§ 16.13 Procedures for centralized administrative offset.

(a) The NRC must notify Treasury of all debts that are delinquent as defined in the FCCS (over 180 days old) so that recovery may be made by centralized administrative offset. This includes those debts the NRC seeks to recover from the pay account of an employee of another agency via salary offset. The Treasury and other Federal disbursing officials will match payments, including Federal salary payments, against such debts. When a match occurs, and all the requirements for offset have been met, the payments will be offset to collect the debt. Prior to offset of the pay account of an employee, the NRC must comply with the requirements of 5 U.S.C. 5514, 5 CFR Part 550, and 10 CFR Part 15. Procedures for notifying Treasury of a debt for purposes of collection by centralized administrative offset are contained in 31 CFR Part 285 and 10 CFR 15.33. Procedures for internal salary offset are contained in § 16.15 of this chapter.

(b) When the NRC determines that an employee of another Federal agency owes a delinquent debt to the NRC, the NRC will, as appropriate:

(1) Arrange for a hearing upon the proper petitioning by the employee;

(2) Provide the Federal employee with a notice and an opportunity to dispute the debt as contained in 5 U.S.C. 5514 and 10 CFR 15.26.

(3) Submit the debt to Treasury for centralized administrative offset and certify in writing that the debtor has been afforded the legally required due process notification.

(4) If collection must be made in installments, the NRC must advise the paying agency of the amount or percentage of disposable pay to be collected in each installment.

(c) *Offset amount.* (1) The amount offset from a salary payment under this section shall be the lesser of:

(i) The amount of the debt, including any interest, penalties, and administrative costs; or

(ii) An amount up to 15% of the debtor's disposable pay.

(2) Alternatively, the amount offset may be an amount agreed upon, in writing, by the debtor and the NRC.

(3) Offsets will continue until the debt, including any interest, penalties, and costs, is paid in full or otherwise resolved to the satisfaction of the NRC.

(d) *Priorities.* (1) A levy pursuant to the Internal Revenue Code of 1986 shall take precedence over other deductions under this section.

(2) When a salary payment may be reduced to collect more than one debt, amounts offset under this section will be applied to a debt only after amounts offset have been applied to satisfy past due child support debt assigned to a State pursuant 26 U.S.C. 6402(c) and 31 CFR 285.7(h)(2).

(e) *Notice.* (1) Before offsetting a salary payment, the disbursing official, or the paying agency on behalf of the disbursing official, shall notify the Federal employee in writing of the date that deductions from salary will commence and of the amount of such deductions.

(2)(i) When an offset occurs under this section, the disbursing official, or the paying agency on behalf of the disbursing official, shall notify the Federal employee in writing that an offset has occurred including:

(A) A description of the payment and the amount of the offset taken;

(B) Identification of NRC as the agency requesting the offset; and,

(C) A contact point within the NRC that will handle concerns regarding the offset.

(ii) The information described in paragraphs (e)(2)(i)(B) and (e)(2)(i)(C) of this section does not need to be provided to the Federal employee when the offset occurs if such information was included in a prior notice from the disbursing official or paying agency.

(3) The disbursing official will advise the NRC of the names, mailing addresses, and taxpayer identifying numbers of the debtors from whom amounts of past-due, legally enforceable debt were collected and of the amounts collected from each debtor. The disbursing official will not advise the NRC of the source of payment from which such amounts were collected.

(f) *Fees.* Agencies that perform centralized salary offset computer matching services may charge a fee sufficient to cover the full cost of such services. In addition, Treasury or a paying agency acting on behalf of Treasury, may charge a fee sufficient to cover the full cost of implementing the administrative offset program. Treasury may deduct the fees from amounts collected by offset or may bill the NRC. Fees charged for offset shall be based on actual administrative offsets completed.

(g) *Disposition of amounts collected.* The disbursing official conducting the offset will transmit amounts collected for debts, less fees charged under paragraph (f) of this section, to NRC. If an erroneous offset payment is made to the NRC, the disbursing official will notify the NRC that an erroneous offset payment has been made. The disbursing official may deduct the amount of the erroneous offset payment from future amounts payable to the NRC. Alternatively, upon the disbursing official's request, the NRC shall return promptly to the disbursing official or the affected payee an amount equal to the amount of the erroneous payment (without regard to whether any other amounts payable to the agency have been paid). The disbursing official and the NRC shall adjust the debtor records appropriately.

8. Section 16.15 is amended by revising the section heading to read as follows:

§ 16.15 Procedures for internal salary offset.

9. Section 16.23 is revised to read as follows:

§ 16.23 Interest, penalties, and administrative charges.

Charges may be assessed for interest, penalties, and administrative charges in accordance with the FCCS, 31 CFR Chapter IX, 901.9.

Dated at Rockville, Maryland, this 16th day of April 2002.

For the Nuclear Regulatory Commission.

Jesse L. Funches,

Chief Financial Officer.

[FR Doc. 02–9885 Filed 4–23–02; 8:45 am]

BILLING CODE 7590–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Metal-Cored Candle Wicks Containing Lead and Candles With Such Wicks; Notice of Proposed Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed Rule.

SUMMARY: The Commission is proposing to declare that metal-cored candle wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances and to ban such wicks and candles with such wicks.[1] The Commission is issuing these proposed rules under authority of the Federal Hazardous Substances Act.

