Dated: May 25, 1994.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 94–13587 Filed 6–2–94; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 346

[Docket No. 80N–0050]

RIN 0905–AA06

Anorectal Drug Products for Over-the-Counter Human Use; Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule with opportunity for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the monograph for over-the-counter (OTC) anorectal drug products. This amendment updates the monograph to incorporate a United States Pharmacopeia (U.S.P.) name change for an active ingredient included in the monograph. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: This final rule is effective January 1, 1995; written comments by August 17, 1994.

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 3, 1990 (55 FR 31776), FDA issued a final monograph for OTC anorectal drug products (21 CFR part 346). That monograph included "Hamamelis water, 'The National Formulary XI' " as an active ingredient in § 346.18(b). "Hamamelis water" was also cited in §§ 346.50 (b)(2)(vi) and (d)(8). Because Hamamelis water had last been included in an official compendium in The National Formulary XI (Ref. 1), it was named in this manner in § 346.18(b).

In 1993 (Refs. 2 and 3), Hamamelis water was proposed for inclusion in U.S.P. XXIII, which becomes official on January 1, 1995. The proposed official name was subsequently changed from "Hamamelis water" to "Witch Hazel" (Ref. 3). To be consistent with the change in compendial status and to give manufacturers advance notice of the need for revised labeling, the agency is changing the name of the ingredient "Hamamelis water" to "witch hazel" in the final monograph for OTC anorectal drug products. These changes will occur in § 346.18(b) in the ingredient listing and in § 346.50 in the introductory text of paragraphs (b)(2)(vi) and (d)(8). These changes will become effective on January 1, 1995.

The amendment will require revised product labeling to substitute witch hazel for hamamelis water. This labeling revision represents a minor clarifying change that does not change the substance of the labeling requirements contained in the final regulations. Because sections 502 (e)(1) and (e)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352 (e)(1) and (e)(3)) require the established name of a drug to be used, any "witch hazel" drug product initially introduced or initially delivered for introduction into interstate commerce after January 1, 1995, will need to bear the new established name "witch hazel."

As noted previously, these changes make the final monograph for OTC anorectal drug products consistent with a change being implemented in the official compendium (U.S.P.). Because the name change follows from a U.S.P. change, the Commissioner has determined that notice and comment are unnecessary (5 U.S.C. 553(b); 21 CFR 10.40(e)(1)). Therefore, publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). This final rule shall become effective on January 1, 1995.

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In this final rule, the labeling change could be implemented by manufacturers at very little cost at the next printing of labels. There are only a few manufacturers of products containing this ingredient. Accordingly, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency invites public comment regarding any economic impact that this rulemaking would have on the labeling of OTC drug products. Types of impact may include, but are not limited to, costs associated with relabeling. Comments regarding the impact of this final rule on OTC drug products should be accompanied by appropriate documentation. The agency will consider any comments to determine whether the regulation should subsequently be modified.

Interested persons may, on or before August 17, 1994, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Written comments on the agency's economic impact determination may be submitted on or before August 17, 1994. Three copies of all 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 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.

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.

References

(1) "The National Formulary," 11th ed., Mack Publishing Co., Easton, PA, p. 158, 1960.

(2) "Pharmacopeial Forum," The United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 5266–5268, May and June 1993.

(3) "Pharmacopeial Forum," The United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 6399–6401, November and December 1993.

List of Subjects in 21 CFR Part 346

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 346 is amended as follows:

PART 346—ANORECTAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 346 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 346.18 *Astringent active ingredients* is amended by revising paragraph (b) to read as follows:

§ 346.18 Astringent active ingredients.

* * * * *

(b) Witch hazel, 10 to 50 percent.

* * * * *

§ 346.50 [Amended]

3. Section 346.50 *Labeling of anorectal drug products* is amended in the heading of paragraph (b)(2)(vi) by removing the words "hamamelis water" and adding in their place the words "witch hazel"; and in the heading of paragraph (d)(8) by removing the words "hamamelis water" and adding in their place the words "witch hazel".

Dated: May 16, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94-13592 Filed 6-2-94; 8:45 am]

BILLING CODE 4160-01-F-M

---

21 CFR Part 347

RIN 0905-AA06

[Docket No. 78N-021A]

Skin Protectant Drug Products for Over-The-Counter Human Use; Astringent Drug Products; Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule with opportunity for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the monograph for over-the-counter (OTC) astringent drug products. This amendment updates the monograph to incorporate a United States Pharmacopeia (U.S.P.) name change for an active ingredient included in the monograph. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: This final rule is effective January 1, 1995; written comments by August 17, 1994.

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 October 21, 1993 (58 FR 54458), FDA issued a final monograph for OTC astringent skin protectant drug products (21 CFR part 347, subpart A). That monograph included "Hamamelis water, U.S.P." as an active ingredient in § 347.10(c). "Hamamelis water" was also cited in §§ 347.50(b)(3) and (d)(3). The designation "U.S.P." was included in § 347.10(c) because the agency anticipated that a final compendial (U.S.P.) monograph would be established for the ingredient prior to the effective date of the final monograph for OTC astringent skin protectant drug products (58 FR 54458 at 54460). Hamamelis water had last been included in an official compendium in The National Formulary XI (Ref. 1).

In 1993 (Refs. 2 and 3), Hamamelis water was proposed for inclusion in U.S.P. XXIII, which becomes official on January 1, 1995. The proposed official name was subsequently changed from "Hamamelis water" to "Witch Hazel" (Ref. 3). To be consistent with the change in compendial status and to give manufacturers advance notice of the need for revised labeling, the agency is changing the name of the ingredient "Hamamelis water" to "witch hazel" in the final monograph for OTC astringent skin protectant drug products. These changes will occur in § 347.10(c) in the ingredient listing and in § 347.50 in the introductory text of paragraphs (b)(3), (c)(2), and (d)(3). These changes will become effective on January 1, 1995.

The amendment will require revised product labeling to substitute witch hazel for hamamelis water. This labeling revision represents a minor clarifying change that does not change the substance of the labeling requirements contained in the final regulations. Because sections 502(e)(1) and (e)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(e)(1) and (e)(3)) require the established name of a drug to be used, any witch hazel drug product initially introduced or initially delivered for introduction into interstate commerce after January 1, 1995, will need to bear the new established name "witch hazel."

As noted previously, these changes make the final monograph for OTC astringent skin protectant drug products consistent with a change being implemented in the official compendium (U.S.P.). Because the name change follows from a U.S.P. change, the Commissioner has determined that notice and comment are unnecessary (5 U.S.C. 553(b); 21 CFR 10.40(e)(1)). Therefore, publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). This final rule shall become effective on January 1, 1995.

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In this final rule, the labeling change could be implemented by manufacturers at very little cost at the next printing of labels. There are only a few manufacturers of products containing this ingredient. Accordingly, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency invites public comment regarding any economic impact that this final rule would have on the labeling of OTC drug products. Types of impact may include, but are not limited to, costs associated with relabeling. Comments regarding the impact of this final rule on OTC drug products should be accompanied by appropriate documentation. The agency will consider any comments to determine whether the regulation should subsequently be modified.

Interested persons may, on or before August 17, 1994, submit to the Dockets Management Branch (address above) written comments regarding this final