Environmental Health Coalition

COALICION de SALUD AMBIENTAL

401 Mile of Cars Way, Suite 310 ◆ National City, CA 91950 ◆ (619) 474-0220 ◆ FAX: (619) 474-1210
ehc@environmentalhealth.org ◆ www.environmentalhealth.org

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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:

Environmental Health Coalition ("EHC") is writing to comment on the U.S. Food and Drug Administration's ("FDA") Draft Guidance related to lead in candy ("the Draft"). EHC is a community-based social and environmental justice organization dedicated to protecting human health and the environment from the impacts of toxic chemicals. Our *Campaign to Eliminate Childhood Lead Poisoning* was established to protect children from the dangers of lead in their environment.

Although the major source of childhood lead poisoning is lead-based paint and dust, lead contaminated candy has become a very significant source of lead, especially for Latino children. FDA has known about the problem of lead in candy for over a decade, yet the problem persists. For more than ten years, millions of children across the country, and particularly Latino children, have unnecessarily ingested lead because of FDA's failure to take the steps necessary to address this serious problem. These unnecessary lead exposures are a tragedy. Given the long delay, the very serious harm caused by lead exposure, and the preventable nature of this exposure, it is critical that FDA take actions that will finally safeguard our children's health. Candy manufacturers cannot be directed to make only modest efforts to reduce lead in candy. The well being of our children demands more.

A. The Draft's Recommendation of a Maximum Lead Concentration of 0.1 ppm is Not Sufficiently Stringent

While EHC applauds FDA's move to recommend a low lead exposure level for candy. The Draft's recommendation of a maximum lead concentration of 0.1 ppm in candy is not sufficiently stringent for three reasons. First, it is based on outdated studies. Second, it ignores the high blood lead levels that millions of

children already have, even without additional lead from candy. Third, it is inconsistent with a lead exposure that is preventable.

1. The Recommended Maximum is Based on Outdated Studies

The Draft's maximum recommended lead level of 0.1 ppm in candy is based on the provisional total tolerable intake level ("PTTIL") of 6 ug lead per day from all sources (air, soil, dust, water and food) for children. *See* "Supporting Document for Recommended Maximum Level for Lead in Candy Likely to Be Consumed Frequently by Small Children" (Dec. 2005), Section V (hereafter "Supporting Document"). Yet, the PTTIL was set *more than a decade ago*. *See* Federal Register, Vol. 58, pg. 33860 (June 21, 1993). The PTTIL was based on the lowest observable effect level ("LOEL") of lead in young children *known at that time:* 10 µg/dL. *See id.* at pg. 33640. This was the Centers for Disease Control's ("CDC's") "level of concern." However, more recently, studies have shown cognitive impairment at blood lead levels of much less than 10 µg/dl. These studies show that levels as low as *2.5 µg/dl* were associated with lower scores in tests of reading and mathematics. *See* e.g., Lanphear *et al.*, 2000; Rogan *et al.*, 2001; Rosen and Mushak, 2001.[i] Significantly, the CDC now recognizes that "no evidence exists of a threshold below which adverse effects are not experienced." CDC, "Lead: Questions and Answers" (CDC website). Thus, there may be no PTTIL appropriate for children. Lead exposures that cause even very low blood lead levels have adverse cognitive effects on children and therefore cannot be said to pose no significant risk.

2. The Recommended Maximum Ignores the High Blood Lead Levels of Millions of Children

Not only is the Draft's recommended maximum of 0.1 ppm lead in candy based on outdated information concerning what blood lead levels cause harm, but this maximum of 0.1 ppm also ignores the reality that millions of children already have dangerously high blood lead levels from other sources of lead. Children that consume other imported products with high levels of lead, or who live in lead "hot spots" with older housing that has leaded paint, lead contaminated soil, and proximity to industries that emit lead into the air cannot afford *any* additional exposure to lead.

3. The Recommended Maximum Is Inconsistent With a Preventable Source of Lead

The Draft recommendation of a maximum of 0.1 ppm lead in candy is inappropriate for a third reason -- because this lead can be eliminated from candy. Where lead exposures are preventable, FDA has previously rejected draft guidance recommending maximum exposure levels. For example, FDA's draft recommendation of a maximum of 0.3 ppm lead in canned milk was

rejected after public comment because of the ability to eliminate lead from the cans. *See* Federal Register, Vol. 58, pg. 33860 (June 21, 1993).

FDA's own Supporting Document recognizes the preventable nature of the lead in candy. Lead is not detected in fresh peppers; rather, it is a contaminant of chili powder that can be avoided at the various stages of the product's life. *See* Supp. Doc., Section IV.c (for example, by not putting chili peppers in contact with the ground during their drying, and by washing the chili peppers before grinding). Lead is not detected in properly processed sugar. *See* Supp. Doc., Section III. Furthermore, salt can be sourced to have practically non-detectable levels of lead. *See* Supp. Doc., Section V.c.ii (recognizing that manufacturers can source salt "at the lower end of the reported lead range for marine salt" which FDA identifies as 0.01 – 0.08 ppm). Thus, by FDA's own assessment, the elimination of detectable levels of lead from candy containing chili powder, sugar, and/or salt is achievable with proper processing and sourcing of ingredients.

