

Guidance for Industry

Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 75 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Michael E. Kashtock at (301) 436-2022.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
December 2005

2005D-0481

GDL1

Guidance for Industry¹

Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy

Draft Guidance

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of applicable statutes and regulations. If you want to discuss an alternate approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance provides a recommended maximum lead level in candy² likely to be consumed frequently by small children. FDA considers the recommended maximum lead level to be achievable with the use of good manufacturing practices in the production of candy and candy ingredients and to be protective of human health. For additional discussion of the background and rationale underlying this recommended level, see draft "Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children" at <http://www.cfsan.fda.gov/~lrd/pestadd.html>.

In addition to announcing the recommended maximum lead level, FDA is rescinding the previous .5 ppm guideline for considering enforcement action against candy products likely to be consumed frequently by small children. Further, FDA is reiterating its

¹ This guidance has been prepared by the Office of Plant and Dairy Foods in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

² We have included within the broad category of Mexican style candy, powdered snack mix products, which are generally made in Mexico and typically contain combinations of salt, chili powder, sugar and flavoring. These products, popular with children and adults, may be sold alongside of candy in retail outlets, and can be consumed directly from the container like candy, as well as being sprinkled onto fruits and vegetables or in beverages.

enforcement policy toward the use of lead-based ink on candy wrappers as originally stated in its 1995 letter to the industry on this subject.

FDA considers the issuance of this guidance to be a prudent public health measure 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 be practicably obtained.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. DISCUSSION

A. Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children

FDA is recommending that lead levels in candy products likely to be consumed frequently by small children not exceed 0.1 ppm because such levels are achievable under good manufacturing practices and would not pose a significant risk to small children for adverse effects. This recommended maximum level of 0.1 ppm for lead in candy likely to be consumed frequently by small children is consistent with the FDA's longstanding goal of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can be practicably obtained. This recommendation is further discussed in the supporting document for this guidance noted above.

B. Enforcement Policy for Lead in Candy Likely To Be Consumed Frequently by Small Children

FDA is rescinding the guidance it provided in the 1995 letter that stated that, where frequent consumption of candy products by small children could be anticipated, FDA would consider taking regulatory action against candy with lead levels that exceed 0.5 ppm.

The 0.1 ppm recommended maximum lead level is not an enforcement guideline. FDA intends to consider several factors in bringing enforcement actions regarding lead in candy likely to be consumed frequently by small children, including the level of lead present and the best available consumption data.

C. Enforcement Policy for Use of Lead-Based Inks on Candy Wrappers

FDA is reiterating in this guidance that FDA's policy toward the use of lead-based ink on candy wrappers remains as stated in its 1995 letter to the industry on this subject (available at <http://www.cfsan.fda.gov/~dms/pbguid.html>):

Generally speaking, if lead derived from a lead-based printing ink is found on the portion of the package that directly contacts food or, if such lead could be expected to migrate into the packaged food, the product would likely be regarded as being in violation of the Federal Food, Drug, and Cosmetic Act. Use of the printing ink only on the outer (non-food contact) surface of the package does not ensure that it will not contaminate the food.

Suitable non-lead-based printing inks are widely available for use in food packaging, and we continue to strongly urge all candy manufacturers, including those whose products are offered for import into this country, to refrain from the use of lead-based printing inks on their packaging materials.

In addition, the use of lead-based printing inks on candy wrappers may subject a firm to regulatory action by the U.S. Consumer Product Safety Commission under the Federal Hazardous Substances Act (see <http://www.cpsc.gov/BUSINFO/cndyus.pdf> and <http://www.cpsc.gov/BUSINFO/cndymex.pdf> for additional information).