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# Comments of the American Public Health Association
Regarding
# Docket No. 2005D-0481
# Draft Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children

March 13, 2006

In November 2004, the American Public Health Association encouraged the Food and Drug Administration (FDA) to set a lead enforcement standard in all candy—domestic and imported—at 0.1 parts per million (ppm). Furthermore, we urged the FDA to conduct sufficient monitoring to ensure compliance to the lead standard, and to take aggressive enforcement action when standards are exceeded. We appreciate the opportunity to comment on the proposed guidance for industry regarding lead in candy.

**I. The American Public Health Association applauds the FDA for setting the lead enforcement standard at 0.1 ppm.**

We are pleased that the FDA has proposed to reduce the acceptable levels of lead in candy from 0.5 ppm to 0.1 ppm. Under the old standard, children eating a small 20 gram candy bar with a lead concentration of 0.5 ppm would potentially exceed the FDA's maximum recommended daily dietary lead intake by as much as 67%. The new standard closely aligns with the National Academy of Sciences' Food Chemicals Codex specification for lead in sugar, which is also 0.1 ppm. More importantly, the new 0.1 ppm standard recognizes that lead poisoning is one of the most common and preventable pediatric health problems today. Since the neurological damage caused by lead appears to be irreversible, the FDA's new 0.1 ppm standard will significantly help to prevent many related health problems, including mental health problems.

**II. The American Public Health Association urges FDA to conduct sufficient monitoring of candy and to take aggressive enforcement action when its lead standards are exceeded.**

While the new 0.1 ppm standard is laudable, we are very concerned that such a standard is meaningless if not enforced. In its proposed guidance, FDA does not propose a strong enforcement mechanism—or any mechanism at all, as far as we can tell. Not only does the FDA admit that the proposed guidance for industry is simply a recommendation, the proposed guidance rescinds previous enforcement guidelines without replacing them. Under the old 0.5 ppm standard, FDA clearly stated that "we [FDA] have the authority to take regulatory action against any food product that contains a poisonous or deleterious substance that may render the product injurious to individuals." By rescinding this and other enforcement language without replacement, and stating that the new 0.1 ppm standard is simply FDA's "current thinking on a

topic and should be viewed only as recommendations," we believe the FDA undermines the intent of changing the standard.

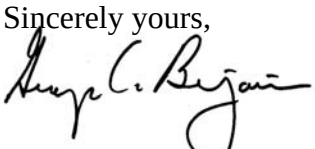
We are pleased that the FDA has stated its intention to "closely monitor" the lead levels in candy, as well as work with counterparts in the Mexican food safety community to do the same. Nevertheless, we reiterate the need to monitor *and* enforce the new 0.1 ppm standard. Without appropriate enforcement, we worry that the monitoring of lead in candy will only provide data on the problem, rather than safeguard the health of children.

The American Public Health Association strongly encourages the FDA to include strong enforcement guidance along with the new 0.1 ppm standard. We suggest either removing the language that rescinds the previous guidance, or replacing it with new guidance that clearly communicates FDA's intent to monitor candy and take aggressive enforcement action when the new 0.1 ppm standard is exceeded.

**III. The American Public Health Association encourages the development of an aggressive prevention and education program for people to learn more about the danger and effects of consuming candy with high lead concentration.**

While the FDA's guidance helps clarify the new 0.1 ppm standard for industry, we encourage the FDA to work with the Centers for Disease Control and Prevention (CDC), state and local public health departments, and other public health agencies and organizations, to educate the public about the danger and effects of eating candy contaminated with lead. Such education is particularly important among persons whose primary language is not English, especially persons who recently immigrated from Mexico or other Latin American countries, where they don't necessarily enjoy the benefits of an assertive FDA to protect their food supply.

Sincerely yours,



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