DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 80N-0238]

Wart Remover Drug Products for Over-The-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a reproposal of the tentative final monograph (proposed rule) for over-the-counter (OTC) wart remover drug products to reflect new data and information. This reproposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by May 26, 1987. New data relating to this notice by March 27, 1988. Comments on the new data by May 27, 1988. These dates are consistent with the time periods specified in the agency's revised procedural regulations for reviewing and classifying OTC drugs (21 CFR 330.10). Written comments on the agency's economic impact determination by July 27, 1987.

ADDRESS: Written comments, objections, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 3, 1980 (45 FR 65609), 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 wart remover drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. The agency's proposed regulation, in the form of a tentative final monograph, for OTC wart remover drug products was published in the **Federal Register** of September 3, 1982 (47 FR 39102). Interested persons were invited to file by November 2, 1982, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal.

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 advanced notice of proposed rulemaking to establish a monograph for OTC corn and callus remover drug products. 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). In developing that proposal, the agency recognized that although the etiology and pathology of corns and calluses is different from that of warts, the Category I active ingredient, salicylic acid, and its mode of action, keratolysis, is common to both rulemakings.

Because no comments were submitted to the advance notice of proposed rulemaking for OTC wart remover drug products, the agency's tentative final monograph on OTC wart remover drug products proposed only minor changes from the Panel's recommendations. However, a number of comments as well as other data and information were submitted in response to the publication of the advance notice of proposed rulemaking for OTC corn and callus remover drug products. Based on that new data and information, the agency proposed a number of changes in the tentative final monograph for OTC corn and callus drug products (52 FR 5412).

Because of the similarities and overlap between the rulemakings for OTC corn and callus remover drug products and OTC wart remover drug products, the agency is proposing modifications in the tentative final monograph for OTC wart remover drug products to be consistent with the tentative final monograph for OTC corn and callus remover drug products. Because of the number of changes, the agency is restating its position on the establishment of a monograph for OTC wart remover drug products by reproposing Subpart B of Part 358 (21 CFR Part 358 Subpart B). Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC wart remover drug products. The definition of a wart remover drug product has been revised to be consistent with the corn/callus tentative final monograph.

A summary of the proposed changes and modifications that appear in the reproposed tentative final monograph follows:

(1) The tentative final monograph has been expanded to also include the use of a plaster vehicle containing 12 to 40 percent salicylic acid. In addition, the agency is proposing the term "collodion-like" in place of "a collodion vehicle" in describing the vehicle for liquid formulations of OTC wart remover drug products. The definition of a wart remover drug product also has been revised to be consistent with the definition of a corn and callus remover drug product, as proposed in § 358.503(a) of the tentative final monograph for OTC corn and callus remover drug products.

(2) A number of the warnings have been revised to conform with the warnings proposed in § 338.550(c) of the tentative final monograph for OTC corn and callus remover drug products.

(3) The directions for use of wart remover drug products have been revised to be similar to those proposed in § 338.550(d) of the tentative final monograph for OTC corn and callus remover drug products.

(4) Other changes have been made to conform to the format and content of other recent OTC drug tentative final monographs, e.g., the provision for other truthful and nonmisleading statements has been included in the indications section.

(5) Because of the changes summarized above, many of the paragraphs within the various sections have been redesignated.

Interested persons may communicate with the agency about the submission of data and information relating to this notice by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

The agency has examined the economic consequences of this proposed rulemaking 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 proposed rule for

OTC wart remover drug products, is a major rule.

The agency has determined that 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.

Interested persons may, on or before May 26, 1987, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before July 27, 1987. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before March 27, 1988, may also submit in writing new data relating to this notice. Written comments on the new data may be submitted on or before May 27, 1988. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA–305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Data and comments submitted in response to the tentative final monograph for OTC wart remover drug products, published in the **Federal Register** of September 3, 1982 (47 FR 39102), have not yet been evaluated by the agency. Persons who previously submitted data and comments may wish to reevaluate them in light of this reproposed tentative final monograph.

Data and comments submitted in response to this reproposal as well as data and comments submitted in response to the tentative final monograph published in the **Federal Register** of September 3, 1982 (47 FR 39102), will be considered by the agency in establishing a final monograph. Data submitted after the closing of the administrative record on May 27, 1988, will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 358

Labeling, Over-the-counter drugs, Wart remover drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended by adding Part 358 (proposed in the **Federal Register** of September 3, 1982; 47 FR 39108), Subpart B to read as follows:

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

* * * * *

Subpart B—Wart Remover Drug Products

Sec.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

* * * * *

Subpart B—Wart Remover Drug Products

§ 358.101 Scope.

(a) An over-the-counter wart 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.

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

§ 358.103 Definitions.

As used in this subpart:

(a) *Wart remover drug product.* A topical agent used for the removal of common or plantar warts.

(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.

§ 358.110 Wart remover active ingredients.

The active ingredient of the product consists of any of the following when used within the specified concentration and in the dosage form established for each ingredient:

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

(b) Salicylic acid 5 to 17 percent in a collodion-like vehicle.

§ 358.150 Labeling of wart 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 "wart remover."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in this paragraph (b). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of 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 common warts. The common wart is easily recognized by the rough 'cauliflower-like' appearance of the surface."

(2) "For the removal of plantar warts on the bottom of the foot. The plantar wart is recognized by its location only on the bottom of the foot, its tenderness, and the interruption of the footprint pattern."

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

(1) *For products containing any ingredient identified in § 358.110.* (i) "For external use only."

(ii) "Do not use this product if you are a diabetic or have poor blood circulation, except under the advice and supervision of a doctor."

(iii) "Do not use on irritated skin or on any area that is infected or reddened."

(iv) "If discomfort persists, see your doctor."

(v) "Do not use on moles, birthmarks, warts with hair growing from them, genital warts, or warts on the face or mucous membraces."

(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 § 358.110(a).* "Wash affected area and dry thoroughly." (If appropriate: "Cut plaster to fit wart.") "Apply medicated plaster. Repeat procedure every 48 hours as needed (until wart is removed) for up to 12 weeks."

(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 wart. Let dry. Repeat this procedure once or twice daily as needed (until wart is removed) for up to 12 weeks."

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

(f) The phrase "or podiatrist" may be used in addition to the word "doctor" in any of the labeling statements in this section when a product is labeled with the indication identified in § 358.150(b)(2).

Dated: February 1, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 87-6703 Filed 3-26-87; 8:45 am]

BILLING CODE 4160-01-M