DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR PART 348

[Docket No. 78N-0301]

External Analgesic 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 notice of proposed rulemaking in the form of an amended tentative final monograph that modifies the indications for which over-the-counter (OTC) hydrocortisone-containing external analgesic drug products are generally recognized as safe and effective and not misbranded, by including additional warnings and directions for products labeled for "external anal itching." FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Hemorrhoidal Drug Products and public comments on the advance notice of proposed rulemaking for OTC anorectal drug products that was based on those recommendations. The agency's proposal concerning OTC anorectal drug products was published in the **Federal Register** of August 15, 1988; (53 FR 30756). These proposals are 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 October 24, 1988. New data by August 25, 1989. Comments on the new data by October 25, 1989. 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 December 21, 1988.

ADDRESS: Written comments, objections, new data, 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 Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 4, 1979 (44 FR 69768), 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 external analgesic drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (Topical Analgesic Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these drug classes. Interested persons were invited to submit comments by March 6, 1980. Reply comments in response to comments filed in the initial comment period could be submitted by April 3, 1980.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC external analgesic drug products was published in the **Federal Register** of February 8, 1983 (48 FR 5852).

In the **Federal Register** of May 27, 1980 (45 FR 35576), 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 anorectal drug products, together with the recommendations of the Advisory Review Panel on OTC Hemorrhoidal Drug Products (Hemorrhoidal Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in that drug class. Interested persons were invited to submit comments by August 25, 1980. Reply comments in response to comments filed in the initial comment period could be submitted by September 24, 1980.

In accordance with § 330.10(a)(10), the data and information considered by the Panels were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

In response to the advance notice of proposed rulemaking on OTC anorectal drug products, one comment pointed out that the Panel did not consider the status of hydrocortisone for use in OTC anorectal drug products and requested that this use be clarified because another Panel's recommended labeling for OTC external analgesic drug products containing hydrocortisone included a claim "for itchy genital and anal areas." (See comment 25 in the Notice of Proposed Rulemaking for OTC Anorectal Drug Products published in the **Federal Register** of August 15, 1988; (53 FR 30756 at 30766) and the Notice of Proposed Rulemaking for OTC External Analgesic Drug Products (48 FR 5852).)

In this tentative final monograph (proposed rule) that amends Part 348 (as proposed in the **Federal Register** of February 8, 1983; 48 FR 5852), FDA states for the first time its position that the labeling of OTC hydrocortisone-containing external analgesic drug products for "external anal itching" should be consistent with the general warnings and directions for all OTC anorectal drug products. Accordingly, the agency is amending the tentative final monograph for OTC external analgesic drug products to include for hydrocortisone-containing products the warnings and directions proposed in § 346.50(c)(2), (3), and (4), and (d)(1) of the tentative final monograph for OTC anorectal drug products, published in the **Federal Register** of August 15, 1988; (53 FR 30756 at 30783 and 30784).

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 no one of these rules, including this proposed rule for OTC external analgesic 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 external analgesic drug products is not expected to pose such an impact on small businesses. 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 substanital or significant economic impact that this rulemaking would have on OTC external analgesic drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling repackaging, or reformulating.

Comments regarding the impact of this rulemaking on OTC external analgesic drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on OTC external analgesic drug products, a period of 120 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. 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 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 October 24, 1988, 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 December 21, 1988. 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 brakcets 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 August 25, 1989, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before October 25, 1989. 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.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on October 25, 1989. Data submitted after the closing of the administrative record 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 348

External analgesic drug products, Labeling, Over-the-counter drugs.

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 in Part 348 as follows:

PART 348—EXTERNAL ANALGESIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 348 is revised to read as follows:

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.

2. In Subpart C, § 348.50 (c)(9) and (d)(3) are added to read as follows:

§ 348.50 Labeling of external analgesic drug products.

* * * * *

(c) * * *

(9) *For products containing hydrocortisone preparations identified in § 348.10(d) (1) and (2) that are labeled with the indication "* * * for external anal itching."* In addition to the warnings in paragraph (c)(1) of this section, the labeling of the product also contains the warnings proposed in § 246.50(c) (2), (3), and (4) of this chapter. (See the **Federal Register** of August 15, 1988; 53 FR 30756.)

(d) * * *

(3) *For products containing hydrocortisone preparations identified in § 348.10(d) (1) and (2).* In addition to the applicable directions in paragraph (d)(1) of this section, the labeling of the product also contains the directions proposed in § 346.50(d)(1) of this chapter. (See the **Federal Register** of August 15, 1988; 53 FR 30756.)

Dated: April 28, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

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