policy, generally follows the Administrative Procedure Act (APA) Notice of Proposed Rulemaking and public comment procedures specified in 5 U.S.C. 553 in the development of its regulations. The APA provides exceptions to its notice and public comment procedures when an Agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that under 5 U.S.C. 553(b)(3)(B), good cause exists for waiver of Notice of Proposed Rulemaking and public comment procedures on this regulation since opportunity for public comment is unnecessary in this case because the statutory provision on which the regulation is based simply makes permanent the exclusion in section 1612(b)(13) and allows for no discretion. Therefore, this rule is being issued as a final rule and will become effective on the date it is published in the **Federal Register.**

Regulatory Procedures

Executive Order 12291

The Secretary has determined that this is not a major rule under Executive Order 12291 since the program and administrative costs of this regulation will be insignificant and the threshold criteria for a major rule are not otherwise met. Therefore, a regulatory impact analysis is not required.

Paperwork Reduction Act

This regulation imposes no additional reporting and recordkeeping requirements requiring Office of Management and Budget clearance.

Regulatory Flexibility Act

We certify that this regulation will not have a significant economic impact on a substantial number of small entities because this rule affects only individuals and States. Therefore, a regulatory flexibility analysis as provided in Pub. L. 96-354, the Regulatory Flexibility Act, is not required.

(Catalog of Federal Domestic Assistance Program No. 13.807, Supplemental Security Income Program.)

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income.

Dated: July 13, 1988.

Dorcas R. Hardy,

Commissioner of Social Security.

Approved: August 25, 1988.

Otis R. Bowen,

Secretary of Health and Human Services.

Part 416 of Chapter III of Title 20 of the Code of Federal Regulations is amended as follows:

PART 416—[AMENDED]

1. The authority citation for Subpart K of Part 416 continues to read as follows:

Authority: Secs. 1102, 1602, 1611, 1612, 1613, 1614(f), 1621, and 1631 of the Social Security Act; 42 U.S.C. 1302, 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, and 1383; sec. 211 of Pub. L. 93-66, 87 Stat. 154; sec. 2639 of Pub. L. 98-369, 98 Stat. 1144.

§ 416.1157 [Amended]

2. Section 416.1157 is amended by removing "through September 1987" from the first sentence of paragraph (a) and by removing "and before October 1, 1987" from the first sentence of paragraph (c).

[FR Doc. 88-21060 Filed 9-14-88; 8:45 am]
BILLING CODE 4190-11-M

Food and Drug Administration

21 CFR Parts 336, 341, and 357

[Docket No. 88N-0070]

Over-the-Counter Drug Products; Final Monographs for Antiemetic, Antitussive, Bronchodilator, and Anthelmintic Drug Products; Updating and Technical Changes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations that establish conditions under which over-the-counter (OTC) antiemetic, antitussive, bronchodilator, and anthelmintic drug products are generally recognized as safe and effective and not misbranded. These amendments will update these final monographs by making noncontroversial technical changes that clarify the age ranges for children's dosages. These changes will result in more accurate and consistent OTC drug regulations.

DATES: Effective October 17, 1988; comments by October 17, 1988.

ADDRESS: Written comments 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: This document amends four final OTC drug monographs in (1) 21 CFR Part 336 for OTC antiemetic drug products (as set forth in the **Federal Register** of April 30, 1987; 52 FR 15886); (2) 21 CFR Part 341 for OTC antitussive drug products (as set forth in the **Federal Register** of August 12, 1987; 52 FR 30042); (3) 21 CFR Part 341 for OTC bronchodilator drug products; and (4) 21 CFR Part 357, Subpart B for OTC anthelmintic drug products. The amendments revise the wording of the age ranges for children's dosages currently contained in the final monographs, as necessary, to clarify and indicate uniformly that the adult dosages are also for children 12 years of age and over; that the dosages for children 6 years of age and older and for children 6 to 12 years of age are for children 6 years of age to under 12 years of age; and that the dosages for children 2 to 6 years are for children 2 years of age to under 6 years of age. These amendments do not change the actual age ranges specified in the final monographs.

