DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 81N-0122]

RIN 0905-AA06

Corn and Callus Remover Drug Products for Over-the-Counter Human Use; Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) corn and callus remover drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on corn and callus remover drug products that have come to the agency's attention. This final monograph is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: August 14, 1991.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 5, 1982 (47 FR 522), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC corn and callus remover drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by April 5, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by May 5, 1982.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, after deletion of a small amount of trade secret information.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC corn and callus remover drug products was published in the **Federal Register** of February 20, 1987 (52 FR 5412). Interested persons were invited to file by April 21, 1987, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal. Interested persons were invited to file comments on the agency's economic impact determination by June 22, 1987. New data could have been submitted until February 20, 1988, and comments on the new data until April 20, 1988. Final agency action occurs with the publication of this final monograph, which is a final rule establishing a monograph for OTC corn and callus remover drug products.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA is no longer using the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but is using instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III).

As discussed in the proposed regulation for OTC corn and callus remover drug products (52 FR 5412), the agency advised that the conditions under which the drug products that are subject to this monograph will be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication in the **Federal Register**. Therefore, on or after August 14, 1991, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In response to the proposed rule on OTC corn and callus remover drug products, one manufacturer submitted comments. No requests for oral hearing before the Commissioner were received. Copies of the comments received are on public display in the Dockets Management Branch. Any additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch (address above).

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the notices of proposed rulemaking. The volumes are on public display in the Dockets Management Branch.

I. The Agency's Conclusions on the Comments

1. One comment requested the agency to reexamine the various dosage forms that could be used for OTC corn and callus remover drug products. The comment noted that the Miscellaneous External Panel had safety concerns about the potential irritation caused by salicylic acid on sites adjacent to the treatment area. These concerns resulted in the Panel designating dosage forms that adequately deliver the product to the affected site, while avoiding contact with surrounding skin. The comment contended that, inasmuch as the agency determined in the tentative final monograph that contact of salicylic acid with surrounding skin does not present a safety problem, the necessity of restrictive dosage forms should be reconsidered.

The comment listed the following vehicles for products containing salicylic acid that were submitted to the Panel: collodion-like, ointment/salve, plaster/pad, liquid/balm, cream, and lotion. The comment also listed the following vehicles for currently marketed products (OTC or prescription) containing salicylic acid: collodion-like, ointment/salve, plaster/pad, liquid/balm, and gel. The comment urged the agency to allow the use of any vehicle that delivers salicylic acid to the

affected site in the approved dosage ranges of 12 to 40 percent. The comment suggested adding a new paragraph to the definitions in § 358.503 as follows: (d) *Conventional topical vehicles.* An ointment, gel, cream, liquid or other appropriate topical vehicle that delivers the active corn and callus remover to the affected area." The comment also suggested that additional labeling be added to the monograph in § 358.550 to describe the additional topical dosage forms as follows: "Wash affected area and dry thoroughly. Apply sufficient amount to cover the corn or callus. Rub in. Repeat this procedure once or twice daily as needed (until the corn/callus is removed) for up to 14 days. (If desired, soak feet in warm water to assist in removal.) Wash hands thoroughly after application."

The agency has reviewed the submissions on corn and callus remover drug products that were made to the Miscellaneous External Panel (Ref. 1) and has identified the following vehicles (either listed on product labeling or in the manufacturer's list of ingredients contained in these products, or used as the dosage form in the submitted studies): collodion-like, salve, plaster, disk, pad, and cream. Based on the data and information contained in those submissions, the Panel recommended that products containing salicylic acid in a plaster, pad, disk, or collodion vehicle be classified in Category I. However, the Panel classified salicylic acid in an ointment vehicle as Category II because of a lack of data on both safety and effectiveness (47 FR 522 at 527).

In the tentative final monograph, the agency noted that some collodion liquid formulations contain other inactive ingredients or varying amounts of solvent and proposed use of the term "collodion-like" instead of "collodion" in specifying the vehicle for liquid formulations (52 FR 5412 at 5414). The agency also proposed to use the term "plaster" to include "disk" and "pad" because these dosage forms are similar in nature (52 FR 5417).

