

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 PHSAA?

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.*  
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**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.*

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**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,