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**Parekh et al.**

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(54) **SUBCOATED SIMULATED CAPSULE-LIKE  
MEDICAMENT**

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

This patent is subject to a terminal disclaimer.

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**Related U.S. Application Data**

(60) Division of application No. 09/389,793, filed on Sep. 3, 1999, now Pat. No. 6,214,350, which is a division of application No. 09/292,211, filed on Apr. 15, 1999, now Pat. No. 6,120,801, which is a division of application No. 08/802,185, filed on Feb. 18, 1997, now Pat. No. 5,916,592, which is a continuation of application No. 07/784,623, filed on Oct. 31, 1991, now Pat. No. 5,658,589, which is a continuation-in-part of application No. 07/345,599, filed on Apr. 28, 1989, now abandoned.

- (51) **Int. Cl.**<sup>7</sup> ..... **A61K 9/48**
- (52) **U.S. Cl.** ..... **424/463**; 424/451; 424/453; 424/456; 424/464; 424/474
- (58) **Field of Search** ..... 424/463, 456, 424/451, 453

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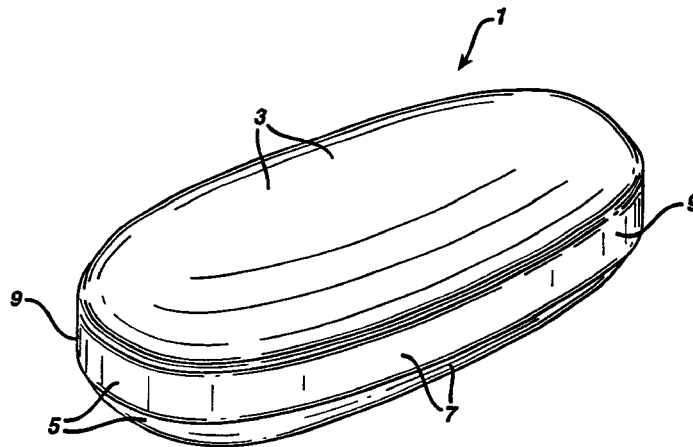
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(57) **ABSTRACT**

A simulated capsule-like medicament comprising a subcoating of a mixture of a water-soluble, film-forming polymer, e.g. hydroxypropylmethyl cellulose and a hydrophobic plasticizer, e.g. castor oil, which promotes a smooth uniform and substantially bubble free outer coating, e.g. gelatin, for the capsule-like medicament; capsule-like medicaments which are slightly bowed in shape; and a process of making such medicaments.

