



Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

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TO: LaJuana D. Caldwell  
Director, Office of Executive Secretariat  
Food and Drug Administration

FROM: Acting Director, Division of Issues  
Management and Executive Secretariat  
Centers for Disease Control and Prevention

SUBJECT: FDA Draft Guidance for Industry: Lead in Candy Likely To Be Consumed  
Frequently by Small Children

The Centers for Disease Control and Prevention's (CDC) Lead Poisoning Prevention Branch, National Center for Environmental Health, is providing comments on *FDA Draft Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy; Draft Supporting Document: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* [Docket No. 2005D-0481] (*Federal Register*/ Vol. 70, No. 247/ Tuesday, December 27, 2005). Although CDC's National Center for Environmental Health's comments did not get to FDA by the deadline, we would appreciate having them considered as you revise the guidance.

Laura Yerdon Martin

Attachment

2006-3152

Centers for Disease Control and Prevention  
Comments on FDA Draft Guidance for Industry:  
Lead in Candy Likely to be Consumed Frequently by Small Children

The Lead Poisoning Prevention Branch, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), has reviewed the Food and Drug Administration's (FDA) Guidance for Industry, Lead in Candy Likely to be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy. CDC supports the intent of the guidance and believes it is essential to our ability to reduce lead exposure in children.

CDC suggests the following changes in the wording of the guidance:

**General Comment**

**Omit "likely to be consumed frequently by small children" in all instances throughout the document.**

Rationale: Lead exposure during pregnancy can cause permanent damage to the developing fetus. In addition, recent studies suggest that current lead exposure is an accurate predictor of academic performance in school age children. Thus, this guidance should not be focused solely on young children but rather be inclusive of other populations at high risk.

If FDA chooses to include the phrase "likely to be consumed frequently by small children"; considering changing 'small' to 'young' children in the title and throughout the document.

**Other comments specific to a particular section**

**Pg 3 II B. Change the text to read "FDA is rescinding the guidance it provided in the 1995 letter that stated that, where frequent consumption of candy products could be anticipated, FDA would consider taking regulatory action against candy with lead levels that exceed 0.5 ppm. FDA now intends to consider several factors in bringing enforcement actions regarding lead in candy, including the level of lead present, the best available consumption data for a particular product and the 6  $\mu\text{g}/\text{day}$  provisional tolerable intake level. These factors rather than a specific guidance lead level will be used to determine whether enforcement is necessary."**

Rationale: It is our understanding that FDA was limited by the previous enforcement guidance level of 0.5 ppm. This problem is not solved by establishing another, albeit lower, guidance level. In addition, in 1979, FDA stated its intention to reduce consumers' lead exposure to the lowest level that can be practicably obtained. FDA also recognizes that the industry will target the product to meet the guideline. The information reported to FDA by industry indicates that the vast majority of candy samples were well below the proposed 0.1 ppm guidance level. With good manufacturing practices most, if not all candy, would have concentrations of lead well below 0.1 ppm.

**Pg 3- II C. Change the text to read “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>): 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.”**

Rationale: The paragraph beginning “Generally speaking....” just adds confusion. The primary messages here should be that (1) alternatives are widely available and (2) the FDA policy remains in place.