

final rule that may issue based upon this proposal become effective 30 days following its publication.

**FOR FURTHER INFORMATION CONTACT:**

Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5916.

In FR Doc. 95-17505, appearing on page 37507 in the **Federal Register** of Thursday, July 20, 1995, the following corrections are made:

1. On page 37510, in the second column, in the first paragraph, in line 6, the phrase "and the FASEB" is corrected to read "of FASEB".

2. On page 37511, in the first column, in the fourth paragraph, in the sixth line from the bottom of the paragraph, "the 30-min (min) test" is corrected to read "the 30-minute (min) test".

3. On page 37513, in the second column, in the first full paragraph, in line 20, the phrase "just before to clinic visits." is corrected to read "just before clinic visits."

4. On page 37514, in the second column, in the second paragraph, in line 12, the phrase "front of maxillary and" is corrected to read "front maxillary and".

5. On page 37515, in the second column, in the first full paragraph, in line 7, the phrase "whose parents consumed" is corrected to read "who consumed".

6. On page 37520, in the second column, in the last paragraph, in line 1, the phrase "In its March 1979, review" is corrected by removing the comma after the date.

7. On page 37521, in the second column, in the second paragraph, in line 1, the phrase "In its August 1979, review" is corrected by removing the comma after the date.

8. On page 37527, in the third column, in reference 21, the name "Bánóczy" is corrected to read "Bánóczy".

9. On page 37529, in the first column, in reference 73, the word "Carigenicity" is corrected to read "Cariogenicity".

**§ 101.80 [Corrected]**

10. On page 37530, in the first column, in § 101.80 *Health claims: dietary sugar alcohols and dental caries*, in paragraph (c)(2)(i)(D), the phrase "paragraph (C) of this section." is corrected to read "paragraph (c)(2)(i)(C) of this section."

Dated: August 23, 1995.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

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**21 CFR Parts 310 and 341**

[Docket No. 95N-0205]

Rin 0905-AA06

**Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Monograph for OTC Bronchodilator Drug Products; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of proposed rulemaking; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to September 27, 1995, the period for comments for the notice of proposed rulemaking to amend the monograph for over-the-counter (OTC) bronchodilator drug products that was published in the **Federal Register** of July 27, 1995. That document proposed to remove the ingredients ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racephedrine hydrochloride from the final monograph for OTC bronchodilator drug products and to classify these ingredients as not generally recognized as safe and effective for OTC use. FDA is taking this action in response to several requests to extend the period for comments to allow interested persons adequate time to assess and respond to the proposal.

**DATES:** Written comments by September 27, 1995.

**ADDRESSES:** Submit 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 July 27, 1995 (60 FR 38643), FDA published a notice of proposed rulemaking to amend the final monograph for OTC bronchodilator drug products to remove the ingredients ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racephedrine hydrochloride and to classify these ingredients as not generally recognized as safe and effective for OTC use. Interested persons were given until August 28, 1995 to submit comments on the proposal.

In the proposal, the agency indicated that these ingredients should no longer

be included in the final monograph for OTC bronchodilator drug products based on their extensive use in illicit drug manufacture and their potential for causing harm as a result of misuse and abuse. This proposed amendment to the monograph, if finalized, would remove these ingredients from the OTC market whether present as single ingredient products or in combination with other cough-cold ingredients.

FDA has received requests from a manufacturers' association and two manufacturers of OTC bronchodilator drug products to extend the comment period until October 27, 1995, to permit adequate development of comments by industry and other interested parties. The requests stated that the extension is necessary because of the summer vacation season and the inability to develop a responsive submission in 30 days as provided in the proposed monograph amendment.

One comment indicated that FDA's action could set a precedent for the agency to take action later concerning OTC drug products containing pseudoephedrine and phenylpropanolamine, which are also included in the Domestic Chemical Diversion Control Act of 1993 as  $\geq$  listed chemicals  $\geq$  used as precursors in the clandestine manufacture of methamphetamine and metcathinone. The comment added that because the proposed amendment to the monograph could have profound implication on the entire OTC drug industry, additional time to comment is necessary to evaluate the legal and policy implications for companies who make products containing pseudoephedrine and/or phenylpropanolamine.

