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

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 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)(2) to read as follows:

§ 358.150 Labeling of wart remover drug products.

* * * * *

(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" (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."

* * * * *

Dated: September 9, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-23447 Filed 9-25-92; 8:45 am]

BILLING CODE 4160-01-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 58

[MI12-5586; FRL-4513-3]

Modification of the Ozone Monitoring Season; Michigan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Ozone (O_3) is required to be monitored at National Air Monitoring Stations (NAMS) and State and Local Air Monitoring Stations (SLAMS) only during the "ozone season" as designated in the Aerometric Information Retrieval System (AIRS) files on a state by state basis. Previously, the ozone season for Michigan had been designated as April 1 through October 31. A review of monitoring data for the past 5 years revealed that high ozone concentrations do not occur during the month of October in Michigan. Therefore, pursuant to 40 CFR 58.13(a)(3), USEPA agreed with the State's request to modify its ozone season and has determined that Michigan is now subject to an April-September monitoring timeframe. The modified ozone season will apply to 1992 ozone monitoring data and future monitoring efforts unless otherwise revised.

EFFECTIVE DATE: This action will be effective November 27, 1992 unless notice is received within 30 days that someone wishes to submit adverse or critical comments. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Camille Szematowicz, Air Toxics and Radiation Branch, Regulation Development Section, U.S. Environmental Protection Agency, Region 5, Chicago, Illinois 60604, (312) 886-6081.

SUPPLEMENTARY INFORMATION: The State of Michigan monitors for ozone and submits data to AIRS as required to determine the air quality and attainment status of metropolitan areas, and to recognize trends in air quality. 40 CFR 58.13(a)(3) provides that the Regional Administrator may exempt periods or seasons from consecutive hourly averages for continuous State and Local Air Monitoring Station (SLAMS) analyzers. Part 58 appendix D, lists the current ozone season on a state by state basis. The Michigan season is listed as April through October.

On February 28, 1992, the Michigan Department of Natural Resources (MDNR) requested that USEPA modify the State's current ozone season to the period April 1 through September 30. In order to support its position the State submitted 5 years of air monitoring data for the month of October. USEPA has reviewed the State's submittal in accordance with the Office of Air Quality Planning and Standards (OAQPS) document "Guideline on Modification to Monitoring Seasons for Ozone" (March 1990). Consistent with the guidelines, Michigan's air monitoring data indicates that for the five most recent years (1987-1991), there have been no recorded ozone concentrations above the 0.100 ppm guideline during the month of October. USEPA approved Michigan's request to eliminate the month of October from its official monitoring season, and as required by the above mentioned guidance document, OAQPS concurred on this approval on May 29, 1992. Valdas V. Adamkus, Regional Administrator,