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Andrew C. von Eschenbach, M.D.
Acting Commissioner of Food and Drugs
Care of Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Docket Number 2005D-0481

Dear Acting Commissioner von Eschenbach:

The American Academy of Pediatrics, a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, appreciates this opportunity to offer comments on draft guidance entitled "Lead in Candy Likely to be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy," which was made available on the FDA website beginning December 22, 2005.

Background

Lead exposure damages the central nervous system, resulting in cognitive impairment as measured by IQ tests. Other aspects of brain or nerve function, especially behavior, also may be affected. Children with elevated lead are more likely to have attentional dysfunction, increased aggression, experience reading disabilities, and fail to graduate from high school, and delinquency.¹ Further, there is no known "safe" level of bloodlead in children.² *No study has determined a level of lead in blood that does not impair child cognition.* Thus, commonly encountered blood lead concentrations have lasting negative effects. In fact, several studies suggest that the drop in IQ is greater as blood lead values increase from 1 to 10 µg/dL than for a rise from 10 to 20 µg/dL.^{3, 4}

Not only would more stringent regulation of lead improve the health of America's children, but several studies have shown that stricter lead regulation makes economic sense as well. If childhood lead exposure affects cognitive function and its consequences, such as graduating from high school, then it is plausible that reducing these exposures would improve social function, employment, and earnings.

The Academy commends FDA for including powdered snack mix products containing combinations of salt, chili powder, sugar and flavoring within the broad category of Mexican-style candy subject to regulation in the December 2005 draft guidance. Prior to 2005, FDA did not regulate the lead content in “seasonings” based upon the presumption that seasonings were consumed in such small quantities that they did not pose a significant health risk. However, the Agency has now acknowledged that many children consume the seasonings in large quantities, like candies, thus posing a health threat. The Academy praises FDA for altering its policy and including powdered snack mixes in the December 2005 draft guidance.

Recommendations for FDA Action

FDA should acknowledge that there is no known safe level of lead exposure. The Academy urges FDA to eliminate the statement in the December 2005 draft guidance that the new 0.1 ppm recommended maximum lead level “would not pose a significant risk to small children for adverse effects.”⁵ As noted, evidence continues to build that commonly encountered blood lead concentrations, even those less than 10 µg/dL, may impair cognitive function. No studies have definitively determined that a “safe” level of lead exists and FDA’s official documents should reflect this reality. Moreover, the FDA guidance appears to assume that the candies represent the only route of lead exposure being experienced. When the lead in candies is combined with lead exposure from other environmental sources, the total could be much higher.

FDA should continue to use an enforcement guideline to regulate the level of lead in imported candy. The AAP encourages FDA to continue to utilize an enforcement guideline approach to regulating levels of lead in imported candy. In 1995, FDA sent a letter to manufacturers, importers, and distributors establishing a 0.5 ppm enforcement guideline for levels of lead in imported candy. With the implementation of that guideline, FDA warned that lead levels exceeding 0.5 ppm could constitute a basis for regulatory action, “in cases where frequent consumption of the candy by small children could be anticipated.” In the December 2005 draft guidance, FDA proposes rescinding this enforcement guideline in favor of a *recommendation* that lead levels in candy products not exceed 0.1 ppm. The 0.1 ppm recommended maximum lead level is not an enforcement guideline. Instead, under the draft guidance, FDA intends to consider several factors in deciding whether to bring enforcement actions, including the level of lead present and the best available consumption data.

Replacing the enforcement guideline with a recommendation implies that FDA will not take decisive action to mitigate the health risks posed by children consuming candy containing lead. In 2002, the Centers for Disease Control and Prevention (CDC) issued a report containing data on lead levels in candy imported from Mexico. Of approximately 1,000 cases of elevated blood levels (BLLs) among California children reported to the California Department of Health Services between May 2001 and January 2005, candy produced in Mexico was identified as a possible exposure source in approximately 150 cases.⁶ FDA must send a clear signal that it will act swiftly if lead exposure from imported candy poses a health risk, specifically when its consumption allows children to exceed the maximum daily allowable intake for lead, not just when blood lead levels are excessively high, as with these 150 children.

Furthermore, under the enforcement guideline approach, FDA retains discretion over whether or not to bring an enforcement action. Thus, the implementation of a recommendation does not provide FDA with any increased flexibility in determining how to best utilize enforcement resources.

FDA should lower the 10 microgram per-serving limit implemented in a 2004 import alert to comport with the Agency's own 6 microgram daily limit recommendation for children under 6 years of age and act to prohibit foods that exceed this limit. FDA recommends that children less than 6 years of age not consume more than 6 micrograms of lead per day. In 2004, FDA issued an import alert permitting an enforcement action to occur when the total amount of lead per candy serving equaled or exceeded 10 micrograms, even if the product contained 0.5 ppm or less lead. Although it is not mentioned in the 2005 draft guidance, the use of a 10 microgram per-serving limit in the 2004 import alert clearly runs counter to FDA's own 6 microgram total daily limit recommendation for children under 6 years of age. Further, the safety evaluations for lead in foods used to evaluate the lead concentration in food are based on average intake values and do not thus protect individual children who may be frequent consumers of the product. Thus, this further protection is needed for those children.

In conclusion, the Academy commends FDA for acknowledging the dangers posed by candy-like seasonings contaminated with lead. We encourage FDA to address the concerns detailed above in embarking upon the development of a strong, enforceable standard. If the Academy can be of further assistance, please do not hesitate to contact Cindy Pellegrini or Stephanie Russell in our Washington, DC office at 202-347-8600. We look forward to working with you to protect the health of our nation's children.

Sincerely,



Eileen M. Ouellette, MD, JD, FAAP
President
American Academy of Pediatrics

cc: Environmental Protection Agency
Consumer Product Safety Commission
Centers for Disease Control

¹ Centers for Disease Control and Prevention. Managing elevated blood lead levels among young children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention. Atlanta: US Department of Health and Human Services; 2002. At: http://www.cdc.gov/nceh/lead/CaseManagement/caseManage_main.htm.

² American Academy of Pediatrics Committee on Environmental Health. Lead Exposure in Children: Prevention, Detection, and Management. *Pediatrics* Vol. 116 No. 4 October 2005.

³ Canfield RL, Henderson CR Jr, Cory-Slechta DA, Cox C, Jusko TA, Lanphear BP. Intellectual impairment in children with blood lead concentrations below 10 µg per deciliter. *N Engl J Med* 2003;348:1517-26.

⁴ Lanphear BP, Hornung R, Khoury J, et al. Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. *Environ Health Perspect* 2005;113:894-899.

⁵ FDA. Lead in Candy Likely to be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy. December 2005. Available at <http://www.cfsan.fda.gov/guidance.html>.

⁶ CDC. Childhood Lead Poisoning Associated with Tamarind candy and Folk Remedies—California, 1999-2000. *MMWR* 2002;51:68 4-6.