DATES: Written comments in response to this notice must be received by the Commission no later than July 8, 2002.

Comments on elements of the proposed rules that, if issued, would constitute collection of information requirements under the Paperwork Reduction Act may be filed with the Office of Management and Budget (''OMB'') and with the Commission. Comments will be received by OMB until June 24, 2002.

[1] The Commissioners voted 2–0 to issue this notice of proposed rulemaking.

ADDRESSES: Comments should be mailed, preferably in five (5) copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814; telephone (301) 504–6800. Comments also may be filed by facsimile to (301) 504–0127 or by e-mail to *cpsc-os@cpsc.gov.* Comments should be captioned ''NPR for Candle Wicks Containing Lead.''

Comments to OMB should be directed to the Desk Officer for the Consumer Product Safety Commission, Office of Information and Regulatory Affairs, OMB, Washington, DC 20503. The Commission asks commenters to provide copies of such comments to the Commission's Office of the Secretary, with a caption or cover letter identifying the materials as comments submitted to OMB on the proposed collection of information requirements for the proposed ban on certain candle wicks and candles made with such wicks.

FOR FURTHER INFORMATION CONTACT: Kristina Hatlelid, Ph.D., M.P.H., Project Manager, Directorate for Health Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0994, ext. 1389.

SUPPLEMENTARY INFORMATION:

A. Background

On February 24, 2000, the U.S. Consumer Product Safety Commission (CPSC or Commission) received a petition from Public Citizen requesting that the Commission ban candles with lead-containing wicks and wicks sold for candle-making that contain lead. On February 29, 2000, CPSC received a similar petition from the National Apartment Association and the National Multi Housing Council. These petitions were docketed collectively under the Federal Hazardous Substances Act (FHSA) (Petition No. HP 00–3) on March 17, 2000.

After analysis of the available data on lead-cored candle wicks and the information provided by the petitioners, the CPSC staff transmitted a briefing package to the Commission recommending that the Commission proceed with rulemaking to ban lead-cored candle wicks. The staff recommended that a lead-cored wick be defined as a wick containing a metal core with greater than 0.06 percent lead by weight in the metal, since laboratory test data indicate that burning candles with metal-cored wicks with lead concentrations of 0.06 percent or less by weight does not result in detectable emissions of lead into the air. On February 20, 2001, the Commission issued an advance notice of proposed rulemaking (ANPR) that could lead to a ban on metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks. 66 FR 10863.

B. The Product

Lead-cored wicks are candle wicks with a metal wire in the center made of lead or lead alloy. The metal core is used to provide structural rigidity to the wick, *i.e.*, to keep the wick straight during candle production, and to provide an upright wick during burning.

C. The Risk of Illness

As a lead-cored wick candle burns, some of the lead may vaporize and be released into the air. This airborne lead may be inhaled. Some of this lead may deposit onto floors, furniture, and other surfaces in the room where children may be exposed to it. One cannot tell by looking at the wick core if it is made of lead, and there is no simple way for a consumer to determine its lead content. The presence of lead in a wick can be determined only by laboratory analysis.

Similarly, one cannot tell if lead is being released from a burning candle by observing smoke or soot; nor can one tell that lead is not being released by the lack of visible emissions. Determination of lead in room air or on surfaces must be done by professionals.

The toxic effects of lead and the risk to consumers, especially children, from exposure to lead emitted from lead-cored wick candles, including neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems, were detailed in the Commission briefing package on Petition No. HP 00–3.[2] In that briefing package, CPSC staff concluded that, under reasonable assumptions, exposure of children to indoor air lead levels from candles emitting 430 micrograms of lead per hour or more could result in elevated blood levels (greater than 10 micrograms of lead per deciliter of blood). Laboratory investigations by CPSC staff and others indicate that lead-cored wick candles can emit more than 3,000 μg of lead per hour during candle burning.[3] Thus, the Commission believes that under certain expected use conditions, the lead emitted from burning candles with lead-cored wicks presents a risk to consumers of substantial illness from exposure through inhalation of airborne lead. Children may also be exposed to lead that deposits onto surfaces in the room.

Several countries have acted on this issue. Officials in Canada issued an advisory in January, 2001, warning consumers that some candles sold in Canada contained lead-cored wicks, and offering advice on making informed purchasing decisions.[4] Officials in Australia and New Zealand have instituted provisional bans on candles with wicks containing any amount of lead.[5] Australia is now considering making the ban permanent.

Denmark issued a more comprehensive order in December 2000 banning a number of products containing lead.[6] Chafing dish candles and other candles are specifically included in the ban. The order defines a lead-containing product as one in which lead represents more than 50 mg/kg (0.005 percent) of the homogeneous components.

D. Statutory Authority

This proceeding is conducted under provisions of the FHSA. 15 U.S.C. 1261–1278. It involves three actions. First, pursuant to section 3(a) of the FHSA, the Commission is proposing to declare that metal-cored candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks are hazardous substances. (Proposed 16 CFR 1500.12(a)(2)). Second, pursuant to section 2(q)(1)(B) of the FHSA, the Commission is proposing to ban such wicks and candles with such wicks. (Proposed 16 CFR 1500.17(a)(13)). Third, pursuant to section 10(a) of the FHSA, the Commission is proposing to require that manufacturers and importers of metal-cored wicks and candles test and/or maintain records of testing performed by the supplier of the metal-cored wicks or the metal used in the metal cores. *Id.* The testing records must demonstrate compliance for the lots of wicks and/or

[2] 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. This and other CPSC materials for this rulemaking referenced in this preamble are available in PDF format on the CPSC World Wide Web site at *www.cpsc.gov.* Select ''Library (FOIA),'' Electronic Reading Room—Freedom of Information Act Information,'' ''2001 FOIA Information, and ''Commission Briefing Packages.'' Then scroll down to the materials captioned ''Ban of Candle Wicks.''

