Based on current trends and actual reclassification petitions received, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff that are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Dated: December 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–7804 Filed 12–23–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0481]

Draft Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy; Draft Supporting Document: Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy.'' This draft guidance provides a recommended maximum lead level in candy likely to be consumed frequently by small children. FDA considers the recommended maximum level to be protective of human health and to be achievable with the use of good manufacturing practices in the production of candy and candy ingredients. The agency is also announcing the availability of a draft supporting document entitled ''Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children.'' These two documents are intended to assist candy manufacturers in achieving reduced lead levels in their products consistent with the agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that practically can be obtained.

DATES: Submit written or electronic comments on the draft guidance by March 13, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance and/or draft supporting document to the Division of Plant Product Safety (HFS–305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance and/or draft supporting document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance and draft supporting documents.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2022.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy.'' This draft guidance provides a recommended maximum lead level in candy likely to be consumed frequently by small children. FDA considers the recommended maximum level to be protective of human health and to be achievable with the use of good manufacturing practices in the production of candy and candy ingredients. FDA notes that the recommended level is not for enforcement purposes. In addition, FDA is rescinding previous guidance provided in a 1995 letter to the industry regarding an enforcement level. Finally, this draft guidance reiterates FDA's enforcement policy toward the use of lead based ink on candy wrappers as stated in the 1995 letter to the industry. FDA also is announcing the availability of a draft document entitled ''Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children.'' The draft supporting document provides additional background and rationale for the recommended maximum level. These two documents are intended to assist candy manufacturers in achieving reduced lead levels in their products consistent with the agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that practically can be obtained.

The agency has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). The draft guidance is being issued as a level 1 draft guidance consistent with GGPs. The draft guidance represents the agency's current thinking on lead levels in candy that are achievable with the use of good manufacturing practices in the production of candy and candy ingredients and that also provides for the protection of human health. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance and draft supporting document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and draft supporting document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/guidance.html.*

Dated: December 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–24494 Filed 12–22–05; 8:45 am]

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