DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 80N–0238]

RIN 0905–AA06

Wart Remover Drug Products for Over-the-Counter Human use; Proposed Amendment of the Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the final monograph for over-the-counter (OTC) wart remover drug products to revise the directions for products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by March 29, 1994. Written comments on the agency's economic impact determination by March 29, 1994. FDA is proposing that any final rule that may issue based on this proposal become effective 12 months after the date of publication in the **Federal Register**.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 1990 (55 FR 33246), FDA issued a final monograph for OTC wart remover drug products (21 CFR part 358). The final monograph included in § 358.110(c) (21 CFR 358.110(c)) products containing 15 percent salicylic acid in a karaya gum, glycol plaster vehicle. Such products were included in the monograph based on the agency's evaluation of data from three clinical studies (Ref. 1) (see comment 13, 55 FR 33246 at 33253). The directions for such products were included in § 358.150(d)(3) (21 CFR 358.150(d)(3)), as follows:

"Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly." (If appropriate: "Cut plaster to fit wart.") "Apply medicated plaster at bedtime, leave in place for at least 8 hours; in the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

In discussing the labeling for these products (also in comment 13), the agency stated:

If there are any special directions that relate to using a particular product, then such information should appear as part of the manufacturer's additional directions for the product. The monograph provides the minimum directions necessary for use of the product. Manufacturers may supplement these directions with additional information necessary to use their specific product. For example, the agency notes that the manufacturer's directions for its specific product include statements to "keep plastic film on the top of pad facing up and to apply sticky bottom side to the wart." The agency finds no need to include such directions in this final monograph; however, manufacturers may add such information, as appropriate, to the labeling of their products.

Subsequently, the agency became aware that a manufacturer of this product had the following additional statements in its product's labeling (Ref. 2): (1) "Smooth wart surface with emery file supplied," and (2) "Apply a drop of warm water to the wart, keeping the surrounding skin dry." The agency has rereviewed the clinical studies (Ref. 1) for this product and determined that this additional labeling information is based on the manner in which the clinical studies were performed. The agency notes that use of an emery file and application of a drop of warm water to the wart site as part of the directions for this type of product were not included in the labeling suggestions made by the manufacturer when the final monograph was being prepared (see comment 13).

The agency is concerned that similar products in the marketplace may have different directions—some recommending use of an emery file and a drop of warm water to prepare the wart site and others not mentioning use of an emery file and a drop of warm water. The agency believes this situation could lead to consumer confusion. (Although the agency is aware of only one such marketed product, this does not rule out small volume operations and private label products.)

The clinical studies (Ref. 1) did not show that using an emery file and a drop of warm water were necessary to prepare the wart site before application of the medicated plaster. However, these studies also did not show that these procedures were not necessary, that any adverse effects occurred, or that any interference with the product's safety and effectiveness occurred when an emery file and a drop of warm water were used. Because the procedure used in the studies included the use of an emery file and a drop of warm water, the agency has determined that these items should be part of the directions for this product. The agency is also making a minor format revision in one sentence of the directions. Accordingly, the agency is proposing to amend the directions in § 358.150(d)(3) for 15 percent salicylic acid in a karaya gum, glycol plaster vehicle, to read as follows:

For products containing salicylic acid identified in § 358.110(c). "Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly. Gently smooth wart surface with emery file supplied." (If appropriate: "Cut plaster to fit wart.") "Apply a drop of warm water to the wart, keeping the surrounding skin dry. Apply medicated plaster at bedtime and leave in place for at least 8 hours. In the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

References

(1) Comment No. RPT2, Docket No. 80N–0238, Dockets Management Branch.

(2) Labeling for Trans-Ver-Sal, included in OTC Volume 16CFMA, Docket No. 80N–0238, Dockets Management Branch.