These changes in the current wording of the age ranges for children's dosages are not related to the notice of intent on pediatric dosing information for OTC human drugs published by the agency in the **Federal Register** of June 20, 1988 (53 FR 23180). Any regulatory changes that may result from that notice of intent will be incorporated in the four final OTC drug monographs identified above, in a future issue of the **Federal Register.**

Because these labeling revisions represent minor clarifying changes that do not change the substance of the labeling requirements contained in the final monographs and because OTC drug products on the market may currently be in compliance with the labeling designated in the above-mentioned final monographs, the agency has determined that these labeling revisions do not need to be implemented on the effective date of this final rule, but may be implemented by manufacturers at their next printing of labels for affected products.

The agency has examined the economic consequences of this final rule 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 final rule amending the final OTC monographs for antiemetic, antitussive, bronchodilator, and anthelmintic 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 amending the final OTC monographs for antiemetic, antitussive, bronchodilator, and anthelmintic drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

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.

As noted above, these amendments institute changes that are of a nonsubstantive nature. Because the amendments are not controversial and because, when effective, they provide clarification of final OTC drug monographs, FDA finds that the usual notice and comment procedures are unnecessary. The amendments, therefore, shall become effective October 17, 1988. However, interested persons may, on or before October 17, 1988, submit written comments on these amendments to the Dockets Management Branch (address above). Three copies of any 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 336

Labeling, Over-the-counter drugs, Antiemetic drug products.

21 CFR Part 341

Labeling, Over-the-counter drugs, Antitussive drug products, Bronchodilator drug products.

21 CFR Part 357

Labeling, Over-the-counter drugs, Anthelmintic drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations 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(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, § 336.50 is amended by revising paragraphs (d) (1), (2), (3), and (4) to read as follows:

§ 336.50 Labeling of antiemetic drug products.

* * * * *

(d) * * *

(1) *For products containing cyclizine hydrochloride identified in § 336.10(a).* Adults and children 12 years of age and over: Oral dosage is 50 milligrams every 4 to 6 hours, not to exceed 200 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 25 milligrams every 6 to 8 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor.

(2) *For products containing dimenhydrinate identified in § 336.10(b).* Adults and children 12 years of age and over: Oral dosage is 50 to 100 milligrams every 4 to 6 hours, not to exceed 400 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 25 to 50 milligrams every 6 to 8 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 2 to under 6 years of age: Oral dosage is 12.5 to 25 milligrams every 6 to 8 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor.

(3) *For products containing diphenhydramine hydrochloride identified in § 336.10(c).* Adults and children 12 years of age and over: Oral dosage is 25 to 50 milligrams every 4 to 6 hours, not to exceed 300 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 12.5 to 25 milligrams every 4 to 6 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor.

(4) *For products containing meclizine hydrochloride identified in § 336.10(d).* Adults and children 12 years of age and over: Oral dosage is 25 to 50 milligrams once daily, or as directed by a doctor.

* * * * *

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR Part 341 continues 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.

4. In Subpart C, § 341.74 is amended by revising paragraphs (d)(1) (i), (ii), and (iii) to read as follows:

§ 341.74 Labeling of antitussive drug products.

* * * * *

(d) * * *

(1) *Oral antitussives*—(i) *For products containing chlophedianol hydrochloride identified in § 341.14(a)(1).* Adults and children 12 years of age and over: Oral dosage is 25 milligrams every 6 to 8 hours, not to exceed 100 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 12.5 milligrams every 6 to 8 hours, not to exceed 50 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor.

(ii) *For products containing codeine ingredients identified in § 341.14(a)(2).* Adults and children 12 years of age and over: Oral dosage is 10 to 20 milligrams every 4 to 6 hours, not to exceed 120 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 5 to 10 milligrams every 4 to 6 hours, not to exceed 60 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age. Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

(iii) *For products containing dextromethorphan or dextromethorphan*

hydrobromide identified in § 341.14(a) (3) and (4). The dosage is equivalent to dextromethorphan hydrobromide. Adults and children 12 years of age and over: Oral dosage is 10 to 20 milligrams every 4 hours or 30 milligrams every 6 to 8 hours, not to exceed 120 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 5 to 10 milligrams every 4 hours or 15 milligrams every 6 to 8 hours, not to exceed 60 milligrams in 24 hours, or as directed by a doctor. Children 2 to under 6 years of age: Oral dosage is 2.5 to 5 milligrams every 4 hours or 7.5 milligrams every 6 to 8 hours, not to exceed 30 milligrams in 24 hours, or as directed by a doctor. Children under 2 years of age: Consult a doctor.

