labeled ''Conforms to 16 CFR 1500.17(a)(13)'' and bears a number or other designation that relates back to the test results for that lot. For purposes of this paragraph (a)(13)(i)(D), the term ''outer container or wrapper'' does not include the immediate container in which candle(s) is/are intended to be displayed at retail or during use in the home, unless that container or wrapper is also the only container or wrapper in which the candle(s) is/are shipped to a retailer. For purposes of this paragraph (a)(13)(i)(D), a lot of metal-cored wick candles shall consist of all of the candles covered by any report of testing required by paragraph (a)(13)(i)(B) of this section.

(ii) *Metal-cored candle wicks.* Lots of metal-cored candle wicks manufactured or imported on or after _____, ____ 2002 [insert date 180 days after promulgation of final rule] unless:

(A) The metal core of each candle wick has a lead content (calculated as the metal) of not more than 0.06 percent of the total weight of the metal core;

(B) The manufacturer, importer, private labeler, or distributor of each lot of metal-cored candle wicks conducts, or obtains a report of the results of, reasonable and representative tests on either the candle wicks in that lot, or on the metal used to produce the wicks that were used in that lot, that establish that the lead content of the metal used in the wicks is not more than 0.06 percent (of the total weight of the metal core);

(C) The records of such testing are in English, identify each lot of candle wicks to which the test results apply, identify all numbers or other designations used to represent each lot on the label of containers as required in paragraph (a)(13)(ii)(D) of this section, are maintained in the United States for as long as the candle wicks the testing pertains to are being distributed plus three (3) years, and are made available for inspection and copying within 48 hours of a request by any officer, employee, or agent acting on behalf of the Consumer Product Safety Commission; and

(D) Each outer container or wrapper in which candle wicks from a lot subject to paragraphs (a)(13)(ii)(B) and (a)(13)(ii)(C) of this section are shipped, including each outer container or wrapper of such candle wicks distributed to a retail outlet, is labeled ''Conforms to 16 CFR 1500.17(a)(13)'' and bears a number or other designation that relates back to the test results for that lot. For purposes of this paragraph (a)(13)(ii)(D), the term ''outer container or wrapper'' does not include the immediate container in which candle wick(s) is/are intended to be displayed or sold at retail, unless that container or wrapper is also the only container or wrapper in which the candle wick(s) is/are shipped to a retailer. For purposes of this paragraph (a)(13)(ii)(D), a lot of metal-cored wicks shall consist of all of the candle wicks covered by any report of testing required by paragraph (a)(13)(ii)(B) of this section.

(iii) *Findings—(A) General.* In order to issue a rule under section 2(q)(1) of the FHSA, 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the FHSA requires the Commission to make certain findings and to include these in the regulation. These findings are discussed in paragraphs (a)(13)(iii)(B) through (D) of this section.

(B) *Voluntary Standard.* (1) One alternative to the ban that the Commission considered is to take no mandatory action, and to depend on a voluntary standard. One organization has a standard for candle wicks intended to address the potential for substantial illness posed by such wicks and candles with such wicks. The Commission has found that the standard is technically unsound and that substantial compliance with it is unlikely. Furthermore, there is no evidence that the standard has been adopted and implemented by candle wick or candle manufacturers.

(C) *Relationship of Benefits to Costs.* The Commission estimates that the ban will reduce the potential for exposure to lead and resulting lead poisoning because there is no ''safe'' level of lead in the blood. The annual cost to the candle/wick industry of the ban is estimated by the Commission to be in the range of $500,000 to $800,000. On a percentage basis these costs represent only 0.03 to 0.04 percent of the overall value of candle shipments in 1999, which was approximately $1.8 billion. Accordingly, the Commission finds that the benefits from the regulation bear a reasonable relationship to its costs.

(D) *Least burdensome requirement.* The Commission considered the following alternatives: No action; labeling all metal-cored candles with wicks containing more than 0.06 percent lead by weight of the metal; and relying on the voluntary standard. Neither no action, nor labeling, nor reliance on the voluntary standard would adequately reduce the risk of illness. Therefore the Commission finds that a ban on candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks is the least burdensome requirement that would prevent or adequately reduce the risk of illness.

Dated: April 18, 2002.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

The following documents contain information relevant to this rulemaking, can be accessed on the World Wide Web at *www.cpsc.gov,* and are available for inspection at the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814:

1. Briefing memorandum from Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, to the Commission, ''Petition HP 00–3 to Ban Lead-cored Candle Wicks,'' December 12, 2000.

2. Memorandum from K.M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, to Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences, ''Review of Lead Emissions from Candles,'' November 15, 2000.

3. Memorandum from Carolyn Meiers, Engineering Psychologist, Human Factors, to Kristina Hatlelid, Ph.D., M.P.H., Directorate for Health Sciences, ''Labeling of Candles with Lead-cored Wicks (Petition HP 00–3),'' October 18, 2000.

4. Briefing memorandum from Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, to the Commission, ''Proposal to Ban Lead-Cored Candle Wicks,'' March 18, 2002.

5. Memorandum from Mary F. Donaldson, CPSC Directorate for Economic Analysis to Kristina Hatlelid, CPSC Directorate for Health Sciences, ''Preliminary Regulatory Analysis of a Proposed Ban of Lead in Candlewicks,'' March 5, 2002.

