

CPATH ♦ Center for Policy Analysis on Trade and Health

Bringing a Public Health Voice to Trade and Sustainable Development

Andrew C. von Eschenbach, M.D
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Docket No. 2005D-0481 “Lead Levels in Candy Likely to be Consumed Frequently by Small Children: Recommended Maximum level and Enforcement Policy.”

March 12, 2006

Dear Dr. von Eschenbach,

On behalf of four major health organizations and our members, we are writing in response to the U.S. Food and Drug Administration’s (FDA) Draft Guidance for “Lead Levels in Candy Likely to be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy.” We thank you for your willingness to work with public health organizations and we are pleased to see that the FDA is proposing to reduce the recommended maximum limit of lead in candy from the previous 0.5 ppm. The proposed limit of 0.1 ppm is a positive step towards removing all preventable lead, if this standard is accompanied by strong enforcement measures. However, we are concerned that the guidelines appear to propose a *weakening* of enforcement from previous FDA standards.

There is no safe level of lead in blood, i.e, there is no threshold below which negative effects of lead on children’s developmental outcome is absent. It is certainly possible to eliminate lead in candy, and thus, we absolutely must strive to do so.

The FDA supporting documents for the guidelines repeatedly state that lead intake from these products will be “well below the Provisional Tolerable Total Intake Level (PTTIL) of 6 mcg/day,” without further considering the other sources of lead that contribute to the child’s dietary exposures. Preschool children consume about 4 mcg lead per day, on average. Individual foods need to be well below this level as they are adding to the child’s daily consumption and should not be considered as the sole contributor to daily consumption. Depending on serving size, even lead at 0.1 ppm could significantly contribute to the child’s lead intake. Foods with 1 mcg/lead per serving or higher should be labeled as such, so they can be used sparingly or avoided in small children. We are concerned that the proposed guidelines do not mandate labeling of candy products with at least 1 mcg lead/serving.

Salt-based and spicy candy, primarily imported from Mexico and often sold as “seasoning,” is especially popular with Hispanic children. Alarming cases of lead exposure have been traced to such candy. States such as California are very concerned about this issue and have passed strong legislation to protect citizens from dangerous lead levels in candy.

As the Orange County Register reported in its 2004 special feature, Mexican candy containing high levels of lead has indeed been sold in the U.S., even with the current federal standards. This situation was the impetus for California’s legislation of stronger regulatory authority. We cannot rely on industry to comply voluntarily. The confectioner industry has consistently lobbied for lax regulations, using NAFTA and the idea of “uniformity” in their defense. Potential federal legislation (HR 4167: National Uniformity of Food Act) will nullify stricter state standards, by requiring state food safety laws to be identical to federal standards. Thus, the proposed FDA guidelines pose an even greater risk to our children if HR 4167 is made into law.

We are disturbed that the proposed guidelines specifically rescind the previous enforcement level of 0.5 ppm, and leave us with no replacement. We are not appeased by the proposed guidelines’ statement of intent 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.” This is a clear watering down of previous standards, and would leave us with guidelines that have little chance of actually protecting our children. We urge you to amend the guidelines to include explicit, strong enforcement mechanisms, including using the FDA’s authority to take regulatory action against any candy product found to contain lead levels above 0.1 ppm.

In summary, we recommend that the FDA guidelines include mandated labeling for candy products containing 1mcg lead/serving and strong enforcement mechanisms for the 0.1 ppm lead limit. Thank you for your consideration of our concerns, as the health of our children is at risk. We welcome the opportunity to work with you to amend the guidelines and hope that you will respond to our concerns.

Sincerely,

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