[3] *Id.*

[4] Health Canada Advisory 2001–02, January 2001.

[5] Commonwealth of Australia Consumer Protection Notice No. 11 of 1999 under the Trade Practices Act of 1974, September 1999; New Zealand Ministry of Consumer Affairs Unsafe Goods Notice under the Fair Trading Act 1986, June 2000.

[6] Danish Environmental Protection Agency Ministry of Environment and Energy Council Directive 89/677/EEC and implementing orders.

candles and must maintain a line of continuity between the two.

The Commission is proposing to declare that metal-cored candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks are ''hazardous substances'' within the meaning of section 2(f)(1)(A) of the FHSA because they are toxic, and ''may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use * * *.'' 15 U.S.C. 1261(f)(1)(A). A proceeding to classify a substance as a hazardous substance under section 3(a) of the FHSA is governed by, *inter alia,* sections 701(e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 371(e)–(g). *See* 15 U.S.C. 1262(a)(2).

Under section 2(q)(1)(B) of the FHSA, the Commission may classify as a ''banned hazardous substance'' any hazardous substance intended for household use which, notwithstanding the precautionary labeling required by the FHSA, presents such a hazard that keeping the substance out of interstate commerce is the only adequate means to protect the public health and safety. 15 U.S.C. 1261(q)(1)(B). A proceeding to classify a substance as a banned hazardous substance under section 2(q)(1)(B) of the FHSA is governed by the requirements set forth in section 3(f) of the FHSA, and by sections 701(e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act (''FDCA'') (21 U.S.C. 371(e)). *See* 15 U.S.C. 1261(q)(2) and 1262(f).

The February 20, 2001, ANPR was the first step necessary to declare the specified candle wicks and candles to be banned hazardous substances under section 2(q)(1). *See* 15 U.S.C. 1262(f). The proposed regulations issued today continue the regulatory process in accordance with the requirements of 15 U.S.C. 1262(a) and (h). Under the rules proposed today, metal-cored candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks would be declared to be hazardous substances and would be banned.

If the Commission proceeds to issue a final rule banning these wicks and candles, it must publish the text of the final rule and a final regulatory analysis that includes: (1) A description of the potential costs and benefits of the rule; (2) A description of alternatives considered by the Commission (including a description of their potential costs and benefits and an explanation of why they were not chosen); and (3) a summary of significant issues raised by comments on the preliminary regulatory analysis published with these proposed rules. 15 U.S.C. 1262(i)(1). The Commission also must make findings that: (1) any relevant voluntary standard is unlikely to adequately reduce the risk of injury or substantial compliance with the voluntary standard is unlikely; (2) the expected benefits of the regulation bear a reasonable relationship to expected costs; and (3) the regulation imposes the least burdensome requirement that would adequately reduce the risk of injury. 15 U.S.C. 1262(i)(2).

Procedures established by section 701(e) of the FDCA would govern Commission action to finalize the hazardous substance declaration and the banning rule. 15 U.S.C. 1262(a)(2) and 1261(q)(2). These procedures provide that once the Commission issues a final rule, persons who would be adversely affected by the rule have a period of thirty (30) days in which to file objections stating reasonable grounds therefor, and to request a public hearing on those objections. 21 U.S.C. 371(e). Should valid objections be filed, a hearing to receive evidence concerning the objections would be held and the presiding officer would issue an order after the hearing, based upon substantial evidence. 21 U.S.C. 371(e); 16 CFR part 1502.

E. Response to Comments on the ANPR

Eleven comments were received in response to the ANPR. Nine comments were in favor of the proposal to ban lead-cored wicks. One commenter opposed forcing companies to compensate for parents who are not preventing their children from being exposed to lead emissions from such wicks. One commenter opposed a mandatory rule and submitted a voluntary standard that would ban the use of domestically produced metal-cored wicks containing greater than 0.01 percent lead and imported wicks with metal cores, irrespective of lead content. The issues raised by commenters and the Commission responses to them are discussed below.

1. Federal Regulation

Comments: Nine of the eleven comments support the proposal to ban lead-cored wicks. One dissenting comment from a consumer stated that the candle industry should not be made to bear the burden for parents who do not adequately protect their children. One commenter, representing a standards organization, submitted a voluntary standard to take the place of a mandatory rule. About half of the commenters, including a representative of the National Candle Association (NCA), stated that a voluntary standard would not adequately remove lead-cored wicks from commerce.

Response: The CPSC does not believe it is reasonable to expect that parents alone can protect children from all consumer product hazards, especially if potential hazards are not readily apparent. The Commission believes that a mandatory standard is necessary, in part because of the failure of the industry to maintain conformance with a voluntary commitment to eliminate lead wicks made in 1974, and recognizes that the NCA and its member firms support the development of the mandatory rule.