**8 Claims, 2 Drawing Sheets**



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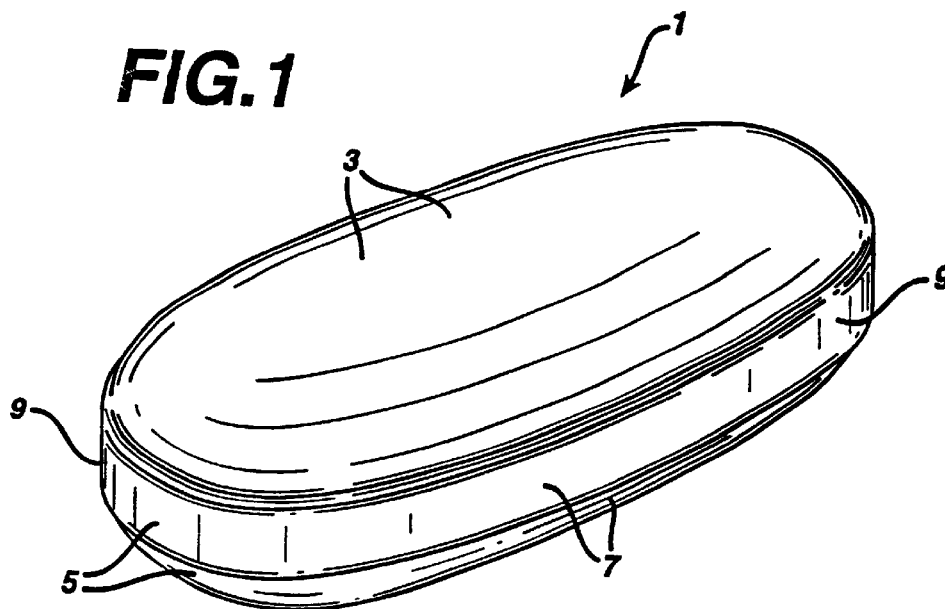
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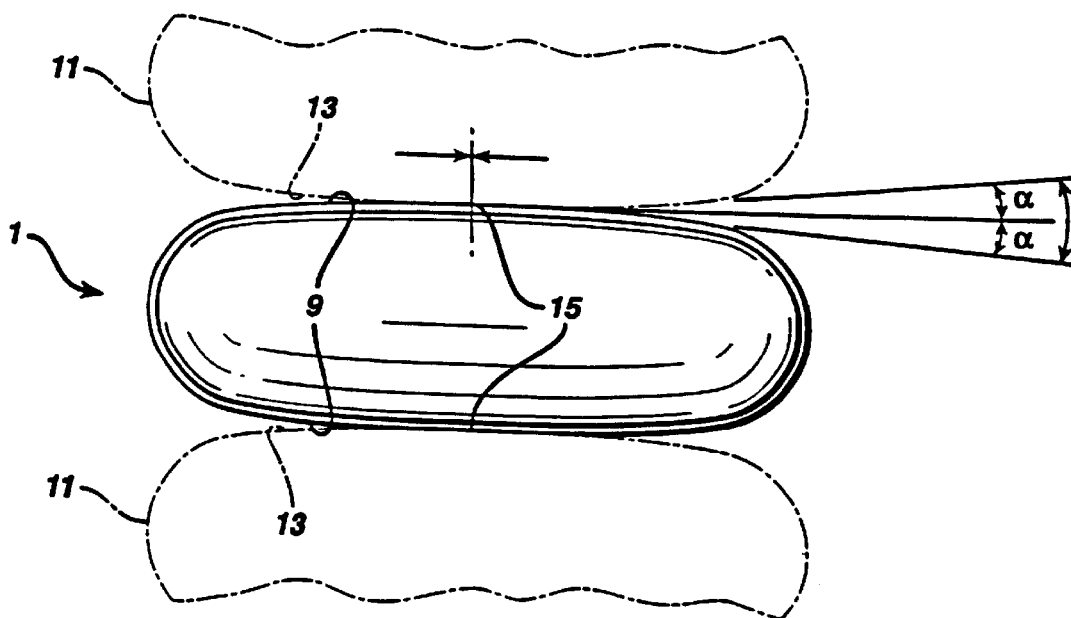
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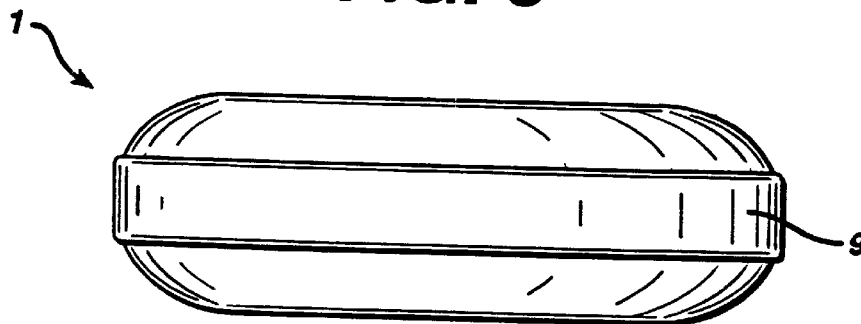
**FIG. 1**



