

are indeed safe and effective for that use.

Given the present authorities contained in the BPCA and the pediatric rule, this ANPRM is intended to solicit comments on the most appropriate ways to balance FDA's interest in timely pediatric studies of and adequate pediatric labeling for human drugs and biological products that are used or will be used in the treatment of children and FDA's interest in not imposing unnecessary human drug and biologic study requirements. FDA is particularly interested in what mechanisms, if any, may be necessary to augment the programs described in the BPCA and what present authorities, if any, are perhaps now redundant because of the BPCA.

Therefore, FDA is soliciting comments on these issues. The agency is particularly interested in the relationship between the approach to acquiring pediatric labeling information promulgated in the pediatric rule, and the approaches authorized in the BPCA. While FDA is interested in hearing any comments the public would like to submit on this issue, questions of specific interest to FDA include:

1. What changes to the pediatric rule, if any, would be necessary to integrate the BPCA and the pediatric rule more effectively?

2. How would the criteria used by NIH and FDA under section 3 of the BPCA to request studies of already approved drugs relate to the standards promulgated in the pediatric rule and described in 21 CFR 201.23, 314.55, and 601.27 for requiring pediatric labeling for certain drugs and biological products? Which criteria are more appropriate for determining when studies are conducted?

3. What provisions, if any, of the BPCA could apply to biological products regulated under section 351 of the PHSA?

4. How does the provision in section 3 of the BPCA providing for a recommendation for a formulation change relate to the pediatric rule provision stating that in certain cases a sponsor may be required to develop a pediatric formulation? Should pediatric formulations be required in certain cases?

Resolution of these and other questions will be required before FDA can determine the optimum approach to ensuring that human drugs and biologics used in children have adequate information regarding the safe and effective use of these products in pediatric patients.

II. Requests for Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document by July 8, 2002. Two 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 Docket Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This document was reviewed by the Office of Management and Budget under Executive Order 12866.

Dated: April 18, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-9980 Filed 4-19-02; 12:00 pm]

BILLING CODE 4160-01-S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA # 225]

Schedule of Controlled Substances: Proposed Rule: Rescheduling of Buprenorphine From Schedule V to Schedule III

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The DEA is extending the comment period and time to request a hearing on the **Federal Register** Notice of proposed rulemaking entitled "Schedule of Controlled Substances: Proposed Rule: Rescheduling of Buprenorphine From Schedule V to Schedule III" published on March 21, 2002 (67 FR 13114).

DATES: The period for public comment that was to close on April 22, 2002, will be extended to May 22, 2002.

ADDRESSES: Comments should be submitted to the Administrator, Drug Enforcement Administration, Washington, DC 20537, Attn.: DEA Federal Register Representative (CCR).

FOR FURTHER INFORMATION CONTACT: Frank L. Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: The DEA published a notice of proposed rulemaking (67 FR 13114) to reschedule

buprenorphine from Schedule V to Schedule III of the Controlled Substances Act (CSA). The proposed rescheduling action is based on a scientific and medical evaluation and recommendation by the Department of Health and Human Services and an evaluation of this and other information by DEA. On April 12, 2002, DEA received a request for a sixty day extension of the period in which to comment and request a hearing. The requestor indicated that the additional time is necessary to obtain and evaluate the nearly one hundred scientific articles cited by DEA in support of its scheduling proposal. Upon consideration of this request, a thirty day extension of the time to comment and request a hearing is granted. This allows sufficient time for interested persons to evaluate and consider all relevant information and respond accordingly. Therefore, the comment period and time to request a hearing is extended to May 22, 2002. Comments must be received by the DEA on or before this date.

Dated: April 18, 2002.

Asa Hutchinson,

Administrator.

[FR Doc. 02-10044 Filed 4-19-02; 3:03 pm]

BILLING CODE 4410-09-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG-107184-00]

RIN 1545-AY04

Guidance Necessary To Facilitate Electronic Tax Administration

AGENCY: Internal Revenue Service (IRS), Treasury.