A mandatory standard would: (1) Apply to all domestic and imported candle and wick products containing metal-cored wicks regardless of a company's membership in a trade organization or knowledge of applicable standards; (2) deter manufacturers from making non-conforming wicks or candles and enable the staff to seek civil penalties for violations; (3) increase compliance by retailers and distributors who often require that products meet applicable federal standards; and (4) through cooperative efforts with the U.S. Customs Service, prevent non-complying products from entering the U.S.

2. Voluntary Standards

Comment: Voices of Safety International (VOSI) proffered a voluntary standard for lead in candle wicks, specifying that domestically produced metal-cored wicks contain no more than 0.01 percent lead in the metal. The standard further specifies that imported candle wicks may not contain metal cores. The VOSI standard includes a methodology, based on tensile strength of metals, for determining whether metal-cored wicks comply with the specified maximum lead content. VOSI also asserted that the provision of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, concerning adoption of voluntary consensus standards by federal agencies applies to this proceeding.

Response: The CPSC staff analysis of the submitted standard uncovered a number of difficulties concerning the scope of the standard, the proposed tensile test methodology, and the acceptance of the standard by the intended industry. The Commission thus finds preliminarily that the VOSI standard is not likely to result in the elimination or adequate reduction of the risk at issue in this proceeding and that substantial compliance with it is

unlikely. See a more detailed discussion of the bases for these findings in Section F.2, *Voluntary Standards,* below.

VOSI's assertion that the NTTAA applies to this proceeding is incorrect. Office of Management and Budget (OMB) Circular A–119 expressly excludes from the NTTAA requirements ''independent regulatory commissions insofar as they are subject to separate statutory requirements regarding the use of voluntary consensus standards,'' as is the Commission under the FHSA. *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,* OMB Circular A–119, February 10, 1998, at section 5.

3. Health Effects

Comments: A number of commenters reiterated the harmful effects of lead exposure in children and the potential for lead exposure from candles.

Response: As discussed above, the toxic effects of lead and the risk to consumers, especially children, from exposure to lead emitted from lead-cored wick candles were presented in the initial CPSC staff briefing package on Petition No. HP 00–3.[7]

4. Substitute Materials

Comments: Three commenters discussed available substitutes and their use by manufacturers. Three commenters reiterated that other countries have issued bans on the import and sale of lead-containing wicks. The National Candle Association stated that use of lead-cored wicks has been broadly discontinued domestically, and that zinc-cored wicks currently in use would comply with a ban on metal-cored wicks exceeding 0.06 percent lead by weight in the metal. One commenter claimed that paper- or cotton-cored wicks would not be acceptable because they are less rigid than zinc and have a higher burning rate.

Response: The CPSC staff economic analysis supports the proposition that alternatives to the use of lead core are available. The staff believes that no wick manufacturer in the U.S. currently uses lead core in the production of its wicks. The Commission preliminarily concludes, based on that analysis, that the cost to manufacturers or consumers of a ban on lead-cored wicks would be small.

The CPSC staff has found no basis for the commenter's claim that paper-or cotton-cored wicks are unacceptable alternatives to lead-cored wicks.

As discussed above, Canada, Australia, New Zealand, and Denmark have acted on this issue, limiting the use of lead in candle wicks or providing guidance to consumers.

5. Metal-Cored Wicks

Comments: Two commenters expressed concern about the presence of even small amounts of lead in metal-cored wicks.

Response: Metals, such as zinc, may be used in candle wicks. The lead content of the zinc used in zinc-cored wicks has been determined by CPSC and others to range from about 0.0005 percent to 0.06 percent by weight in the metal.[8] CPSC laboratory and other tests have shown no detectable levels of airborne lead emissions from candles with metal wicks containing 0.06 percent lead or less by weight. Therefore, the Commission is proposing a ban on metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks, but is not proposing to limit the use of metal cores that contain 0.06 percent lead or less.

6. Labeling

Comments: Three commenters believe that regulating lead-cored wick candles by requiring warning labels would not adequately protect public health, and one commenter suggested that candles that comply with the proposed 0.06 percent maximum lead limit should be labeled with that information.

Response: The CPSC agrees that lead-cored wicks and candles containing lead-cored wicks should be banned and that precautionary labeling is not an acceptable strategy for protecting vulnerable populations from lead poisoning that may be induced by burning candles with lead-cored wicks.[9] The Commission does not believe that requiring individual complying candles to be labeled would add to the safety of these products.

The proposed rule would require labeling of each shipping container of metal-cored wicks, and each shipping container of candles with metal-cored wicks, with the statement ''Conforms to 16 CFR 1500.17(a)(13)'' and a number or other designation that relates back to the test results demonstrating compliance for the wicks/candles in that shipping container. CPSC specifically invites interested parties to comment on this feature of the proposal.

F. Alternatives to Proposed Ban

1. No Action

If the Commission took no action, lead-cored candle wicks could continue to be sold in the U.S. In the mid-1970's the domestic candle industry stopped using lead in wicks, but lead-cored wicks reappeared on the domestic market some time thereafter. While the domestic industry states that it has now voluntarily eliminated lead in their wicks, imports may continue to be a source of lead in the absence of a mandatory standard. Under the no action scenario, CPSC enforcement staff would be limited to taking action against lead-containing wicks under the FHSA on a case-by-case basis.