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 12866. The agency therefore concludes that no one of these rules, including this proposed rule amending the final monograph for OTC wart 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 wart remover drug products is not expected to pose such an impact on small business. The final rule may require some very minor relabeling; however, such relabeling should be a one time nominal cost. The agency is currently aware of only one such product in the marketplace, and it

already has this labeling. Other manufacturers who may market this product will have 1 year after publication of the final rule to implement this labeling. The cost to do so will be minimal. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC wart remover drug products. Types of impact may include, but are not limited to, costs associated with relabeling or repackaging. Comments regarding the impact of this rulemaking on OTC wart remover drug products should be accompanied by appropriate documentation. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

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.

Interested persons may, on or before March 29, 1994, submit written comments on the proposed regulation to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before March 29, 1994. Three copies of all comments are to be submitted, except that individuals may submit one copy. Comments and objections 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 358

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 358 be amended 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. Section 358.150 is amended by revising paragraph (d)(3) to read as follows:

§ 358.150 Labeling of wart remover drug products.

* * * * *

(d) * * *

(3) For products containing salicylic acid identified in § 358.110(c). "Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly. Gently smooth wart surface with emery file supplied." (If appropriate: "Cut plaster to fit wart.") "Apply a drop of warm water to the wart, keeping the surrounding skin dry. Apply medicated plaster at bedtime and leave in place for at least 8 hours. In the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

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Dated: September 13, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–1790 Filed 1–27–94; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MN–14–1; FRL–4830–2]

Approval and Promulgation of Implementation Plans; Minnesota

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Proposed rule.

SUMMARY: In this action, the USEPA is proposing to disapprove the revision to Minnesota's State Implementation Plan (SIP) for sulfur dioxide (SO_2) for the Dakota County/Pine Bend area of Air Quality Control Region 131. Assuming no other substantive, adverse public comments are received, the USEPA will proceed with a final approval of the submittal when the Minnesota Pollution Control Agency (MPCA) addresses the concerns detailed in this notice and submits the Administrative Orders to USEPA before the end of the 30-day comment period. The USEPA's action is based upon a revision request which was submitted by the State to satisfy the requirements of the Clean Air Act. The revisions are the result of a call for SIP revision issued by USEPA on December 5, 1984, based on monitored violations. The revisions in the Minnesota submittal are in the form of non-expiring Findings and Orders for Koch Refining Company and Koch Sulfuric Acid Unit, Continental Nitrogen and Resources Company, and Northern States Power Company–Inver Hills Generating Facility.

DATES: Comments on this requested revision and on the proposed USEPA action must be received by February 28, 1994.

ADDRESSES: Written comments should be addressed to: William L. MacDowell, Chief, Regulation Development Section, Air Enforcement Branch (AE–17J), United States Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Randy Robinson, Air Enforcement Branch, Regulation Development Section (AE–17J), U.S. Environmental Protection Agency, Region 5, Chicago, Illinois 60604, (312) 353–6713.

SUPPLEMENTARY INFORMATION:

I. Background

USEPA published the designation of Air Quality Control Region (AQCR) 131 as a primary nonattainment area for SO_2 on March 3, 1978, and October 5, 1978. In response to Part D requirements of the Clean Air Act, Minnesota Pollution Control Agency (MPCA) submitted a final SO_2 plan on August 4, 1980. USEPA published its final rule approving and promulgating the Minnesota Part D SIP for SO_2 for AQCR 131 on April 8, 1981 (46 FR 20996). On December 5, 1984 (49 FR 47488), USEPA issued a call for SIP revisions for the Minnesota SO_2 SIP for Dakota County declaring the SIP inadequate based on 1982 monitored violations. The SIP call required that the MPCA submit a revision to the Twin Cities SO_2 SIP demonstrating attainment of the SO_2 National Ambient Air Quality Standard (NAAQS) in the Pine Bend Area by September 1985.

The promulgation of a Good Engineering Practice stack height rule, along with difficulties negotiating a control strategy with Koch Refining Company, and the selection of an appropriate computer model, delayed the submittal. On September 10, 1987, the MPCA submitted revisions to the operating permits for five sources and requested redesignation to attainment for all of AQCR 131 except the Pine Bend and St. Paul Park areas.

As a result of numerous USEPA comments, MPCA withdrew the Pine Bend SO_2 SIP while passage of the 1990 Clean Air Act Amendments delayed