B. The Draft's Supporting Document Mischaracterizes the Health Risks Of Candy With a Recommended Maximum of 0.1 ppm Lead

The Draft's Supporting Document includes a section entitled "Health Protection Considerations" that characterizes the health risk to children from the lead exposures anticipated to result from the Draft's recommended maximum of 0.1 ppm lead in candy. *See* Supporting Document, Section V. The characterization of the anticipated health risks is critically flawed because its point of reference is the PTTIL of 6 µg/day of lead, which is outdated and ignores the reality that millions of children already have dangerously high blood lead levels (see above). However, even if the PTTIL were valid, the characterization of anticipated lead exposures as posing no significant risk of adverse effects is obviously incorrect, as is evident with a couple examples.

First, as to Mexican-Style Candy containing chili, FDA calculates that children 4-6 years of age in the 90th percentile of consumption would consume 1.31 µg/day of lead from candy. *See* Supporting Document, Section V.c.i. Thus, **this candy alone would represent 20% or 1/5th** of a child's PTTIL of 6 µg/day. Second, as to Salt-Based Powdered Snack Mixes with Sugar, FDA calculates that children 4-6 years of age in the 90th percentile of consumption would consume 2.3 µg/day of lead from candy. *See* Supporting Document, Section V.c.ii. Thus, **this candy alone would represent more than 38%** of a child's PTTIL of 6 µg/day. With additional lead from food, water, air, soil, and dust, the lead from these candies cannot be characterized as posing no significant risk.

Furthermore, FDA's calculations assume that the concentrations of lead in these candies will be well below the Draft's recommended maximum of 0.1ppm. If, however, the candies contain the maximum 0.1 ppm lead, the consumption of Mexican-Style Candy containing chili would be 3.6 ug/day of lead (36 grams/day candy with 0.1 ppm lead), **representing greater than 50%** of a child's PTTIL;

the consumption of Salt-Based Powdered Snack Mixes with Sugar would be 2.9 ug/day (28.75 grams/day candy with 0.1 ppm lead), **representing almost 50%** of a child's PTTIL.

C. Given the Absence of any Known Safe Level of Lead Exposure for Small Children, and the Preventable Nature of Lead Contamination of Candy, FDA Guidance Should Recommend the Elimination of All Preventable Lead From Candy

Given the absence of any safe level of lead exposure for children and the preventable nature of the lead contamination in candy, FDA's Guidance should recommend a non-detectable level of lead in candy. While it may not be immediately possible for candy manufacturers to achieve non-detectable lead levels consistently, the non-detectable level is unquestionably the only health-based recommendation possible. The goal cannot be merely to do what is easy. The goal must be to eliminate all preventable exposures to lead.

D. The Draft Recommended Maximum Lead Concentration of 0.1 ppm is More Appropriately the FDA's Interim Enforcement Action Level

EHC is completely in agreement with the Supporting Document's conclusion that candy manufacturers can achieve a 0.1 ppm concentration of lead in candy today simply by purchasing chili powder from washed chilis and purchasing marine, rather than mined, salt. Because of this, the FDA's Guidance should include an enforcement policy specifying that any candy containing more than 0.1 ppm lead will be considered for an enforcement action, including the possibility of mandated recalls, penalties, and embargoes until the company can prove all preventable lead has been eliminated. Furthermore, the Guidance should alert candy manufacturers that when lower lead levels are achievable, the 0.1 ppm enforcement action level will be reduced.

E. The Guidance Should Recognize the Importance of State Regulatory Efforts to Eliminate Preventable Lead from Candy

If FDA fails to establish an enforcement policy and action level to eliminate all preventable lead in candy, its Guidance should recognize that state laws requiring the elimination of all preventable lead from candy should be deemed to protect an important public interest that would be otherwise unprotected. FDA should also recognize that the interest in protecting children from preventable lead exposures is paramount.

F. The Guidance on the Use Of Lead-Based Inks on Candy Packaging Should Be More Extensive

The Draft Guidance on the use of lead-based inks on candy packaging does not go far enough. Lead-based inks are not the only source of lead in packaging

materials. Many different packaging components may contain lead, including ceramic containers with lead glaze. The Guidance should specify that all candy packaging materials that may come in contact with candy, or a child consuming the candy, should not be used under the following circumstances:

(a) If they are ceramic, they leach lead in excess of 100 ppb (i.e., 0.100 ppm) of lead when tested pursuant to ASTM Method C-738 (24-hour acetic acid leaching protocol);
(b) If they are not ceramic, they contain any intentionally added lead or, if no lead has been intentionally added, contain lead in excess of 20 ppm based on total lead content analysis following complete digestion of the packaging material in nitric acid.