The agency's determination in the tentative final monograph that salicylic acid does not present a safety problem to surrounding skin was based on additional data (52 FR 5416). These data supported revising the Panel's recommended directions in § 358.550(d)(2) and deleting the warning recommended in § 358.550(c)(1)(iv) concerning avoiding contact of salicylic acid-collodion products with the skin around a corn or callus by using a ring of petrolatum to protect that skin. These data did not address the effectiveness of various dosage forms containing salicylic acid and cannot be used as the basis to support the inclusion of additional dosage forms in the final monograph as suggested by the comment.

Because the comment did not submit any data to support the safety and effectiveness of salicylic acid used in any of the additional requested dosage forms, whether marketed OTC or by prescription, the agency has no basis to add any additional dosage forms to the final monograph. Accordingly, the comment's suggested addition to § 358.503 is not being included in this final monograph. In addition, because the comment's suggested topical dosage forms are not being added to the monograph, there is no basis to include the directions for these dosage forms suggested by the comment. The agency will consider amending the monograph at a later date if adequate supporting data are submitted as a petition to amend the monograph.

References

(1) OTC Volumes 160003, 160073, 160079, 160097, 160098, 160099, 160100, 160101, 160133, 160256, 160282, 160283, 160293, 160294, 160380, and 160398.

2. One comment recommended that the definition of "collodion-like vehicle" in proposed § 358.503 be slightly modified to read as follows: "A solution containing pyroxylin or film-forming vehicle in an appropriate solvent that leaves a transparent cohesive film when applied to the skin in a thin layer." The comment contended that this revised definition would clarify that "any appropriate vehicle similar to a collodion (*e.g.*, collodion-like) would be acceptable," and that this flexibility of choice of vehicles allows for scientific improvement and refinement beyond the vehicles commonly used today, without necessitating amendment of a final monograph. The comment added that its request comports with the agency's rationale for expanding the definition from "collodion" to "collodion-like" (52 FR 5412 at 5414) and is consistent with the broad definition the agency gave to "plaster vehicle," which allows for improved topical patches utilizing technologies beyond those specifically in use today.

While the agency has tried to be flexible in the monograph definitions to allow for reasonable product improvement and innovation, it does not agree with the comment's proposed modification of the definition of a collodion-like vehicle. Addition of the words "film-forming vehicle" in the definition would make the definition too broad, would expand the definition beyond vehicles that are similar to collodion, and could allow any "film-forming vehicle" to be used. If this occurred, it could result in the introduction into the market of a wide variety of natural and synthetic film-forming compounds whose impact on the safety and effectiveness of salicylic acid is unproven and unknown. It is possible that such compounds could eventually be included in the final monograph, but data would be needed to support their interaction with salicylic acid used in corn and callus remover drug products. Accordingly, the agency is not revising the definition of "collodion-like vehicle" in § 358.503 at this time, but will consider doing so in the future if vehicles of the type requested by the comment are found to be acceptable for inclusion in the monograph.

3. One comment agreed with the appropriateness of the new indication ("relieves pain by removing corns and calluses") proposed in § 358.550(b)(2). The comment noted that this indication is permitted only in conjunction with the indication proposed in § 358.550(b)(1), which states "for the removal of corns and calluses." Requesting that the new indication also be allowed to be used with an indication that is similar to, but not precisely the same wording as the "FDA approved" indication proposed in § 358.550(b)(1), the comment proposed that the following language be added to § 358.550(b)(2): "This indication is permitted only in conjunction with either the indication set out in paragraph (b)(1) of this section, or such other truthful or nonmisleading statement that conveys the removal indication."

The agency's labeling policy for stating the indications for use of OTC drug products in 21 CFR 330.1(c)(2) allows manufacturers to do what the comment has requested. Under this labeling policy, the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling.

In addition to allowing "Approved Uses" (indications that have been established in an applicable final monograph), this regulation allows manufacturers to use other truthful and nonmisleading statements describing only those indications for use that have been established in an applicable monograph. The introductory language in § 358.550(b) in the final monograph makes reference to the labeling provisions in § 330.1(c)(2). Accordingly, it is not necessary for the agency to incorporate the comment's suggested revision in § 358.550(b)(2).

