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 August 26, 1993 (58 FR 45216 and 45217), the agency proposed to revise the same warning in § 336.50(c)(1) for diphenhydramine and the other antiemetic ingredients listed in § 336.10 (21 CFR 336.10) (58 FR 45216 at 45217) and the same warning in § 338.50(c)(3) (21 CFR 338.50(c)(3)) for diphenhydramine used as an OTC nighttime sleep-aid (58 FR 45217 at 45218) to be consistent with the warning in § 341.72(c)(2) for OTC antihistamine drug products.

No comments were received in response to the proposed monograph amendment. Therefore, the agency is finalizing the amendment as proposed. Elsewhere in this issue of the **Federal Register**, the agency is also finalizing the amendment to the final monograph for OTC nighttime sleep-aid drug products mentioned above.

In the proposal (58 FR 45216 at 45217), the agency advised that any final rule resulting from the proposal would be effective 12 months after its date of publication in the **Federal Register**. Therefore, on or after April 11, 1995, any OTC drug product that is not in compliance with the final rule may not 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 the rule that is repackaged or relabeled after the effective date of the rule must be in compliance with the rule 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 rule at the earliest possible date.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (58 FR 45216 at 45217). The agency has examined the economic consequences of this final rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12866, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). This rulemaking for OTC antiemetic drug products is not expected to have an impact on small businesses. This final rule will require a minor, one-time labeling revision, which manufacturers will have 1 year to implement. The impact of this final rule appears to be minimal. Therefore, the agency concludes that this final rule is not a major rule as defined in Executive Order 12866. Further, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

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.

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, 21 CFR part 336 is 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: March 4, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–8511 Filed 4–8–94; 8:45 am]

BILLING CODE 4160–01–F

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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; Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend the final 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 final rule 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 final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: April 11, 1995.

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 August 26, 1993 (58 FR 45216 and 45217), the agency proposed to revise the same warning in § 336.50(c)(1) (21 CFR 336.50(c)(1)) for diphenhydramine and the other antiemetic ingredients listed in § 336.10 (21 CFR 336.10) (58 FR 5216 at 45217) and the same warning in § 38.50(c)(3) for diphenhydramine used as an OTC nighttime sleep-aid (58 FR 45217 at 45218) to be consistent with the warning in § 341.72(c)(2) for OTC antihistamine drug products.

No comments were received in response to the proposed monograph amendment. Therefore, the agency is finalizing the amendment as proposed. Elsewhere in this issue of the **Federal Register**, the agency is also finalizing the amendment to the final monograph for OTC antiemetic drug products mentioned above.

In the proposal (58 FR 45217 at 45218), the agency advised that any final rule resulting from the proposal would be effective 12 months after its date of publication in the **Federal Register**. Therefore, on or after April 11, 1995, any OTC drug product that is not in compliance with the final rule may not 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 the rule that is repackaged or relabeled after the effective date of the rule must be in compliance with the rule 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 rule at the earliest possible date.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (58 FR 45217 at 45218). The agency has examined the economic consequences of this final rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12866, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). This rulemaking for OTC nighttime sleep-aid drug products is not expected to have an impact on small businesses. This final rule will require a minor, one-time labeling revision, which manufacturers will have 1 year to implement. The impact of this final rule appears to be minimal. Therefore, the agency concludes that this final rule is not a major rule as defined in Executive Order 12866. Further, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

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.

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, 21 CFR part 338 is 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 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: March 4, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–8533 Filed 4–8–94; 8:45 am]

BILLING CODE 4160–01–F

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

[Rulemaking No. 102]

Camp Counselors; Limitation of Program Participation

AGENCY: United States Information Agency.

ACTION: Interim rule with request for comments.

SUMMARY: The Agency hereby amends existing regulations governing camp counselor exchanges in order to permit a limited opportunity for program participation in excess of two summers.

DATES: This interim rule will take effect April 11, 1994. The Agency will accept written comments regarding this rule for thirty days from date of publication.

ADDRESSES: Comments regarding this rule should be addressed as follows: United States Information Agency, Office of the General Counsel, Rulemaking 102, 301 4th Street, SW., Washington, DC 20547.