* * * * *

5. In Supart C, § 341.76 is amended by revising paragraphs (d)(1), (d)(2)(i)(*a*), and (d)(2)(ii) to read as follows:

§ 341.76 Labeling of bronchodilator drug products.

* * * * *

(d) * * *

(1) *For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, or racephedrine hydrochloride identified in § 341.16 (a), (b), (c), and (f).* Adults and children 12 years of age and over: Oral dosage is 12.5 to 25 milligrams every 4 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Do not exceed recommended dose unless directed by a doctor. Children under 12 years of age: Consult a doctor.

(2) * * *

(i) * * *

(*a*) Inhalation dosage for adults, children 12 years of age and over, and children 4 to under 12 years of age: Start with one inhalation, then wait at least 1 minute. If not relieved, use once more. Do not use again for at least 3 hours. The use of this product by children should be supervised by an adult. Children under 4 years of age: Consult a doctor.

* * * * *

(ii) *For use in a hand-held rubber bulb nebulizer.* The ingredient is used in an aqueous solution at a concentration equivalent to 1 percent epinephrine. Inhalation dosage for adults, children 12 years of age and over, and children 4 to under 12 years of age: 1 to 3 inhalations not more often than every 3 hours. The use of this product by children should be supervised by an adult. Children under 4 years of age: Consult a doctor.

* * * * *

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

6. The authority citation for 21 CFR Part 357 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.

7. In Subpart B, § 357.150 is amended by revising the text of paragraph (d)(1) to read as follows:

§ 357.150 Labeling of anthelmintic drug products.

* * * * *

(d) * * *

(1) Adults, children 12 years of age and over, and children 2 years to under 12 years of age: Oral dosage is a single dose of 5 milligrams of pyrantel base per pound, or 11 milligrams per kilogram, of body weight not to exceed 1 gram. Dosing information should be converted to easily understood directions for the consumer using the following dosage schedule: * * *

* * * * *

Dated: August 17, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–21054 Filed 9–14–88; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[T.D. 8229]

Employment Taxes and Collection of Income Tax at Source; Waiver of Employment Tax Return Filing Requirements in Case of Certain No Liability Returns

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that authorize the waiver of employment tax return filing requirements in the case of certain no liability tax returns. This type of waiver is being authorized, because it was determined that such a waiver would result in a saving of resources for both affected employers and the Internal Revenue Service. These regulations affect certain seasonal and intermittent employers.

DATES: The regulations are effective on September 15, 1988. However, no change in filing requirements occu revised instructions to a tax providing a change are issued.

FOR FURTHER INFORMATION CONTACT: Joel S. Rutstein of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224 (Attention: CC:LR:T) (202–566–3297, not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

Currently, seasonal and intermittent employers must file Form 941 (Employer's Quarterly Federal Tax Return) each calendar quarter regardless of whether wages are paid in that quarter. This is a burden to these employers and a corresponding burden on the Internal Revenue Service in that the Service must expend resources on mailing and processing these "no liability" returns.

Explanation of Provisions

The amendments to the regulations provide that the instructions to an employment tax return form may waive the requirement that the return be filed in the case of certain no liability tax returns. The instructions to Form 941 will be revised to prospectively allow certain seasonal and intermittent employers not to file Forms 941 for quarters in which they pay no wages.

Special Analyses

A general notice of proposed rulemaking is not required by 5 U.S.C. 553 for final regulations subject to 5 U.S.C. 553(b)(B). Accordingly, the final regulations do not constitute regulations subject to the Regulatory Flexibility Act (5 U.S.C. Chapter 6).

The Commissioner of Internal Revenue has determined that this final rule is not a major rule as defined in Executive Order 12291 and that a regulatory impact analysis therefore is not required.

Drafting Information

The principal author of these final regulations is Joel S. Rutstein of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

List of Subjects in 26 CFR 31

Employment taxes, Income taxes, Lotteries, Railroad retirement, Social