The agency is revising the language in § 358.550 (b) and (b)(2) to remove any possible confusion that may have existed and to be consistent with the language used in other recently published final OTC drug monographs. Section 358.550(b)(2) will now read as follows: "In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain the following statement: 'Relieves pain by removing corns and calluses.' " The following statement is being added to the introductory language in § 358.550(b): "* * * and may contain the additional phrase listed in paragraph (b)(2) of this section * * *."

4. One comment suggested "a slight variation" to the warning proposed in § 358.550(c)(1)(ii), to read as follows: "Do not use if you are diabetic or have poor circulation or if there is any inflammation or irritation of the affected area." The comment stated that this proposed revision is preferable because it combines the warnings in § 358.550(c)(1) (ii) and (iii) and is stronger in its exhortation against use by diabetics and those with poor circulation. The comment contended that advising diabetics against the use of salicylic acid is medically sound and standard physician practice. The comment concluded that, for medical and product liability reasons, it would prefer to retain its label warning (suggested above) that it has used in recent years on its corn and callus remover drug products. The comment did not include any documentation in support of this more stringent, combined warning.

The same request was submitted to the rulemaking for OTC wart remover drug products and has been addressed in the final monograph for those products, which is being published elsewhere in this issue of the Federal Register.

The agency has determined that there is adequate support for a stronger warning, as requested by the comment. In addition, based on the serious consequences that can result from misuse, the agency believes it is better to err on the side of caution and to have the labeling of these OTC drug products state that the product should not be used under certain conditions rather than state an "except under" condition for use. Therefore, the agency is agreeing with the comment's suggested approach but is revising its recommended warning slightly for clarity. The revised warning appears in § 358.550(c)(1)(ii) of this final monograph as follows: "Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation." This revised warning now contains the same information as the warning proposed in § 358.550(c)(1)(iii), and that warning is not included in this final monograph. Accordingly, the warning proposed in paragraph (c)(1)(iv) of the tentative final monograph is redesignated as paragraph (c)(1)(iii) in this final monograph. (For a more detailed discussion, see the final monograph for OTC wart remover drug products published elsewhere in this issue of the **Federal Register.**)

5. One comment observed that clinical studies involving salicylic acid in a plaster vehicle showed that soaking of the corn/callus prior to removing the plaster slightly enhanced removal of the corn/callus (Ref. 1). The comment felt that similar results could be expected with salicylic acid in a collodion-like vehicle. Agreeing with the agency's position that prior soaking was not necessary to the effectiveness of these products, the comment requested that the directions in § 358.550(d) allow "soaking" as an option, as follows:

(1) *For products containing salicylic acid identified in § 358.510(a).* "Wash affected area and dry thoroughly." (If appropriate: "Cut plaster to fit corn/callus.") "Apply medicated plaster. After 48 hours remove the medicated plaster. Repeat this procedure every 48 hours as needed (until corn/callus is removed) for up to 14 days. (If desired, soak feet in warm water to assist in removal.)"

(2) *For products containing salicylic acid identified in § 358.510(b).* "Wash affected area and dry thoroughly. Apply one drop at a time to sufficiently cover each corn or callus. Let dry. Repeat this procedure once or twice daily as needed (until corn/callus is removed) for up to 14 days. (If desired, soak feet in warm water to assist in removal.)"

In the tentative final monograph for OTC corn and callus remover drug products (52 FR 5412), the agency reviewed the results of the study mentioned by the comment (Ref. 1). In this study, the effect of soaking as a means of increasing efficacy of salicylic acid in removing soft corns was evaluated. At that time, the agency determined that soaking of the corn/callus after treatment was unnecessary and deleted "soaking" from the previously-proposed directions for these products (52 FR 5416).