The Guidance may recognize an exception to the above requirement if the packaging material is encased by a film which contains no detectable lead (as measured following nitric acid digestion at a LOQ of 100 ppb), provided that the film is affixed in a manner that assures that the film is an effective barrier to the migration of lead contained in underlying materials. In order to determine that the film is an effective barrier to migration of lead contained in underlying materials, a leach test of the film-affixed packaging material should be performed to verify that less than 100 ppb of lead leaches out when tested pursuant to ASTM Method C-738 (24-hour acetic acid leaching protocol).

In addition, the Guidance should include an enforcement policy regarding candy packaging containing lead-based inks and/or not meeting the standards identified above. Such packaging should be subject to an enforcement action, including the possibility of mandated recalls, penalties, and embargoes.

G. The Draft Guidance Alone is Insufficient to Protect Children From Lead in Candy – Additional FDA Action is Necessary

The suggested revisions to the Draft will increase the protection offered to children from the damaging effects of lead in candy. Yet, more than mere guidance is needed. EHC has a number of recommendations in this regard:

Recommendation #1: FDA should make it a priority to take enforcement action against candy manufacturers who are exceeding the applicable lead enforcement action level and/or the requirements for candy packaging.

Recommendation #2: FDA should purchase and analyze Mexican-style candy, and maintain a database of the lead levels found in candy and in candy packaging. FDA should work cooperatively with State authorities in compiling this database, which should include the results obtained by state and local health departments. This database should be accessible to the public so that state and local health departments may properly advise parents.

Recommendation #3: FDA should verify that a manufacturer's voluntary recall has been effective, and FDA should take enforcement action if the recall has not been effective.

Recommendation #4: FDA should work closely with the Consumer Safety Product Commission ("CSPC") to 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. Without such assistance, it is unlikely that many Mexican candy manufacturers will be able to comply.

Recommendation #5: 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.

Recommendation #6: 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.

Recommendation #7: Should FDA fail to establish a lead action level and/or candy packaging enforcement policy, FDA should validate current state laws such as California's AB 121, in order to safeguard the public's health, especially, Latino children.

H. Conclusion - Getting the lead out of Candy

Thank you for your consideration of our comments and recommendations. We have long awaited FDA action on this crucial environmental justice issue.[ii] We are counting on FDA to issue guidance that is highly protective and includes an enforcement policy that will eliminate all preventable lead. To issue Guidance that relies on outdated studies and that only recommends the reduction of lead is a disservice to children, especially the Latino children who consume these toxic treats on a daily basis.

FDA should not be minimizing the health risks from lead, especially preventable exposures from candy products. We are informed that at its press conference announcing the Draft Guidance, an FDA representative responded to media inquiries by stating that up to 1 to 2 micrograms of lead per day from Mexican Candy or salt-based snacks would not result in measurable differences in blood lead levels. These comments were highly inappropriate. They suggest to industry that it is not important to reduce, let alone eliminate, lead from candy; they are contrary to the recent studies cited above; and they are insensitive to the Latino community whose children are disproportionately exposed to lead from many sources, and for whom an additional exposure of 1 to 2 micrograms of lead per day from candy will have serious adverse health effects.

Lead exposure is the number one environmental health threat to children under 6 years old. It causes damage to the central nervous system, reduces IQ, and

causes learning disabilities, behavior problems, hyperactivity, and increased aggression. But childhood lead poisoning is also considered the most preventable environmental disease among young children. We have eliminated lead from paint and gasoline; FDA should take the necessary next steps towards eliminating lead from candy.

Should you have any questions, please feel free to contact Leticia Ayala, Campaign Director for EHC's Campaign to Eliminate Childhood Lead Poisoning at (619) 474-0220 ext. 121.

Sincerely,

Diane Takvorian

Diane Takvorian
Executive Director

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[i] Lanphear, B.P., K.N. Dietrich, P. Auinger, and C. Cox, "Cognitive Deficits Associated with Blood Lead Concentrations below 10 micrograms per dl in US Children and Adolescents," Public Health Reports (2000), 115, 521-529; Rogan, W.J., K.N. Dietrich, J.H. Ware, D.W. Dockery, M. Salganik, *et al.*, "The Effect of Chelation Therapy with Succimer on Neuropsychological Development in Children Exposed to Lead," North England Journal of Medicine (2001), 344, 1421-1426; Rosen, J.F. and P. Mushak, "Primary Prevention of Childhood Lead Poisoning-- The Only Solution," North England Journal of Medicine (2001), 344, 1470-1471.

[ii] California's Department of Health Services has a database identifying elevated blood levels. Although the database is limited, about 70 percent of the listed surnames appear to be Latino. *See* Environmental Working Group, "Lead Astray" (April 2000).