(c) for the control of seborrheic dermatitis or psoriasis. "If condition covers a large area of the body, consult your doctor before using this product."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions". More detailed directions applicable to a particular product formulation may also be included.

(1) *For products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated to be applied and then washed off after brief (a few minutes) exposure (e.g., shampoos, preshampoo rinses, postshampoo rinses).* "For best results use at least twice a week or as directed by a doctor."

(2) *For products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated so as to be applied and left on the skin or scalp (e.g., creams, ointments, lotions, hairgrooms).* "Apply to affected areas one to four times daily or as directed by a doctor."

(3) *For products containing active ingredients for the control of seborrheic dermatitis or psoriasis of the skin when formulated as soaps.* "Use on affected areas in place of your regualr soap."

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

(f) *Other allowable statements.* The following phrases are considered truthful and nonmisleading and may be used elsewhere in the labeling in place of the term "For the relief of" or "Controls" in the indication statements identified in paragraph (b) of this section: "fights," "reduces," "helps eliminate," "helps stop," "controls recurrence of," "fights recurrence of," "helps prevent recurrence of," "reduces recurrence of," "helps eliminate recurrence of," "helps stop recurrence of."

§ 358.752 Labeling of drug products for the control of cradle cap.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as "cradle cap (insert product form)."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "Relieves scaly inflammation of the scalp associated with cradle cap." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed above, may also be used, as provided in § 330.1(c)(2), subject to the provisions in section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only."

(2) "Avoid contact with the eyes—if this happens, rinse thoroughly with water."

(3) "If condition worsens or does not improve after regular use of this product as directed, consult a doctor."

(d) *Directions.* [Reserved]

(e) The word "physician" may be substituted for the wold "doctor" in any of the labeling statements in this section.

Dated: May 3, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

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21 CFR Part 348

[Docket No. 78N-0301]

External Analgesic Drug Products for Over-the-Counter Human Use; Amendment to Tentative Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Further 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 adding an indication for use in the symptomatic treatment of seborrheic dermatitis and psoriasis. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products and public comments on the advance notice of proposed rulemaking for OTC dandruff, seborrheic dermatitis, and psoriasis drug products that was based on those recommendations. The agency's proposal concerning OTC dandruff, seborrheic dermatitis, and psoriasis drug products is being published elsewhere in this issue of the **Federal Register.** 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 September 29, 1986. New data by July 30, 1987. Comments on the new data by September 30, 1987. 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 November 28, 1986.

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 Drugs and Biologics (HFN-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 reponse 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 December 3, 1982 (47 FR 54646), 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 dandruff, seborrheic dermatitis, and psoriasis drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External 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 3, 1983. Reply comments in response to comments filed in the initial comment period could be submitted by April 4, 1983.

In accordance with § 330.10(a)(10), the data and information considered by the Panel 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 this tentative final monograph (proposed rule) to amend Part 348 (as proposed in the **Federal Register** of February 8, 1983; 48 FR 5852), FDA states for the first time its position on the use of OTC hydrocortisone-containing external analgesic drug products for the relief of symptoms associated with seborrheic dermatitis and psoriasis. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC external analgesic drug products.

This proposal constitutes FDA's tentative adoption of the Miscellaneous External Panel's conclusions and recommendations on OTC drug products containing hydrocortisone and hydrocortisone acetate for the symptomatic relief of seborrheic dermatitis and psoriasis as modifed on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above).