The agency has re-evaluated this study and determined that it did not include a "non-soaking" group, but that all test subjects soaked the corn for either 5 minutes or 15 minutes before attempting removal of the corn. Although this study did not show that soaking is necessary for salicylic acid to be effective, it also does not show that any adverse effects occur if the corn is soaked before it is removed. The agency notes that although the study was conducted on soft corns, the same findings are relevant to the removal of hard corns/calluses and warts because the Category I active ingredient, salicylic acid, and its mode of action, keratolysis, are the same for all three conditions.

The agency has examined the directions for use for a number of currently marketed corn and callus remover drug products and notes that most include soaking a short period of time (*e.g.*, 5 minutes) before attempting removal of the corn/callus. Although some of the products include directions to use warm water for soaking, others do not specify water temperature (Refs. 2 and 3).

There is no evidence that using different soaking times or temperatures is likely to alter the effectiveness of the corn/callus remover drug products. The agency believes that warm water (as the Panel suggested) or cold water could be used effectively for soaking but that warm water would be more comfortable. Soaking immediately before removal of the corn/callus may aid in the desquamation of epidermal tissue and may make it easier to remove the corn/callus. In discussing corn and callus remover drug products, the Panel stated that "Moisture is essential for salicylic acid to exert its action and for maceration and desquamation of epidermal tissue to take place" (47 FR 522 at 526).

Based on the Panel's recommendations, the agency's reevaluation of the study discussed above, and on the historical and current use of corn/callus remover drug products, the agency is including soaking of the corn/callus in warm water for 5 minutes prior to removal as an optional direction for those manufacturers who wish to give consumers the option to do so.

Accordingly, the agency is revising § 358.550(d) in this final monograph to read as follows:

(1) *For products containing salicylic acid identified in § 358.510(a).* "Wash affected area and dry thoroughly." (If appropriate: "Cut plaster to fit corn/callus.") "Apply medicated plaster. After 48 hours remove the medicated plaster. Repeat this procedure every 48 hours as needed for up to 14 days (until corn/callus is removed)." (Optional: "May soak corn/callus in warm water for 5 minutes to assist in removal.")

(2) *For products containing salicylic acid identified in § 358.510(b).* "Wash affected area and dry thoroughly. Apply one drop at a time to sufficiently cover each corn/callus. Let dry. Repeat this procedure once or twice daily as needed for up to 14 days (until corn/callus is removed)." (Optional: "May soak corn/callus in warm water for 5 minutes to assist in removal.")

References

(1) Goodman, J.J., and L. Farris, "Evaluation of Safety and Effectiveness of 20% Salicylic Acid for the Removal of Soft Corns," (Scholl Study No. S–82–47), draft of unpublished study, Coded LET, Docket No. 81N–0122, Dockets Management Branch.

(2) "Physicians' Desk Reference for Nonprescription Drugs," 10th Ed., Medical Economics Co., Oradell, NJ, p. 739, 1989.

(3) Labels of currently marketed OTC corn/callus remover drug products included in OTC Volume 16IFM, Docket Number 81N–0122, Dockets Management Branch.

II. Summary of Significant Changes From the Proposed Rule

1. The agency is revising the introductory language in § 358.550 (b) and (b)(2) to clarify how the indications statements may be used and be consistent with the language used in other recently published final OTC drug monographs. (See comment 3 above.)

2. The agency is revising the warning proposed in § 358.550(c)(1)(ii) regarding use of corn/callus remover drug products by diabetics and is incorporating therein the warning proposed in § 358.550(c)(1)(iii). Based on this revision, the warning proposed in § 358.550(c)(1)(iv) is being redesignated as paragraph (c)(1)(iii). (See comment 4 above.)

3. The agency is revising the directions proposed in § 358.510 to give manufacturers the option of including information about soaking of the corn/callus in warm water for 5 minutes prior to removal. (See comment 5 above.)

