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Via internet <http://www.accessdata.fda.gov/> and U.S. Mail

Michael E. Kashtock
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Guidance for Industry: Lead in Candy Likely to Be Consumed Frequently by
Small Children: Recommended Maximum Level and Enforcement Policy
(Docket Number: 2005D-0481)

Dear Mr. Kashtock:

The Center for Environmental Health and Communities for a Better Environment are writing to comment on the Food and Drug Administration (FDA) Draft Guidance for Industry regarding lead in candy (“Draft Guidance”). The Center for Environmental Health (CEH) is a non-profit organization based in Oakland, California, that seeks to protect the public from environmental and consumer health hazards. CEH is committed to environmental justice, reducing the use of toxic chemicals, supporting communities in their quest for a safer environment, and corporate accountability. A focus of CEH’s work for the last several years has been eliminating hazards to children from lead in consumer products, including Mexican-style candy. Communities for a Better Environment (CBE) is an environmental health and justice non-profit organization also based in California, with over 27 years experience working to empower communities and prevent and reduce toxic hazards to human health and the environment.

We support the lowering of the maximum lead level in candy that would trigger enforcement by FDA from the previous level of 0.5 parts per million (ppm). However, CEH has serious concerns that the proposed guidance level of 0.1ppm is not protective of children’s health. We are also concerned that the Draft Guidance does not clearly establish enforcement guidelines, fails to provide clear standards for candy packaging, and will be ineffective without additional action on the part of the FDA.

I. The Recommended Maximum Level of 0.1 ppm is not protective of children’s health

The Draft Guidance’s recommended maximum lead level of 0.1 ppm in candy is based on a provisional total tolerable intake level of 6 ug/day¹ that relies on an outdated blood lead level (BLL) of concern of 10 ug/dL. Studies have consistently shown intellectual impairment in children at BLL’s significantly lower than 10 ug/dL²⁻⁴, and the Centers for

Disease Control and Prevention clearly state that “no evidence exists of a threshold below which adverse effects are not experienced”⁵. The use of the BLL of 10 ug/dL as the basis for the FDA’s Guidance is thus inappropriate and the 0.1 ppm level fails to protect children from the long-term effects of chronic lead exposure. Given the absence of any safe level of lead exposure for children, FDA’s Guidance should recognize that the only health-based recommendation for lead in candy is no lead.

The Supporting Document to the Draft Guidance states that the recommended maximum level of 0.1 ppm in candy will allow for lead exposure to children up to 1.31 micrograms per day for chili-containing Mexican-style candies and 2.3 micrograms per day for salt-based powdered snack mixes. These calculations are based on lead levels below the 0.1 ppm standard; candies containing the maximum 0.1 ppm lead would actually result in even higher lead consumption by children. This is a completely avoidable source of lead that will add to the health risks of thousands of children who already have elevated blood lead levels from sources such as older housing and soil. These children cannot afford additional exposure from candy or any other preventable sources. It is especially important that FDA adopt a more stringent standard for lead in Mexican-style candies because these candies are most often eaten by Latino children. This children, like other children in communities of color and low income communities, are already more likely to be exposed to lead from sources such as inadequate housing and proximity to lead-emitting industrial facilities.

II. Lower levels of lead are feasible

Testing of candy by CEH and other organizations has shown consistently that levels of lead well below 0.05 ppm are attainable, and the Supporting Document to the Draft Guidance recognizes that lead in candy is preventable by good manufacturing processes. It is inappropriate for FDA to recommend a maximum lead level that is not a health-based standard when there is no evidence that a lower level is not easily achieved. Instead, FDA should make a clear recommendation to manufacturers to lower lead contamination to the greatest extent possible.

III. The Recommended Maximum Level should be an Interim Enforcement Level

The Supporting Document to the Draft Guidance states that “even for high-chili-content candy and powdered snack mix products, we believe that candy with appropriately sourced ingredients will not exceed 0.1 ppm lead”. However, the Draft Guidance fails to state that candies above this concentration will be subject to enforcement action by the FDA, instead saying the Agency will “consider several factors” before bringing enforcement action. CEH strongly believes that candies with greater than 0.1 ppm lead need to trigger enforcement by the FDA to protect the health of children. That enforcement should include the possibility of recalls, penalties and embargoes until the manufacturer proves that the lead contamination problem has been solved. The Guidance should also alert candy manufacturers that the enforcement level will be lowered as lower lead levels become achievable.

IV. The Draft Guidance on candy packaging is incomplete

The Draft Guidance on the use of lead-based inks on candy packaging fails to establish a comprehensive standard for lead in packaging materials. The Supporting Document to the Draft Guidance recognizes that lead-based glazes on ceramic packaging can be an important source for candy contamination. The Guidance should set a clear standard for lead in packaging materials, which will safeguard against all potential sources of candy contamination, including ones that may not yet be recognized.

V. The Guidance needs to recognize state standards

If FDA fails to establish an enforcement policy and action level that eliminates all preventable lead from candy, the Guidance should recognize that state laws requiring the elimination of all preventable lead from candy protect an important public interest that would otherwise be unprotected.

VI. Additional action from FDA is needed

While the suggested revisions to the Draft Guidance will greatly strengthen its effectiveness in protecting children from unnecessary health affects associated with lead in candy, further action on FDA's part is needed. CEH urges the Agency to adopt policies to accomplish the following recommendations.

- a. FDA should prioritize the enforcement of the 0.1 level and the requirements for packaging.
- b. FDA should verify that voluntary recalls by manufacturers have been effective and take enforcement action against manufacturers if it finds that recalls have not been effective.
- c. FDA should conduct comprehensive testing of Mexican-style candy and make that data available to the public.
- d. FDA should establish a bilingual (English/Spanish) hotline for all candy manufactures to access information about what they need to do to comply with FDA's Guidance.
- e. FDA should set up an information booth, and offer a workshop, at the next Candy Expo in Mexico to explain FDA's Guidance and provide relevant information.
- f. FDA should commission a study of methods to eliminate residual lead in washed chilis grown in Mexico. Such study should be made available to all chili powder manufacturers.

Without these additional measures by the FDA, it is unlikely that manufacturers will comply with the Guidance.

I urge the FDA to issue guidance on lead in candy that includes the recommendations described above. Such a policy would recognize health-based goals for the elimination of

lead from candy; establish a clear enforcement action level and policy; and adopt a comprehensive standard for lead in candy packaging. Thank you for considering our comments.

Sincerely,

Michael Green
Executive Director
Center for Environmental Health

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Staff Attorney
Communities for a Better Environment

References:

1. U.S. Food and Drug Administration (2005). "Supporting Document for Recommended Maximum Level for Lead in Candy Likely to Be Consumed Frequently by Small Children". Accessed online 3/9/2006 at <http://www.cfsan.fda.gov/~dms/pbcandy.html>
2. Lanphear *et al.* (2005). Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. *Environmental Health Perspectives* 114(7): 894-899
3. Canfield *et al.* (2003). Intellectual impairment in children with blood lead concentrations below 10 micrograms per deciliter. *New England Journal of Medicine* 348: 1517-1526
4. Bellinger and Needleman (2003). Intellectual impairment and blood lead levels. *New England Journal of Medicine* 349: 500-502
5. Centers for Disease Control and Prevention. "Lead – Questions and Answer". Accessed online 3/9/2006 at <http://www.cdc.gov/lead/qanda.htm>