2. Voluntary Standards

In 1974, the Candle Manufacturers Association industry group submitted a statement informing the Commission of an agreement among candle manufacturers to convert to substitutes for lead-cored wicks in candles by the end of the third quarter 1974. They also agreed not to import candles with lead-cored wicks. Further, the major domestic wick manufacturer at that time agreed to discontinue the production of lead-cored wicks.

Despite this agreement, some wick manufacturers resumed producing lead-cored wicks and some candle manufacturers resumed producing and importing candles with lead-cored wicks after 1974.

In May 2000, a task group for candle wicks was formed under the ASTM F15.45 Candle Products Subcommittee to develop a consensus standard to address the lead content of candle wicks. The task group stopped their standards development process in February 2001 in favor of supporting the CPSC mandatory rulemaking process.

During the public comment period on the ANPR, VOSI proffered a voluntary standard for lead in candle wicks. The VOSI standard specifies that metal-cored wicks may contain no more than 0.01 percent lead in the metal. The standard further specifies that imported candle wicks may not contain metal cores. The standard includes a methodology, based on tensile strength of metals, for determining whether metal-cored wicks comply with the specified maximum lead content.

CPSC technical staff reviewed the standard and noted a number of difficulties. Although the standard states that a maximum of 0.01 percent

[7] *See* fn. 2 above.

[8] See fn. 2 above.

[9] 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. See fn. 2 above for information on the availability of this and other related documents on the Internet and at the CPSC reading room.

lead is required to protect consumer health, no technical or health basis for this level is provided. The CPSC staff maintains that the proposed limit of 0.06 percent lead by weight in the metal is appropriate and supported by the laboratory analyses performed by CPSC staff and others.

The CPSC staff further states that the analytical methodology in the submitted standard is not capable of reliably determining either the presence or concentration of lead in metal-cored candle wicks. The CPSC staff concludes that the tensile strength of a metal alloy would not definitively identify zinc cored wicks with less than the maximum allowable lead content in the metal, but could falsely detect alloys not containing lead, causing them to fail the test and be needlessly prohibited from wick use. The staff states that the metal's lead content, not its physical attributes, is the important characteristic in protecting consumers' health.

The VOSI standard specifies different standards for domestic and imported products. Specifically, the standard specifies that domestically produced metal-cored wicks may contain no more than 0.01 percent lead in the metal but that imported candle wicks may not contain metal cores. The FHSA gives CPSC the authority to regulate hazardous substances. In the absence of evidence that a specific type of metal wick meets the definition of a hazardous substance under the FHSA, the CPSC cannot ban it. Furthermore, a discriminatory approach to imports with no basis in fact would in all likelihood be a violation of the North American Free Trade Agreement (NAFTA), if not other U.S. treaty obligations.

The Commission believes that membership in standards organizations, such as ASTM, serves, in part, to transmit applicable standards to member firms. VOSI has offered no information that its members include candle or wick manufacturers. VOSI has not shown that the standard was developed within an industry consensus framework or is otherwise widely known to candle and wick manufacturers in the United States or elsewhere.[10] Nor has it provided any evidence that there would be substantial compliance with the voluntary standard.

Based on the foregoing analysis, the Commission finds that the VOSI standard is technically unsound, and thus would not result in the elimination or adequate reduction of the risk, and that substantial compliance with it is unlikely.

Even if a technically valid voluntary standard were developed, the Commission maintains that a mandatory standard is necessary to adequately protect public health.

3. Precautionary Labeling

A CPSC Human Factors staff analysis concludes that precautionary labeling of individual candles is not an acceptable strategy for protecting vulnerable populations from lead poisoning that may be caused by burning candles with lead-cored wicks.[11]

That analysis shows that since lead is emitted from a candle when the candle is used as intended, the only preventative measures consumers could take to protect themselves against the hazard would be to not burn candles with lead-cored wicks. No label or subsequent action by the consumer would prevent the release of lead into the air if the candle is used as intended. The staff analysis therefore concludes that it is not realistic to expect consumers to comply with a warning label advising not to burn the candles, but to use them only for decorative purposes.[12]

G. Comment Period

In accordance with section 4 of Executive Order 12889 implementing NAFTA, the Commission is providing a 75 day public comment period on the proposed rules. The Commission is particularly interested in acquiring additional data on the effect the proposed rules would have on prices to consumers and costs to wick and candle manufacturers.

H. Preliminary Regulatory Analysis

1. FHSA Requirement

The Commission has preliminarily determined to issue a rule declaring a ban on metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks. Section 3(h) of the FHSA requires that the Commission prepare a preliminary regulatory analysis for this action. 15 U.S.C. 1261(h). The following discussion addresses this requirement.

2. Introduction

The Commission is considering amending the FHSA regulations to declare that metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances and to ban such wicks and candles. In February 2001, the Commission voted to issue an ANPR that could lead to such a declaration and ban. 66 FR 10863. On April 17, 2002, the Commission voted to issue proposed rules declaring that such wicks and candles with such wicks are hazardous substances and banning them.

3. Required Content of the Regulatory Analysis

To accomplish rulemaking under the FHSA, the Commission must publish preliminary and final regulatory analyses containing a discussion of various factors. These factors include a description of the potential benefits and potential costs of the rule, including any benefits and costs that cannot be quantified in monetary terms, and an identification of those most likely to receive the benefits and bear the costs. The FHSA also requires a description of any reasonable alternatives to the rule, together with a summary description of their costs and benefits, and a brief explanation of why such alternatives were not chosen. 15 U.S.C. 1262(h) and 1262(i). In addition, the Commission must address the requirements of the Regulatory Flexibility Act, which considers effects on small firms, and the requirement for review pursuant to the National Environmental Policy Act.