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

SUMMARY: The IRS is proposing regulations designed to eliminate regulatory impediments to the electronic filing of the Form 1040, "U.S. Individual Income Tax Return." The text of the temporary regulations published in the Rules and Regulations section of this issue of the **Federal Register** also serves as the text of these proposed regulations. These regulations generally affect taxpayers who file Form 1040 electronically and who are required to file any of the following forms: Form 56, "Notice Concerning Fiduciary Relationship"; Form 2120,

“Multiple Support Declaration”; Form 2439, “Notice to Shareholder of Undistributed Long-Term Capital Gains”; Form 3468, “Investment Credit”; and Form T (Timber), “Forest Activities Schedules.”

DATES: Written or electronically generated comments and requests for a public hearing must be received by July 23, 2002.

ADDRESSES: Send submissions to: CC:ITA:RU (REG-107184-00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:ITA:RU (REG-107184-00), Courier’s Desk, Internal Revenue Service, 1111 Constitution Ave., NW., Washington, DC. Alternatively, taxpayers may submit comments electronically directly to the IRS internet site at www.irs.gov/regs.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, James C. Gibbons, (202) 622-4910; concerning submissions of comments and/or requests for a hearing, LaNita Van Dyke, (202) 622-7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collections of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:FP:S, Washington, DC 20224. Comments on the collections of information should be received by June 24, 2002. Comments are specifically requested concerning:

Whether the proposed collections of information are necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection

techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of service to provide information.

The collections of information in this proposed regulation are in §§ 1.48-12T(d)(7), 1.152-3T(c), 1.611-3T(h), 1.852-9T(c), and 301.6903-1T(b). The proposed regulations require taxpayers to retain their tax records for as long as the contents may become material in the administration of any internal revenue law. This information is required for substantiation purposes. This information will be used to verify the information provided by the taxpayer. The likely respondents are individuals.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103. The burden imposed in §§ 1.48-12T(d)(7), 1.152-3T(c), 1.611-3T(h), 1.852-9T(c), and 301.6903-1T(b) will be reflected in Form 3468, Form 2120, Form T (Timber), Form 2439 and Form 56 respectively.

Background

Temporary regulations in the Rules and Regulation section of this issue of the **Federal Register** contain amendments to the Income Tax Regulations (26 CFR part 1) and the Procedure and Administration Regulations (26 CFR part 301) designed to eliminate regulatory impediments to the electronic filing of the Form 1040. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations. Generally, the regulations will be effective for taxable years beginning after December 31, 2001. Taxpayers may, however, rely on these proposed regulations to the extent that the impediments were removed in forms filed for taxable years beginning after December 31, 2000.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 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) does not apply to these regulations. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based upon the fact that the persons responsible for recordkeeping are principally individuals, and the burden is not significant as described earlier in the preamble. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7508(f) of the Internal Revenue Code, this notice 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 electronic or written comments (a signed original and eight (8) copies of written comments) that are submitted timely (in the manner described in the **ADDRESSES** caption) to the IRS. The IRS and Treasury request comments on the clarity of the proposed rules and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested by any person who timely submits 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 Sara Paige Shepherd, Office of Associate Chief Counsel (Procedure and Administration), Administrative Provisions and Judicial Practice Division. However, other personnel from the IRS and the Treasury Department participated in the development of the regulations.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are amended as follows:

PART 1—INCOME TAXES

1. The authority citation for part 1 continues to read as follows:

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

2. Section 1.48–12, paragraph (d)(7)(iii) is revised to read as follows:

§ 1.48–12 Qualified rehabilitated building; expenditures incurred after December 31, 1981.

* * * * *

(d) * * *

(7) * * *

(iii) [The text of proposed paragraph (d)(7)(iii) is the same as the text of § 1.48–12T(d)(7)(iii) published elsewhere in this issue of the **Federal Register**].

3. In § 1.152–3, paragraph (c) is revised to read as follows:

§ 1.152–3 Multiple support agreements.

* * * * *

(c) [The text of proposed paragraph (c) is the same as the text of § 1.152–3T(c) published elsewhere in this issue of the **Federal Register**].

* * * * *

4. Section 1.611–3, paragraph (h) is revised to read as follows:

§ 1.611–3 Rules applicable to timber.

* * * * *

(h) [The text of proposed paragraph (h) is the same as the text of § 1.611–3T(h) published elsewhere in this issue of the **Federal Register**].

5. In § 1.852–9, paragraph (c)(1) is revised to read as follows:

§ 1.852–9 Special procedural requirements applicable to designation under section 852(b)(3)(D).

