

CITY OF BALTIMORE

MARTIN O'MALLEY, Mayor



HEALTH DEPARTMENT

JOSHUA M. SHARFSTEIN, M.D., Commissioner
210 Guilford Avenue
Baltimore, MD 21202

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February 27, 2006

The Honorable Andrew C. von Eschenbach, M.D.
Acting Commissioner
Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
RE: Docket 2005D-0481

Dear Acting Commissioner von Eschenbach:

The Baltimore City Health Department welcomes the opportunity to provide comments on the Food and Drug Administration's (FDA) December 2005 draft guidance: *Lead in Candy Likely to be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy*. This policy reduces the acceptable levels of lead in candy consumed by small children from no more than 0.5 parts per million (ppm) to 0.1 ppm and maintains the enforcement policy for use of lead-based printing ink on candy wrappers.

Although Baltimore City is pleased with both of these actions, we are disappointed that the FDA has chosen to rescind its previous guidance where regulatory action was a clear consideration for candies exceeding the limit. The proposed guidance document explicitly states that the new 0.1 ppm lead level is "not an enforcement guideline."¹ The lack of an enforcement policy leaves areas such as Baltimore City concerned that this may be nothing more than a suggestion from the FDA that may be widely ignored.

Baltimore's Experience

In September 2005, the Baltimore City Health Department undertook an investigation of several stores to determine the prevalence of suspected lead-tainted candies. A dozen stores located in the Hispanic neighborhoods of Baltimore City were discovered to have lead-tainted candy available for sale. Dozens of containers of Lucas Limon, which was supposedly withdrawn from the market a year earlier, were found on the stores' shelves. Twenty-seven candies were then tested by FDA's laboratory. Fifteen of the candies tested positive for lead, with four testing above FDA's new proposed maximum level for lead.

¹ US FDA/CFSAN – Guidance for Industry: Lead in Candy Likely to be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy (December 2005). Online at: <http://cfsan.fda.gov/~dms/pbguid2.html>

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Our analysis of the results for those with results above the 0.1 ppm level revealed that they represent a significant fraction of or exceeded the FDA's own recommended intake for children under the age of six of less than 6 micrograms of lead per day.² One of the four candies had 9 micrograms of lead in just one serving. (See Table 1.)

Table 1. Candies testing above 0.1ppm

Product Name	Lead Level (ppm)	Serving Size	Micrograms of Lead/Serving
Lucas Pelucas	0.35	28 grams	9.8
Super Pinaleta lollipop w/ Chile	0.125	25 grams	3.125
Super Fresaletas	0.124	25 grams	3.125
Baby Lucas	0.102	20 grams	2.04

In mid December 2005, we alerted the public to our findings and expressed concerns about the public health consequences of candy with lead levels over 0.1 ppm. We also expressed concern about FDA's failure to reduce the maximum lead level in candy.

Enforcement

In the new policy, which lowers the recommended limit to 0.1 ppm, FDA rescinds the previous guideline favoring enforcement action against candy products exceeding the limit. In fact, FDA makes the point repeatedly that the 0.1 ppm standard should not necessarily be used for enforcement. The policy states that the new level does "not establish enforceable responsibilities," and it "should be viewed only as [a] recommendation." FDA stresses that *should* in Agency guidance means that something is suggested or recommended, "but not required."

By failing to establish a legally enforceable standard, the FDA has left local authorities without a strong tool use against those who continue to distribute tainted candies to children.

We recommend that FDA amend this guidance to state:

1. No candy should have a lead level over 0.1 ppm.
2. FDA will routinely test candies against this enforcement standard.

² FDA has adopted the CDC levels for tolerable daily lead limits in children. U.S. Food and Drug Administration, Dangers of Lead Still Linger, FDA Consumer (Jan.-Feb. 1998) (online at <http://www.cfsan.fda.gov/~dms/fdalead.html>).

3. FDA will take domestic and border enforcement action against any candies over this level.
4. FDA will consider using the wide range of authorities and penalties under the Food, Drug, and Cosmetic Act against anyone importing, distributing or selling these candies to children.

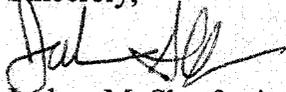
If FDA wants to make an exception for candies that are exclusively consumed by adults, the agency should clearly and narrowly delineate the criteria for this category.

Conclusion

A clear enforcement policy is necessary to eliminate candies exceeding the 0.1 ppm level from store shelves. Without an aggressive approach, we fear this guidance will do little to protect children.

Please do not hesitate to contact Olivia Farrow, Assistant Commissioner for Environmental Health, if you would like additional information. Her phone number is 410 396-4422.

Sincerely,



Joshua M. Sharfstein, M.D.
Commissioner of Health



Olivia Farrow, J.D.
Assistant Commissioner for Environmental Health