4. Analysis of Proposed Hazardous Substance Declaration/Ban[13]

(a) Potential Benefits

The benefits to consumers of eliminating lead-cored wicks as a source of lead exposure are not quantifiable. Nonetheless, the proposed ban may result in positive health benefits in individual cases, and will contribute to the gradual reduction in lead exposure to the U.S. population. Additionally, the Commission did not regulate

[10] As of January 16, 2002, The VOSI world wide web site states, with respect to the candle wick standard, that ''These standards have been approved by VOSI and are for reference only.'' That page of the website goes on to provide for ongoing public review of ''Approved VOSI Public Health Standards.''

Section 3(i)(2) of the FHSA requires that a voluntary standard be ''adopted and implemented'' before the Commission must defer to it rather than promulgating a mandatory standard. Thus, based on VOSI's public statements on the status of its candle wick standard, the Commission would also be justified in eliminating it from further consideration in this rulemaking without reaching its technical and procedural flaws. 15 U.S.C. 1262(i)(2).

[11] See fn. 9.

[12] Id.

[13] The following discussion of potential costs and potential benefits of the proposed rules is extracted from 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. See fn. 2 above for information on the availability of this and other related documents on the Internet and at the CPSC reading room.

candlewicks in the mid-1970s because the industry voluntarily agreed to eliminate lead from candlewicks. A ban of the use of lead in candlewicks will therefore help ensure that lead will not be used in candlewicks in the future.

(b) Potential Costs

The costs of replacing lead-cored candlewicks with non-leaded wicks are expected to be small. The current use of lead in wicks is already small, since none of the NCA members use lead in their wicks beyond the acceptable trace levels found in zinc cores, and information obtained from an industry source indicates that the cost of substitutes for lead-cored wicks is not higher than the cost of wicks made with lead. In fact, when lead-cored candlewicks were available, they cost more per yard than candlewicks made with other materials.

However, there are some costs associated with testing, tracking, maintaining records of candles and candlewicks with metal cores, and labeling of shipping containers. The proposed rule requires firms that manufacturer, import, or otherwise distribute metal-cored candlewicks and candles perform testing or obtain records of testing to assure compliance. Records of testing would have to bear a lot designation that relates to the candles and candlewicks and be retained for as long as the product the testing pertains to is being distributed plus three years. In addition, firms would have to label shipping containers.

Based on discussions with representatives of the candle and candlewick industries, the metal-cored wick testing burden will likely be minimal for domestic manufacturers of candles and candlewicks, because most candlewicks used in the U.S. are produced by a small number of manufacturers, and the testing of the metal used in the wicks already takes place in the course of manufacturing of the metal used in the wire. The recordkeeping associated with the testing may demand, from candlewick manufacturers and distributors, as much as 40 hours per metal candlewick lot produced annually. From a discussion with a representative of the industry, there may be 5 to 15 lots of wire used in candlewick production per year. Recordkeeping by the domestic candlewick manufacturers and distributors may require as much as 200 to 600 hours per year.

Developing a tracking system for lots may involve some costs. Candle and candlewick manufacturers would have to keep track of when lot numbers for wicks with metal cores changed, and adjust any existing identification system to reflect this. According to the National Candle Association, lot identification might be somewhat problematic for the industry.

Importers would also have to obtain appropriate test results, and develop a system of identification in order to track test results with shipments. The differences in the costs of the testing and labeling requirements for importers, relative to domestic candle manufacturers, are not clear, but it seems likely that the coordination of testing and labeling would be somewhat more complex for importers and therefore more costly, since candles are imported from many countries. One large importer did not think the impact of the rule would be substantial, but was unable to describe how the testing requirements would affect costs.

Domestic producers, distributors, private labelers, and importers of candles, as well as importers of candlewicks, would not have to conduct tests as long as they maintain copies of prior test results for metal candlewicks. Recordkeeping may require as much as 40 hours per firm per year. The exact number of manufacturers and importers is not known and not every firm uses metal-cored wicks. If there are 460 domestic producers of candles in the U.S., and an equivalent number of importers of candles and candlewicks, and if we assume that half of all manufacturers and importers have metal in their candlewicks, then the estimated number of hours for complying with the recordkeeping requirements of the rule for these firms could be as high as 18,400 hours. The total estimated annual employee compensation cost for the paperwork burden may be as high as $400,000, industry wide.

For most candle producers, the costs of labeling are likely to be small. The majority of candles are not produced with metal-cored wicks and therefore will not need to be labeled. Additionally, the labeling requirements will add little to the cost of manufacturing candles when labels are needed if existing labeling machines can be used to add the information required by the rule's labeling requirements.

Although the labeling costs are likely to be low, we can estimate the number of boxes of candles that might be affected. If we assume that $270 to $540 million in candle shipments are affected (*i.e.,* 15–30 percent of all candles shipped with metal wicks), and that each shipping container holds 144 candles (*i.e.,* 12 boxes of a dozen candles), perhaps 2 to 4 million shipping containers would need to be labeled annually. If a label costs 5 to 10 cents (not including the initial purchase of the labeling machine), then $100,000 to $400,000 in annual costs would be absorbed by the candle industry for labeling.