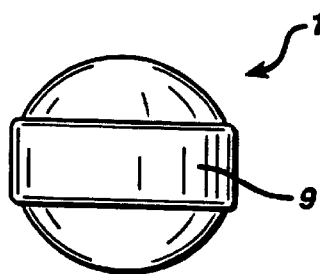
**FIG. 2**



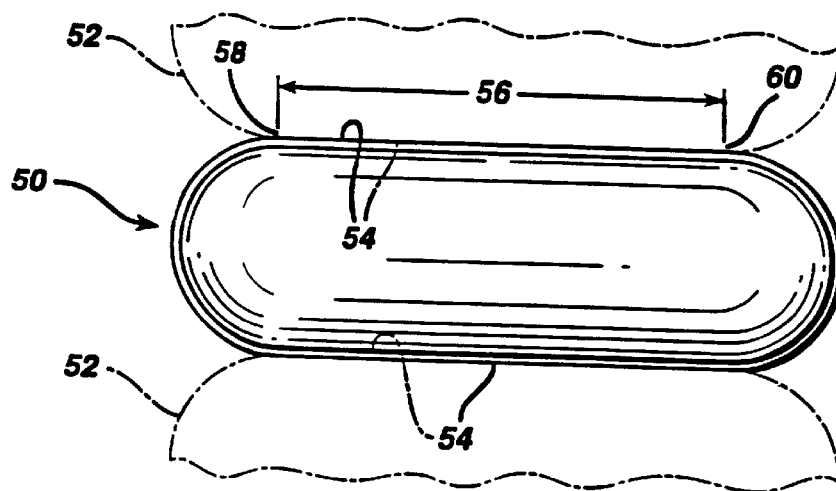
**FIG. 3**



**FIG. 4**



**FIG. 5** PRIOR ART



## SUBCOATED SIMULATED CAPSULE-LIKE MEDICAMENT

This invention is a divisional application of U.S. Ser. No. 09/389,793 filed Sep. 3, 1999, now U.S. Pat. No. 6,214,350 which is a divisional of U.S. Ser. No. 09/292,211 filed Apr. 15, 1999; U.S. Pat. No. 6,120,801 which is a divisional application of U.S. Ser. No. 08/802,185, filed Feb. 18, 1997, now U.S. Pat. No. 5,916,592; which is continuation of U.S. Ser. No. 07/784,623, filed Oct. 31, 1991, now U.S. Pat. No. 5,658,589, which is a continuation-in-part of U.S. Ser. No. 07/345,599 filed on Apr. 28, 1989, abandoned.

### FIELD OF THE INVENTION

This invention relates to subcoated simulated capsule-like medicaments. More particularly this invention relates to a solid medicament caplet core which has been subcoated with a mixture of a water-soluble, film-forming polymer and a hydrophobic plasticizer and coated with a smooth outer coating to provide the appearance of a capsule-like medicament and a process of making such coated medicaments.

### BACKGROUND OF THE INVENTION

Filled two-piece gelatin capsules for the encapsulation of various medicinal agents have been used for administering drugs since the mid-19th century. This capsule form of medicament proved to be very popular because hard gelatin capsules are tasteless, easily administered and easily filled either at a pharmacy or pre-filled in large quantities at commercial plants. While hard shell gelatin capsules are still popular dosage forms for pharmacist dispensed medicaments they have generally been discontinued in many over-the-counter products because of the risk of tampering with their contents.

Absent the susceptibility of capsule form medicaments to tamperings the capsule form was extremely popular with consumers because of a number of advantages. Many consumers prefer the gelatin form of capsule because of the perceived efficacy, taste, feel and swallowability of the gelatin capsule form of medicament.