* * * * *

(c)(1) [The text of proposed paragraph (c)(1) is the same as the text of § 1.852–9T(c)(1) published elsewhere in this issue of the **Federal Register**].

* * * * *

PART 301—PROCEDURE AND ADMINISTRATION

6. The authority citation for part 301 continues to read in part as follows:

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

7. Section 301.6011–1 is revised to read as follows:

§ 301.6011–1 General Requirement of return, statement or list.

[The text of proposed section is the same as the text of § 301.6011–1T

published elsewhere in this issue of the **Federal Register**].

8. Section 301.6903–1(b) is added to read as follows:

§ 301.6903–1 Notice of fiduciary.

* * * * *

(b) [The text of proposed paragraph (b) is the same as the text of § 301.6903–1T(b) published elsewhere in this issue of the **Federal Register**].

* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 02–9820 Filed 4–23–02; 8:45 am]

BILLING CODE 4830–01–P

POSTAL SERVICE

39 CFR Part 111

Firm Pieces in Carrier Route and Presorted Bound Printed Matter Mailings

AGENCY: Postal Service.

ACTION: Request for comment on application of agency rule.

SUMMARY: The Postal Service requests comments from the mailing industry (especially the presort software industry) as to how Bound Printed Matter (BPM) mailings with individually addressed “firm pieces” can be prepared under current eligibility and mail preparation standards. The term “firm piece” is generally used to describe a mailpiece that consists of more than one component (all destined for the same delivery address, which is often a company or business firm) composited into a single mailpiece. The existence of firm packages in Periodicals mailings is due to separate per-copy and per-addressed piece rates that do not exist within other classes of mail. The Postal Service is not proposing to change Domestic Mail Manual (DMM) standards in this notice.

DATES: Comments must be received on or before May 22, 2002.

ADDRESSES: Written comments should be delivered to the Manager, Mail Preparation and Standards, United States Postal Service, 1735 N. Lynn St., Room 3025, Arlington, VA 22209–6038. Comments may be transmitted via facsimile to 703–292–4058 or via e-mail to tdevaugh@email.usps.gov. Copies of all written comments will be available for inspection and photocopying at USPS Headquarters Library, 475 L’Enfant Plaza SW, 11th Floor N, Washington DC 20260–1450 between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Tom DeVaughan, 703–292–3640; or Marc McCrery, 202–268–2704.

SUPPLEMENTARY INFORMATION: On January 7, 2001, the Postal Service adopted new standards for Bound Printed Matter (BPM) that formalized the packaging and sacking or palletizing of BPM mailings according to shape (processing category) and destination entry (if any). These standards were incorporated into the Domestic Mail Manual (DMM). At the same time, new destination entry discounts were implemented. These standards were published for comment in the **Federal Register** on August 29, 2000, as part of the proposed DMM changes to implement the R2000–1 Omnibus Rate Case after extensive meetings with an Implementation Readiness Team (IRT) comprised of mailers, printers, publishers, and mailer associations. No comments were received on the BPM mail preparation standards from the IRT participants or others in the industry, and the final rule was published in the **Federal Register** on December 15, 2000.

After implementation of the new standards on January 7, 2001, the Postal Service has been receiving BPM firm pieces in Presorted BPM mailings that do not comply with the January 2001 eligibility criteria and mail preparation standards for BPM rates. Those standards prescribe specific preparation for flats, irregular parcels weighing less than 10 pounds, irregular parcels weighing 10 pounds or more, and machinable parcels. Although the issue may arise with some traditional BPM mailers (especially those taking advantage of drop ship incentives), it also impacts major printers who print Standard Mail pieces and prepare a portion of their mailings as BPM mail. An exhibit is provided at the end of this notice to illustrate a firm piece.

Firm Package and Firm Piece Preparation

Within Periodicals mailings, a “firm package” is defined in the DMM as two or more copies (pieces) for the same address placed in a single package. For presort eligibility and postage calculation, such pieces are treated in one of two ways:

- If each copy within the firm package has a delivery address, each may be claimed as a separate addressed piece (i.e., the number of pieces within the firm package multiplied by the “piece rate” of postage); or
- The firm package itself may be claimed as only one addressed piece.

In either case, one unit of piece rate postage is paid for each addressed piece claimed. A firm package sorted and