Combined, labeling and recordkeeping may cost the candle industry about $500,000 to $800,000 per year. On a percentage basis, these costs would represent a small fraction (about 0.03 to 0.04 percent) of the overall value of candle shipments which, in 1999, was about $1.8 billion.

Finally, there might also be some costs associated with inventories of uncertified or non-complying candlewicks held by candle manufacturers. These candlewicks would have to be certified or scrapped under the standard. The proposed rule would apply to candles and candlewicks manufactured after the rule's effective date. Although non-complying candlewicks may have been manufactured prior to the effective date, they would not be usable in candles manufactured after the effective date. It is not anticipated, however, that a large amount of candlewick inventory will be affected.

One possible impact of the rule is the movement away from the use of metal core wicks due to the added burden of recordkeeping, labeling and testing. Based on discussions with several candle manufacturers, this has already started to occur. Manufacturers desiring to eliminate metal-cored wicks would have to perform product testing to find a suitable substitute wick for the candle design. The cost of the substitute wick material will not likely be a significant factor in the decision to change wicks because candle wicks are a very low cost item that do not vary much by type. Based on compliance cost and performance factors, each firm will decide whether they will continue to use metal-cored wicks in their candles.

It is anticipated that the costs of the rule, although small, will be absorbed by both consumers and suppliers (including manufacturers and importers). Costs associated with the initial implementation of the rule are likely to be borne by the suppliers. These start-up costs will not likely be passed on to consumers, because the costs may not be uniform across the industry. Some firms may have to develop tracking systems for lot identification, acquire additional labeling machinery, and certify or scrap old candlewicks. Costs associated with ongoing compliance with the rule are expected to be small and these costs will likely be passed along to the consumer in the form of higher prices.

The actual amount of these costs is not clear at this time.

In summary, while the benefits of a ban of lead in candlewicks are likely to be small, the costs of the ban are also small. The action will, however, contribute to the gradual reduction in lead exposure in the U.S. population.

5. Alternatives to the Rule

The Commission has considered several other alternatives, including: no action, product labeling and deferral to a voluntary standard. *See* discussion above at Section F., *Alternatives to Proposed Ban.*

I. Paperwork Reduction Act

The proposed ban regulation will require manufacturers and importers of metal-cored candle wicks and candles with such wicks to perform testing or obtain records of testing, maintain records, and label shipping containers for metal-cored candle wicks and candles with such wicks that they produce or import. For this reason, the rule proposed below contains ''collection of information requirements,'' as that term is used in the Paperwork Reduction Act, 44 U.S.C. 3501–3520. Therefore, the proposed rule is being submitted to the Office of Management and Budget (''OMB'') in accordance with 44 U.S.C. 3507(d) and implementing regulations codified at 5 CFR 1320.11.

Based on estimates made in the course of developing the metal-cored candle wick standard and on information obtained from industry sources, the Commission estimates that complying with the recordkeeping requirements of the proposed banning rule will require approximately 40 hours per metal-cored candle wick lot produced annually. The CPSC staff does not anticipate that domestic producers or distributors of metal-cored candle wicks will conduct testing, since the content of the metal wire used in the candle wicks is analyzed in the course of the manufacturing of the metal. These analyses are provided routinely by the manufacturers of the wire. Since 5 to 15 lots of metal-cored candle wicks are produced per year in the U.S., recordkeeping by domestic metal-cored wick manufacturers under the regulation as proposed would require no more than an estimated 200 to 600 hours per year.

The exact number of manufacturers and importers of candles and of importers of candle wicks is not known. Not every producer/importer uses metal-cored wicks in its candles. CPSC staff estimates that there may be as many as 460 domestic producers of candles. If there are an equivalent number of importers of candles/candle wicks and it is assumed that half of all these manufacturers and importers have metal in their candle wicks, then the estimated number of hours annually that would be expended by these entities for complying with the recordkeeping requirements of the rule may be as high as 18,400.

Combining these two estimates, the estimated total burden on metal-cored wick producers and producers/importers of candles with metal-cored wicks would be 18,600 to 19,000 hours per year.

OMB may comment to CPSC between 30 and 60 days after the publication of the proposed banning rule. Therefore, although OMB will accept comments until June 24, 2002, a comment will be assured of having its maximum effect if it is filed by May 24, 2002.

Comments to OMB should be directed to the Desk Officer for the Consumer Product Safety Commission, Office of Information and Regulatory Affairs, OMB, Washington, DC 20503; telephone (202) 395–7340. The Commission encourages commenters to provide copies of such comments to the Commission's Office of the Secretary, with a caption or cover letter identifying the materials as comments submitted to OMB on the proposed rule to ban certain metal-cored candle wicks and candles with such wicks.

J. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 *et seq.*, generally requires the agency to prepare initial and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. Section 605 of the RFA provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to declare that metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances and to ban such wicks and candles. A copy of the preliminary analysis is available for inspection in the docket for this rulemaking. The assessment reports that the costs to consumers and candle wick and candle manufacturers are likely to be small.

At present, the Commission does not have quantitative information on the number of small businesses that might be affected by the proposed rules, although we believe that almost all domestic candle and candle wick manufacturers are small. The staff assessment concludes that because the incremental cost of the proposals is likely to be small, it is unlikely that the proposals will have a substantial effect on a significant number of small businesses.

