOLLURE

JUVÉDERM VOLLURE

US Serial Number:	87228299	**Application Filing Date:**	Nov. 07, 2016
Filed as TEAS RF:	Yes	**Currently TEAS RF:**	Yes
Register:	Principal		
Mark Type:	Trademark		
TM5 Common Status Descriptor:	LIVE/APPLICATION/Under Examination The trademark application has been accepted by the Office (has met the minimum filing requirements) and that this application has been assigned to an examiner.		
Status:	An Office action suspending further action on the application has been sent (issued) to the applicant. To view all documents in this file, click on the Trademark Document Retrieval link at the top of this page.		
Status Date:	Feb. 22, 2017		

Mark Information

Mark Literal Elements:	JUVÉDERM VOLLURE
Standard Character Claim:	Yes. The mark consists of standard characters without claim to any particular font style, size, or color.
Mark Drawing Type:	4 - STANDARD CHARACTER MARK

Related Properties Information

Claimed Ownership of US Registrations: 3706974, 4380507, 4933963

Goods and Services

Note:
The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: Pharmaceutical preparations for the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin

International Class(es):	005 - Primary Class	**U.S Class(es):**	006, 018, 044, 046, 051, 052
Class Status:	ACTIVE		
Basis:	1(b)		

For: Medical devices for the treatment of wrinkles and folds

International Class(es):	010 - Primary Class	**U.S Class(es):**	026, 039, 044
Class Status:	ACTIVE		
Basis:	1(b)		

Basis Information (Case Level)

Filed Use:	No	**Currently Use:**	No	**Amended Use:**	No
Filed ITU:	Yes	**Currently ITU:**	Yes	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name:	Allergan Holdings France		
Owner Address:	12, Place de la Defense, 4eme etage Courbevoie FRANCE		
Legal Entity Type:	société par actions simplifiée (sas)	**State or Country Where Organized:**	FRANCE

Attorney/Correspondence Information

Attorney of Record - None

Correspondent

Correspondent Name/Address:	SUSAN J. HINCHEY ALLERGAN, INC. 2525 DUPONT DRIVE IRVINE, CALIFORNIA UNITED STATES 92612		
Phone:	714-246-5507	**Fax:**	714-796-9381
Correspondent e-mail:	susan.hinchey@allergan.com matthew.brady@allergan.com	**Correspondent e-mail Authorized:**	Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Feb. 22, 2017	NOTIFICATION OF LETTER OF SUSPENSION E-MAILED	6332
Feb. 22, 2017	LETTER OF SUSPENSION E-MAILED	6332
Feb. 22, 2017	SUSPENSION LETTER WRITTEN	85324
Feb. 17, 2017	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Feb. 16, 2017	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Feb. 16, 2017	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Feb. 16, 2017	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325

Feb. 16, 2017	NON-FINAL ACTION E-MAILED	6325
Feb. 16, 2017	NON-FINAL ACTION WRITTEN	85324
Feb. 14, 2017	ASSIGNED TO EXAMINER	85324
Nov. 10, 2016	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Nov. 10, 2016	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information

TM Attorney: MARTIN, CHRISTINE C

Law Office Assigned: LAW OFFICE 104

File Location

Current Location: TMEG LAW OFFICE 104 - EXAMINING ATTORNEY ASSIGNED

Date in Location: Feb. 22, 2017

Assignment Abstract Of Title Information - Click to Load

Proceedings - Click to Load