[FR Doc. 02–9960 Filed 4–23–02; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 312, 314, and 601

[Docket No. 02N–0152]

Obtaining Timely Pediatric Studies of and Adequate Pediatric Labelingfor Human Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: Given the present authorities contained in the Best Pharmaceuticals for Children Act (BPCA), which was signed into law January 2002, the Food and Drug Administration (FDA) is issuing this advanced notice of proposed rulemaking (ANPRM) to solicit comments on the most appropriate ways to update the 1998

''pediatric rule'' so that it can most effectively address 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. FDA is interested in what mechanisms, if any, may be necessary to augment the programs described in the BPCA and what present authorities, if any, have not proven effective, are now redundant, or need to be updated because of the BPCA.

DATES: Submit written or electronic comments on the ANPRM by July 8, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Terrie Crescenzi, Office of Pediatric Drug Development and Program Initiatives (HFD–960), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, e-mail: crescenzit@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 2, 1998, FDA issued the final pediatric rule that requires manufacturers to assess the safety and effectiveness of certain human drugs and biological products in pediatric patients. This rule became effective in April 1999.

Under this rule, any application for approval of a human drug or biologic with a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration is expected to contain data to assess the safety and effectiveness of the drug or biologic in pediatric patients. The pediatric rule also contains provisions for industry-FDA meetings and early consultation during the investigational study of a drug or biologic to facilitate the design and timely conduct of adequate pediatric studies of the drug or biologic, when appropriate to conduct such studies. In addition, this rule also provided FDA with the ability to require the development of a pediatric formulation, if necessary, to study a particular pediatric group; and to require manufacturers of already marketed human drugs and biologics to conduct certain pediatric studies when they seek approval for certain other changes to their drug or biologic. Manufacturers may obtain from FDA a waiver (e.g., the disease does not occur in the pediatric population) or deferral (e.g., pediatric studies to be conducted later in the development cycle) of some or all of these requirements. Under these provisions, many drugs have been studied in children and many companies have built an infrastructure that fosters pediatric studies of their products. In addition, under these provisions, as new drugs are developed, it has become more routine for companies to evaluate and plan appropriately for studying the new product in children.

For certain human drugs and biologics already on the market, under certain circumstances, the pediatric rule further authorizes FDA to require manufacturers to submit an application containing data adequate to assess whether the product is safe and effective in pediatric populations, even when the company has not submitted an application for certain other changes to their drug or biologic. FDA has, to date, not invoked this latter aspect of the pediatric rule.

After FDA issued its proposed pediatric rule (62 FR 43900, August 15, 1997), but before it issued the final pediatric rule, Congress passed the Food and Drug Administration Modernization Act of 1997 (FDAMA). This act included a provision that authorized specific market exclusivity incentives to manufacturers who voluntarily conducted and submitted to FDA pediatric studies of their drugs as requested by FDA and who met certain statutory criteria. This provision has resulted in numerous pediatric studies of many of the drugs to which it applied. Nonetheless, when FDA issued the pediatric rule, the agency indicated that the FDAMA provisions left some significant gaps in obtaining pediatric studies to provide safety and effectiveness labeling information for certain products. Examples of these ''gap'' products include already marketed drugs no longer under patent or market exclusivity protection, certain antibiotics, biological products approved under section 351 of the Public Health Service Act (PHSA), and products for which the manufacturers simply choose not to perform pediatric studies requested by FDA, despite the exclusivity incentive to do so. The exclusivity incentive provision of FDAMA, as written, does not to apply to biological products approved under section 351 of the PHSA, certain antibiotics, and products that did not have specific existing patent or exclusivity protection that could be prolonged under this authority. In addition, the exclusivity provision could only effectively be employed once with respect to an active ingredient. Thus, if further studies in certain groups of children (for example, neonates) were needed at a later date, the exclusivity provision was restricted and thus did not provide an economic incentive for the additional needed studies. Also, the exclusivity incentive provisions of FDAMA expired on January 1, 2002.

On January 4, 2002, the President signed into law the BPCA. This legislation both reauthorizes the exclusivity incentive program enacted originally in FDAMA (essentially without any change relevant here) and establishes an additional mechanism for obtaining information on the safe and effective use of drugs in pediatric patients. The new BPCA mechanism consists primarily of authorizing several National Institutes of Health (NIH) funding mechanisms, including the NIH Foundation, as vehicles for funding, using both public and private funds, studies of certain drugs under certain circumstances if the manufacturers of those drugs decline to conduct the requested pediatric studies. BPCA also provides a mechanism for including information from such studies in the label of pediatric products. Because it involves paying others to do the studies rather than having to litigate with a company to force it to conduct needed studies, some have argued that this new BPCA mechanism is a more cost- and time-efficient way of achieving the goal of adequate pediatric safety and efficacy labeling of these ''gap'' products than are some of the provisions of the pediatric rule. Others point out that while these NIH funding mechanisms may be used to contract for pediatric studies of certain human drugs, the provision of BPCA for awarding study contracts does not extend to awarding contracts to study human biologics and certain antibiotics. In addition, the public funding of these mechanisms is dependent on yearly congressional appropriations and the private donations are purely voluntary. Whether funds appropriated for such studies will be adequate to ensure that studies are performed and data submitted for all needed drug products remains uncertain. By statute, the BPCA is to sunset in 2007. Because of these uncertainties in funding, limitations on the products covered, and the lack of required early planning regarding pediatrics in a drug's development process, some have argued that without the ''requirement'' provisions of the pediatric rule, FDA will not have the authority it needs to ensure that all medicines used in children of all ages

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,