The OTC procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

A. The Agency's Tentative Adoption of the Panel's Report

1. *Summary of the agency's changes in the Panel's recommendations.* The agency has reviewed the Miscellaneous External Panel's recommendations regarding the use of OTC drug products containing 0.25 to 1 percent hydrocortisone for the relief of symptoms associated with seborrheic dermatitis and psoriasis. As discussed in comment 13 of the tentative final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products (published elsewhere in this issue of the **Federal Register**), the agency has tentatively concluded that data support the general recognition of the safety and effectiveness of using hydrocortisone and hydrocortisone acetate in providing temporary symptomatic relief of the symptoms associated with seborrheic dermatitis and psoriasis. The agency also noted that 0.25 to 0.5 percent concentrations of hydrocortisone and hydrocortisone acetate were determined to be generally recognized as safe and effective ingredients for OTC use in relieving the symptoms associated with a variety of dermatoses as part of the tentative final monograph for OTC external analgesic drug products. The agency further stated that it would be more appropriate to amend the tentative final monograph for OTC external analgesic drug products to add seborrheic dermatitis and psoriasis to the list of conditions for which hydrocortisone has been found to be safe and effective in providing symptomatic relief rather than to include hydrocortisone as an ingredient in the tentative final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products. Therefore, the agency is amending the tentative final monograph for OTC external analgesic drug products to revise the indications for use for hydrocortisone and hydrocortisone acetate to include seborrheic dermatitis and psoriasis to the list of conditions for which these ingredients have been found to be safe and effective in providing symptomatic relief. The agency is not amending the external analgesic tentative final monograph to include concentrations greater than 0.5 to 1 percent at this time. At a later date, the agency will consider the request that concentrations of hydrocortisone greater than 0.5 up to 1 percent be included in the final rule for OTC external analgesic drug products. Hydrocortisone preparations remain in Category III for the treatment of dandruff.

2. *Testing of Category II and Category III conditions.* Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any external analgesic ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

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, Public Law 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 substantial 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 external analgesic drug products for use in the treatment of seborrheic dermatitis and psoriasis, 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 previously invited public comment in the advance notice of proposed rulemaking for OTC dandruff, seborrheic dermatitis and psoriasis drug products regarding any impact that that rulemaking would have on OTC dandruff, seborrheic dermatitis, and psoriasis drug products. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by November 28, 1986. 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) (April 26, 1985; 50 FR 16636) 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.

Exclusivity of Labeling

In the **Federal Register** of April 22, 1985 (50 FR 15810) the agency proposed to change its "exclusivity" policy for the labeling of OTC drug products that has existed during the course of the OTC drug review. Under that policy, the agency had maintained that the terms used in an OTC drug product's labeling were limited to those terms included in a final OTC drug monograph.

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing the exclusivity policy and establishing three alternatives for stating the indications for use in OTC drug labeling. Under the final rule, the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All required OTC drug labeling other than indications for use (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under an OTC drug monograph. The proposed rule in this document is subject to the final rule revising the exclusivity policy.

Interested persons may, on or before September 29, 1986, 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 November 28, 1986. 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 brackets 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 July 30, 1987, 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 September 30, 1987. 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 Docket 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 September 30, 1987. 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

OTC drugs, External analgesic drug products.

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 proposed in the **Federal Register** of February 8, 1983; 48 FR 5852, as follows:

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

1. The authority citation for Part 348 would be 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 5.11.

2. In Subpart C, § 348.50(b) introductory text, (b)(3) introductory text, (3) (i) and (ii) would be revised to read as follows:

§ 348.50 Labeling of external analgesic drug products.

* * * * *

(b) *Indications.* The labeling of the product states, under the heading "Indication(s)," any of the phrases listed in this paragraph, as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed below, may also be used, as provided in § 330.1(c)(2), subject to the provisions in section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

* * * * *

(3) *For products containing any external analgesic active ingredients indentified in § 348.10(d).* The labeling of the product contains one of the following indications: (i) "For the temporary relief of itching associated with minor skin irritations and rashes" [which may be followed by: "due to" (select one or more of the following: "eczema," "insect bites," "poison ivy, poison oak, or poison sumac," "soaps," "detergents," "cosmetic," "jewelry," "seborrheic dermatitis," "psoriasis") and/or ("and for external" (select one or more of the following: "genital," "feminine," and "anal") "itching")].

(ii) "For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to" (select one or more of the following: "eczema," "insect bites," "poison ivy, poison oak, or poison sumac," "soaps," "detergents," "cosmetics," "jewelry," "seborrheic dermatitis," "psoriasis") and/or ("and for external" (select one or more of the following: "genital," "feminine," and "anal") "itching").

Dated: May 3, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

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