(b) *Call for information.* Upon call by the Commission, the Director of the Division of Economic Analysis or the Director's delegee, any person claiming an exemption from speculative position limits under this section must provide to the Commission such information as specified in the call relating to the positions owned or controlled by that person; trading done pursuant to the claimed exemption; the futures, options or cash market positions which support the claim of exemption; and the relevant business relationships supporting a claim of exemption.

Issued in Washington, DC, this 18th day of September 1992, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 92-23223 Filed 9-25-92; 8:45 am]

BILLING CODE 6351-01-M

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; Updating and Technical Changes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the regulations that establish conditions under which over-the-counter (OTC) corn and callus remover drug products are generally recognized as safe and effective and not misbranded. These amendments will update the regulations, by making noncontroversial technical changes in the labeling of those products, to clarify that products contained in a collodion-like vehicle may be applied to the corn and callus with an applicator or a brush. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Effective on October 28, 1992; written comments by November 27, 1992; written comments on the agency's economic impact determination by November 27, 1992.

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, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 1990 (55 FR 33258), FDA issued a final rule for OTC corn and callus remover drug products (21 CFR part 358) that specified the following directions statement for these drug products in a collodion-like vehicle under § 358.550(d)(2) (21 CFR 358.550 (d)(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.")

This final rule revises the wording in these directions to provide for the use of an applicator or a brush, if appropriate, in applying the product. Gelled or highly viscous collodion-like formulations may be more appropriately applied by a brush than an applicator such as a dropper or glass rod. This provision allows for appropriate labeling of OTC corn and callus remover drug products based on the physical characteristics of the product. Also, clinical studies have been conducted in which a brush applicator was used to apply the salicylic acid in a collodion-like vehicle to the affected area (Refs. 1 and 2). The revised directions for using OTC corn and callus remover drug products in a collodion-like vehicle in § 358.550(d)(2) now read:

For products containing salicylic acid identified in § 358.510(b). "Wash affected area and dry thoroughly. Apply" (select one of the following, as appropriate: "one drop" or "small amount") "at a time with" (select one of the following, as appropriate: "applicator" or "brush") "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.")

This labeling revision represents a minor clarifying change that does not change the substance of the labeling requirements contained in the final regulations. Therefore, the agency has determined that this labeling revision does not need to be implemented on the effective date of this final rule. Manufacturers may implement the revision at the next printing of labels for affected products.

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 no one of these rules, including this final rule amending the final monograph 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 business. The only requirement is a minor optional labeling revision if desired, and the agency is allowing this revision to be made at the manufacturer's next printing of labels for affected products. 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.

As noted previously, this final rule institutes a change that is nonsubstantive in nature. Because the revision is not controversial and because, when effective, it provides clarification of a final OTC drug monograph, FDA finds that the usual notice and comment procedures are unnecessary and not in the public interest. The final rule, therefore, shall become effective on October 28, 1992. However, interested persons may, on or before November 27, 1992, submit written comments on this final rule, including the agency's economic impact determination, to the Dockets

Management Branch (address above). Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

References

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

(2) "Supplemental Efficacy Data for Study 83–07" identified as Exhibit #21, dated February 26, 1985, included in OTC Volume 16CFM, Docket No. 80N–0238, Dockets Management Branch.

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, 21 CFR part 358 is amended as follows:

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

1. The authority citation for 21 CFR part 358 is revised 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 358.550 is amended by revising paragraph (d)(2) to read as follows:

§ 358.550 Labeling of corn and callus remover drug products.

* * * * *

(d) * * *

(2) *For products containing salicylic acid identified in § 358.510(b).* "Wash affected area and dry thoroughly. Apply" (select one of the following, as appropriate: "one drop" or "small amount") "at a time with" (select one of the following, as appropriate: "applicator" or "brush") "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.")

* * * * *

Dated: September 9, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92–23446 Filed 9–25–92; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 358

[Docket No. 80N–0238]

RIN 0905–AA06

Wart Remover Drug Products for Over-the-Counter Human Use; Final Monograph; Updating and Technical Changes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the regulations that establish conditions under which over-the-counter (OTC) wart remover drug products are generally recognized as safe and effective and not misbranded. These amendments will update the regulations, by making noncontroversial technical changes in the labeling of those products, to clarify that products contained in a collodion-like vehicle may be applied to the wart with an applicator or a brush. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Effective on October 28, 1992; written comments by November 27, 1992; written comments on the agency's economic impact determination by November 27, 1992.

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, 301–295–8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 1990 (55 FR 33246), FDA issued a final rule for OTC wart remover drug products (21 CFR part 358) that specified the following directions statement for these drug products marketed in a collodion-type vehicle under § 358.150(d)(2) (21 CFR 358.150 (d)(2)):

For products containing salicylic acid identified in § 358.110(b). "Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area 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."

This final rule revises the wording in these directions to provide for the use of an applicator or a brush, as appropriate, in applying the product. Gelled or highly viscous collodion-like formulations may be more appropriately applied by a brush than an applicator such as a dropper or glass rod. This provision allows for appropriate labeling of OTC wart remover drug products based on the physical characteristics of the product. Also, clinical studies have been conducted in which a brush applicator was used to apply the salicylic acid in a collodion-like vehicle to the affected area (Refs. 1 and 2). The revised directions for use for OTC wart remover drug products in a collodion-like vehicle in § 358.150(d)(2) now read:

For products containing salicylic acid identified in § 358.110(b). "Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly Apply" (select one of the following, as appropriate: "one drop" or "small amount") "at a time with" (select one of the following, as appropriate: "applicator" or "brush") "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."

This labeling revision represents a minor clarifying change that does not change the substance of the labeling requirements contained in the final regulations. Therefore, the agency has determined that this labeling revision does not need to be implemented on the effective date of this final rule. Manufacturers may implement the revision at the next printing of labels for affected products.

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 no one of these rules, including this final 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 only requirement is a minor optimal labeling