The Commission requests comment from companies that supply candle wicks and candles that would be affected by these proposed rules. The Commission is particularly interested in information on the likely effect on small businesses of the testing, recordkeeping, and shipping container labeling requirements of the proposed banning rule.

Based on the foregoing assessment, the Commission certifies that the rules to declare that metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances and to ban such wicks and candles, if promulgated in final form as proposed, would not have a significant adverse impact on a substantial number of small businesses or other small entities.

K. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has preliminarily assessed the possible environmental effects associated with the proposed hazardous substance declaration and ban for metal-cored candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks.

The Commission's regulations at 16 CFR 1021.5(c)(1) state that rules or safety standards to provide design or performance requirements for products normally have little or no potential for affecting the human environment. Preliminary analysis of the impact of the rules proposed today indicates that they will have no significant effects on the environment. This would be especially true if the effective date of the banning rule were to enable firms affected by the rule to deplete any existing non-complying inventory. Thus, the Commission concludes that no environmental assessment or environmental impact statement is required in this proceeding.

L. Effective Date

The rule proposed today would provide a period of one-hundred eighty (180) days for depletion of any existing stocks of candle wick material and candles subject to the proposed ban. It would then apply to any metal-cored candle wick containing more than 0.06 percent lead by weight in the metal, and any candle with such a wick, that is manufactured or imported on or after that date.

M. Executive Order 12988

As provided for in Executive Order 12988 (February 5, 1996), the CPSC states the preemptive effect of these proposed regulations as follows.

The FHSA provides that, generally, if the Commission issues a banning rule under section 2(q) of the FHSA to protect against a risk of illness or injury associated with a hazardous substance, ''no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations.'' 15 U.S.C. 1261n(b)(1)(B). Upon application to the Commission, a State or local standard may be excepted from this preemptive effect if the State or local standard (1) provides a higher degree of protection from the risk of injury or illness than the FHSA standard and (2) does not unduly burden interstate commerce. In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical requirement that provides a higher degree of protection than the FHSA requirement for the hazardous substance for the Federal, State or local government's own use. 15 U.S.C. 1261n(b)(2). Thus, with the exceptions noted above, the proposed rule banning metal-cored candle wicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks would preempt non-identical state or local requirements applicable to such wicks and candles designed to protect against the same risk of injury.

N. Trade Secret or Proprietary Information

Any person responding to this notice who believes that any information submitted is trade secret or proprietary should specifically identify the exact portions of the document claimed to be confidential. The Commission's staff will receive and handle such information confidentially and in accordance with section 6(a) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2055(a). Such information will not be placed in the public docket for the rulemaking and will not be made available to the public simply upon request. If the Commission receives a request for disclosure of the information or concludes that its disclosure is necessary to discharge the Commission's responsibilities, the Commission will inform the person who submitted the information and provide that person an opportunity to present additional information and views concerning the confidential nature of the information. 16 CFR 1015.18(b) (1999).

The Commission's staff will then make a determination of whether the information is trade secret or proprietary information that cannot be released. That determination will be made in accordance with applicable provisions of the CPSA; the Freedom of Information Act (FOIA), 5 U.S.C. 552b; 18 U.S.C. 1905; the Commission's procedural regulations at 16 CFR part 1015 governing protection and disclosure of information under provisions of FOIA; and relevant judicial interpretations. If the Commission concludes that any part of the information that has been submitted with a claim that the information is a trade secret or proprietary is disclosable, it will notify the person submitting the material in writing and provide at least 10 calendar days from the receipt of the letter to allow for that person to seek judicial relief. 15 U.S.C. 2055(a)(5) and (6); 16 CFR 1015.19(b).

O. Conclusion

For the reasons stated in this preamble, the Commission preliminarily finds that metal-cored candle wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances, that cautionary labeling required by the FHSA is not adequate for such wicks and candles, and that, due to the degree and nature of the hazard presented by these items, in order to protect the public health and safety it is necessary to keep them out of commerce.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous materials, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, and Reporting and recordkeeping.

For the reasons stated in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulation to read as follows:

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS.

1. The authority for part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261–1278.

2. In § 1500.12, add a new paragraph (a)(2) to read as follows:

§ 1500.12 Products declared to be hazardous substances under section 3(a) of the act.

(a) * * *

(2) metal-cored candle wicks that have a lead content of more than 0.06 percent of the total weight of the metal core, and candles made with such wicks.

3. In § 1500.17, add a new paragraph (a)(13) to read as follows:

§ 1500.17 Banned hazardous substances.

(a) * * *

(13)(i) Candles made with metal-cored wicks. Lots of candles manufactured or imported on or after _____, 2002 [insert date 180 days after promulgation of final rule] made with metal-cored candle wicks, 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 candles with metal-cored wicks conducts, or obtains a report of the results of, reasonable and representative tests on either the candles in that lot, the metal-cored candle wicks used in that lot of candles, or the metal used to produce the wicks that were used in that lot of candles, 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 candles 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)(i)(D) of this section, are maintained in the United States for as long as the candles 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 candles from a lot subject to paragraphs (a)(13)(i)(B) and (a)(13)(i)(C) of this section are shipped, including each outer container or wrapper of such candles 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)(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.

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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