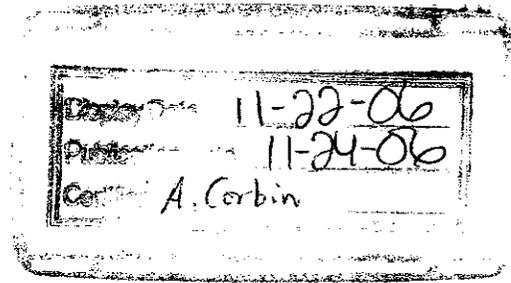


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0481]

DDM



Guidance for Industry: Lead in Candy Likely to Be Consumed Frequently by Small Children; Recommended Maximum Level and Enforcement Policy, Availability; and Supporting Document: Supporting Document for Maximum Recommended 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 final guidance for industry entitled "Guidance for Industry: Lead in Candy Likely to Be Consumed Frequently by Small Children; Recommended Maximum level and Enforcement Policy," and a supporting document entitled "Supporting Document for Maximum Recommended Level for Lead in Candy Likely to Be Consumed Frequently By Small Children." The guidance provides a maximum recommended 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 guidance states FDA's commitment to take enforcement action against candy containing lead at levels that may pose a health risk. 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 can practicably be obtained.

DATES: The guidance and supporting documents are final upon the date of publication. However, you may submit written or electronic comments concerning the guidance and/or supporting document any time.

ADDRESSES: Submit written requests for single copies of the guidance and/or supporting document to the Office of Plant and Dairy Foods (HFS-300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request.

Submit written comments concerning the guidance and/or 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>. To ensure a timelier processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance and supporting document.

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 20740-3835, 301-436-2022, FAX 301-436-2651, or e-mail: michael.kashtock@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 27, 2005 (70 FR 76462), FDA made available a draft guidance for industry entitled "Lead in Candy Likely to Be Consumed Frequently by Small Children; Recommended Maximum Level and

Enforcement Policy” and a draft supporting document entitled “Supporting Document for Maximum Recommended Level for Lead in Candy Likely to Be Consumed Frequently By Small Children” and gave interested parties an opportunity to submit comments by March 13, 2006. The agency considered received comments as it finalized this guidance and supporting document.

This guidance provides a recommended maximum lead level in candy likely to be consumed frequently by small children. FDA considers the maximum recommended 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. In response to comments on the draft guidance, this guidance clarifies FDA’s commitment to take enforcement action against candy containing lead at levels that may pose a health risk. FDA notes that it is rescinding previous guidance provided in a 1995 letter to the industry regarding an enforcement level for lead in candy because the level cited in the 1995 letter is no longer regarded as consistent with the agency’s policy of reducing lead levels in the food supply to reduce consumers’ lead exposure to the lowest level that can practically be obtained. In addition, this 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 supporting document entitled “Supporting Document for Maximum Recommended Level for Lead in Candy Likely to Be Consumed Frequently by Small Children.” The 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 can practically be obtained.

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents FDA'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 provide 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. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**). If you cannot identify the appropriate FDA staff, call the telephone number listed in the title page of the guidance.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance and/or supporting document at any time. 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 guidance and supporting documents 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 guidance and supporting documents at <http://www.cfsan.fda.gov/guidance.html>.

Dated: 11/16/06
November 16, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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