III. The Agency's Final Conclusions on OTC Corn and Callus Remover Drug Products

Based on the available evidence, the agency is issuing a final monograph establishing conditions under which OTC corn and callus remover drug products are generally recognized as safe and effective and not misbranded. Specifically, the agency has determined that the only active ingredients that meet monograph conditions are salicylic acid 12 to 40 percent in a plaster vehicle and salicylic acid 12 to 17.6 percent in a collodion-like vehicle. All other ingredients for corn and callus removal that were considered in this rulemaking are considered nonmonograph ingredients, i.e., glacial acetic acid, allantoin, ascorbic acid, belladonna extract, chlorobutanol, diperodon hydrochloride, ichthammol, iodine, methylbenzethonium chloride, methyl salicylate, panthenol, phenoxyacetic acid, phenyl salicylate, vitamin A, and zinc chloride. Any drug product marketed for use as an OTC corn and callus remover that is not in conformance with the monograph (21 CFR part 358, subpart F) is considered a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)) and misbranded under section 502 of the act (21 U.S.C. 352) and can not be marketed for this use unless it is the subject of an approved application. An appropriate citizen petition to amend the monograph may also be submitted under 21 CFR 10.30.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (52 FR 5412 at 5417). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that not one of these rules, including this final rule for OTC corn and callus remover drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC corn and callus remover drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 358

Corn and callus remover drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act, subchapter D of chapter I of title 21 of the Code of Federal Regulations is amended in part 358 as follows:

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 358 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Subparts C, D, and E are reserved and new subpart F, consisting of § 358.501 to § 358.550, is added to read as follows:

Subparts C and E—[Reserved]

Subpart F—Corn and Callus Remover Drug Products

Sec.

Subparts C and E—[Reserved]

Subpart F—Corn and Callus Remover Drug Products

§ 358.501 Scope.

(a) An over-the-counter corn and callus remover drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it

meets each of the conditions in this subpart and each of the general conditions established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 358.503 Definitions.

As used in this subpart:

(a) *Corn and callus remover drug product.* A topical agent used for the removal of corns and calluses.

(b) *Collodion-like vehicle.* A solution containing pyroxylin (nitrocellulose) in an appropriate nonaqueous solvent that leaves a transparent cohesive film when applied to the skin in a thin layer.

(c) *Plaster vehicle.* A fabric, plastic, or other suitable backing material in which medication is usually incorporated for topical application to the skin.

§ 358.510 Corn and callus remover active ingredients.

The product consists of any of the following active ingredients within the specified concentrations and in the dosage form established for each ingredient.

(a) Salicylic acid 12 to 40 percent in a plaster vehicle.

(b) Salicylic acid 12 to 17.6 percent in a collodion-like vehicle.

§ 358.550 Labeling of corn and callus remover drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "corn and callus remover."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1) of this section and may contain the additional phrase listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) "For the removal of corns and calluses."

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain the following statement: "Relieves pain by removing corns and calluses."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing any ingredient identified in § 358.510.* (i) "For external use only."

(ii) "Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation."

(iii) "If discomfort persists, see your doctor or podiatrist."

(2) *For any product formulated in a flammable vehicle.* (i) The labeling should contain an appropriate flammability signal word, e.g., "extremely flammable," "flammable," "combustible," consistent with 16 CFR 1500.3(b)(10).

(ii) "Keep away from fire or flame."

(3) *For any product formulated in a volatile vehicle.* "Cap bottle tightly and store at room temperature away from heat."

(4) *For any product formulated in a collodion-like vehicle.* (i) "If product gets into the eye, flush with water for 15 minutes."

(ii) "Avoid inhaling vapors."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing salicylic acid identified in § 358.510(a).* "Wash affected area and dry thoroughly." (If appropriate: "Cut plaster to fit corn/callus.") "Apply medicated plaster. After 48 hours remove the medicated plaster. Repeat this procedure every 48 hours as needed for up to 14 days (until corn/callus is removed)." (Optional: "May soak corn/callus in warm water for 5 minutes to assist in removal.")

(2) *For products containing salicylic acid identified in § 358.510(b).* "Wash affected area and dry thoroughly. Apply one drop at a time to sufficiently cover each corn/callus. Let dry. Repeat this procedure once or twice daily as needed for up to 14 days (until corn/callus is removed)." (Optional: "May soak corn/callus in warm water for 5 minutes to assist in removal.")

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

Dated: June 27, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90-19028 Filed 8-13-90; 8:45 am]

BILLING CODE 4160-01-M