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 antiemetic drug products is not expected to pose such an impact on small business. There will be a minor, one-time labeling revision, which manufacturers will have 1 year to implement. Therefore, the agency certifies that this proposed rule 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 antiemetic drug products. Comments regarding the impact of this rulemaking on OTC antiemetic drug products should be accompanied by appropriate documentation.

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.

Interested persons may, on or before October 25, 1993, submit written comments or objections on the proposed regulation to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before October 25, 1993. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections 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 and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 336

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, it is proposed that 21 CFR part 336 be amended as follows:

PART 336—ANTIEMETIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 336 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 336.50 is amended by revising paragraph (c)(1) to read as follows:

§ 336.50 Labeling of antiemetic drug products.

* * * * *

(c) * * *

(1) *For products containing any ingredient identified in § 336.10*—(i) *When labeled for use in adults and for those products that can be and are labeled for use in children under 12 years of age.* "Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland."

(ii) *For those products that can be and are labeled only for children under 12 years of age.* "Do not give this product to children who have a breathing problem such as chronic bronchitis or who have glaucoma, without first consulting the child's doctor."

* * * * *

Dated: August 19, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93-20696 Filed 8-25-93; 8:45 am]

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21 CFR Part 338

[Docket No. 92N-0349]

RIN 0905-AA06

Nighttime Sleep-Aid Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the monograph for over-the-counter (OTC) nighttime sleep-aid drug products to revise a warning required for products that contain diphenhydramine citrate or diphenhydramine hydrochloride. This proposal will ensure that warnings are the same for diphenhydramine salts whether the ingredient is used in OTC nighttime sleep-aid, antihistamine, or antitussive drug products. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments on the proposed regulation by October 25, 1993; written comments on the agency's economic impact determination by October 25, 1993.

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 February 14, 1989 (54 FR 6814), FDA issued a final monograph for OTC nighttime sleep-aid drug products (21 CFR part 338) that included the following warning statement in § 338.50(c)(3) (21 CFR 338.50(c)(3)) for products containing diphenhydramine salts: "Do not take this product if you have asthma, glaucoma, emphysema, chronic pulmonary disease, shortness of breath, difficulty in breathing, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

In § 341.72 of the tentative final monograph for OTC antihistamine drug products, published in the **Federal Register** of January 15, 1985 (50 FR 2200 at 2215), the agency proposed this same warning for all OTC antihistamines. Antihistamines should not be used by people who have any obstructive pulmonary disease in which clearance of secretions is a problem. The agency stated that respiratory distress symptoms, such as difficulty in breathing and shortness of breath, are characteristic of chronic obstructive pulmonary disease. The agency concluded that such descriptive terms should be included in the warning in addition to the names of the diseases, in order to provide more information to the consumer.

In the final monograph for OTC antihistamine drug products, published in the **Federal Register** of December 9, 1992 (57 FR 58356 at 58374), the agency revised this warning to include the broader phrase "breathing problem" to describe symptoms such as shortness of breath and difficulty in breathing related to obstructive pulmonary disease. The change in wording will allow consumers to recognize respiratory distress symptoms more readily. The agency also removed the descriptive term "asthma" from the warning and replaced the term "chronic pulmonary disease" with the term "chronic bronchitis." The revised warning, which appears in § 341.72(c)(2) of the final monograph (21 CFR 341.72(c)(2)), reads as follows: "Do not take this product, unless directed by

a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland."

In the **Federal Register** of December 9, 1992 (57 FR 58378), the agency proposed to amend the monograph for OTC antitussive drug products to include diphenhydramine citrate and diphenhydramine hydrochloride as active ingredients. The agency also proposed that the revised warning in § 341.72(c)(2) of the antihistamine final monograph be used for OTC drug products containing diphenhydramine as an antitussive. The agency is now proposing that the existing warning for diphenhydramine used as an OTC nighttime sleep-aid, which appears in § 338.50(c)(3), be revised to be the same as the warning in § 341.72(c)(2) for OTC antihistamine drug products and in proposed § 341.74(c)(4)(vii)(a) for OTC antitussive drug products.

The agency has examined the economic consequences of this proposed rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the 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 nighttime sleep-aid 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 nighttime sleep-aid drug products is not expected to pose such an impact on small business. There will be a minor, one-time labeling revision, which manufacturers will have 1 year to implement. Therefore, the agency certifies that this proposed rule 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 nighttime sleep-aid drug products. Comments regarding the impact of this rulemaking on OTC nighttime sleep-aid drug products should be accompanied by appropriate documentation.

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.

Interested persons may, on or before October 25, 1993, submit written comments or objections on the proposed regulation to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before October 25, 1993. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections 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 and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 338

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, it is proposed that 21 CFR part 338 be amended as follows:

PART 338—NIGHTTIME SLEEP–AID DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

1. The authority citation for 21 CFR part 338 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 338.50 is amended by revising paragraph (c)(3) to read as follows:

§ 338.50 Labeling of nighttime sleep-aid drug products.

* * * * *

(c) * * *(3) "Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland."

* * * * *

Dated: August 19, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

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