This consumer preference for gelatin capsule-like medicaments provided a challenge to the industry to produce capsule-like medicaments which are tamper-proof yet provide the consumer with the advantages of a hard shell gelatin capsule-like dosage form. Norbert I. Berta developed simulated capsule-like medicaments and a process for making such capsule-like medicaments as disclosed in his U.S. Pat. No. 4,820,524. The entire disclosure of this issued U.S. patent is hereby incorporated herein by reference. Norbert I. Berta has also developed variations of the processes for making simulated capsule-like medicaments and apparatus for producing such medicaments as disclosed in U.S. Pat. No. 4,921,108 filed Dec. 4, 1987; U.S. Pat. No. 4,966,771 filed May 5, 1988; and U.S. Pat. No. 5,314,537 filed May 5, 1988. The simulated capsule-like medicaments developed by Berta were responsive to a long felt need in the industry to provide a simulated substitute for the popular dosage form of gelatin capsules. While gelatin coating of uncoated compressed medicaments such as acetaminophen is possible in accordance with the invention of Berta, it is difficult to control the quality of the surface appearance of such gelatin-coated caplets.

Beyond the development of a simulated capsule-like medicament several factors and considerations must be met to commercially produce a capsule which has a smooth, uniform and substantially bubble free outer coating appear-

ance. A preferred gelatin-coated caplet is one in which two distinctly colored gelatin coating solutions are utilized to produce a bi-colored gelatin-coated caplet. The two overlapping distinctly colored gelatin coatings form a seam about the transverse axis of the medicament. The presence of this seam and the distinct bi-coloring contributes to the consumer's perception of these simulated capsule-like medicaments as equivalents to gelatin capsule dosage forms.

The gelatin coated caplet product must adequately simulate a capsule-like medicament from a consumer's sight and touch perspective and must therefore be absent of discoloration, pits and gouges. The presence of such physical imperfections may erode the consumer's perception as to the gelatin coated caplet's capsule-like nature and the tamper-free nature of this dosage form. Strong consumer confidence in the gelatin capsule-like nature and tamper-resistance of the simulated capsule medicament of the invention is of the utmost importance in the marketing of this dosage form and forms an object of the present invention. It is therefore an object of the present invention to provide a subcoating for a solid caplet medicament core which minimizes bubble formation, discoloration and other aesthetic imperfections to provide for a smooth, uniform and substantially bubble free outer coating appearance to simulated capsule-like medicaments.

### SUMMARY OF THE INVENTION

The foregoing object of providing a simulated capsule-like medicament which has a smooth, uniform and substantially bubble free outer coating appearance has now been accomplished in accordance with the compositions and processes of the present invention.

In accordance with the purposes of the invention, as embodied and fully described herein, the invention comprises a simulated capsule-like medicament comprising: a solid caplet core comprising a medicament; a subcoating composition on the caplet core comprising a mixture of a water-soluble, film-forming polymer and a hydrophobic plasticizer; and a smooth outer coating whereby the subcoating composition promotes a smooth, uniform and substantially bubble free outer coating appearance to the capsule-like medicament.

In another embodiment of the present invention, there is provided a swallowable solid core having a smooth, uniform and substantially bubble free outer coating comprising a solid core containing a medicament which has an exterior surface that is coated with a subcoating composed of a mixture of a water-soluble, film-forming polymer selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, mixtures of hydroxypropyl cellulose and hydroxypropylmethyl cellulose, mixtures of hydroxypropyl cellulose and methyl cellulose wherein the hydroxypropyl cellulose constitutes greater than 50 weight percent but less than 100 weight percent of the mixture of hydroxypropyl cellulose and methyl cellulose, mixtures of hydroxypropyl cellulose and hydroxyethyl cellulose wherein the hydroxypropyl cellulose constitutes greater than 80 weight percent but less than 100 weight percent of the mixture of hydroxypropyl cellulose and hydroxyethyl cellulose, mixtures of hydroxypropylmethyl cellulose and methyl cellulose wherein the hydroxypropylmethyl cellulose constitutes greater than 50 weight percent but less than 100 weight percent of the mixture of hydroxypropylmethyl cellulose and methyl cellulose, mixtures of hydroxypropylmethyl cellulose and hydroxyethyl cellulose wherein the hydroxypropylmethyl cellulose constitutes more than 80

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