FDA emphasizes that this proposal affects ephedrine ingredients only. The proposed amendment does not affect the current OTC marketing status of pseudoephedrine or phenylpropanolamine in any manner. However, because of the comment's concerns that the proposal may have a potential future impact on the OTC drug industry, the agency wants to allow additional time for interested persons and manufacturers to more fully express their views. However, because of the continuing misuse and abuse of OTC ephedrine drug products, the agency has determined that the additional period shall be 30 days only. Therefore, the agency is providing an extension of the period for comments until September 27, 1995.

Interested persons may, on or before September 27, 1995, submit to the Dockets Management Branch (address above) written comments on the proposed monograph amendment.

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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 24, 1995.

**Ronald G. Chesemore,**

*Associate Commissioner for Regulatory Affairs.*

[FR Doc. 95-21480 Filed 8-25-95; 11:05 am]

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 40

[PS-8-95]

RIN 1545-AT25

#### Deposits of Excise Taxes

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking by cross-reference to temporary regulations.

**SUMMARY:** In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to deposits of excise taxes. The text of those temporary regulations also serves as the text of these proposed regulations.

**DATES:** Written comments and requests for a public hearing must be received by November 27, 1995.

**ADDRESSES:** Send submissions to: CC:DOM:CORP:T:R (PS-8-95), room 5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. In the alternative, submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:T:R (PS-8-95), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Concerning submissions, the Regulations Unit, (202) 622-7180; concerning the regulations, Ruth Hoffman, (202) 622-3130 (not toll-free numbers).

#### SUPPLEMENTARY INFORMATION:

##### Background

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Excise Tax Procedural Regulations (26 CFR part 40) relating to deposits of excise

taxes under section 6302. The temporary regulations contain special safe harbor rules for the additional deposit of taxes due in September of each year.

The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations.

#### Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

#### Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) that are submitted timely to the IRS. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time and place for the hearing will be published in the **Federal Register**.

#### Drafting Information

The principal author of these regulations is Ruth Hoffman, Office of Assistant Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury Department participated in their development.

#### List of Subjects in 26 CFR Part 40

Excise taxes, Reporting and recordkeeping requirements.

#### Proposed Amendments to the Regulations

Accordingly, 26 CFR part 40 is proposed to be amended as follows:

## PART 40—EXCISE TAX PROCEDURAL REGULATIONS

*Paragraph 1.* The authority citation for part 40 continues to read in part as follows:

**Authority:** 26 U.S.C. 7805 \* \* \*

**Par. 2.** Section 40.6302(c)-5 is added to read as follows:

#### § 40.6302(c)-5 Use of Government depositaries; rules under sections 6302(e) and (f).

[The text of this proposed section is the same as the text of § 40.6302(c)-5T published elsewhere in this issue of the **Federal Register**.]

**Margaret Milner Richardson,**

*Commissioner of Internal Revenue.*

[FR Doc. 95-21439 Filed 8-28-95; 8:45 am]

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## DEPARTMENT OF JUSTICE

### 28 CFR Part 16

[AAG/A Order No. 107-95]

#### Exemption of Records System Under the Privacy Act

**AGENCY:** Department of Justice.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Justice proposes to exempt a Privacy Act system of records from subsections (c) (3) and (4), (d), (e) (1), (2), (3), (5), and (8), and (g) of the Privacy Act, 5 U.S.C. 552a. This system of records is the "Bureau of Prisons, Office of Internal Affairs Investigative Records, Justice/BOP-012." Information in this system relates to official Federal investigations and law enforcement matters of the Office of Internal Affairs (OIA) of the Federal Bureau of Prisons (BOP), pursuant to the Inspector General Act of 1978, 5 U.S.C. App., as amended by the Inspector General Act amendments of 1988. The exemptions are necessary to avoid interference with the law enforcement functions of the BOP. Specifically, the exemptions are necessary to prevent subjects of investigations from frustrating the investigatory process; to preclude the disclosure of investigative techniques; to protect the identities and physical safety of confidential informants and of law enforcement personnel; to ensure OIA's ability to obtain information from information sources; to protect the privacy of third parties; and to safeguard classified information as required by Executive Order 12356.

**DATES:** Submit any comments by September 28, 1995.