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The Honorable Andrew C. von Eschenbach, M.D.
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857-0001

Dear Acting Commissioner von Eschenbach:

For some time, those of us concerned about the health and well-being of Hispanic children (both in the United States and in Mexico) have eagerly awaited action by the Food and Drug Administration (FDA) to reduce the acceptable level of lead in candy to ensure that children's exposure to lead is minimized, as the Agency committed to do in Spring 2004. We have been concerned particularly about imported candy from Mexico. Therefore, I am extremely pleased to see that through its December 2005 draft guidance, the FDA has proposed that acceptable levels of lead in candy be reduced from no more than 0.5 part per million (ppm) to 0.1 ppm, while also maintaining the enforcement policy toward the use by industry of lead-based printing ink on candy wrappers. I want to express my strong support for both of these actions.

However, I am deeply disturbed by the fact that, while FDA states it will maintain its enforcement policy against industry use of lead-based printing ink on candy wrappers, it appears to be gutting its enforcement policy with respect to the acceptable level of lead in the candy itself. Dropping the stated acceptable level from no more than 0.5 ppm to 0.1 ppm is meaningless if FDA does not intend to enforce the lower standard. The public documents on enforcement of the new 0.1 ppm standard appear to indicate just that - FDA is abrogating its current enforcement policy without replacing it with anything other than a "recommendation" with no teeth.

The notice published in the *Federal Register* on December 27, 2005, reads, "...FDA is rescinding previous guidance provided in a 1995 letter to the industry regarding an enforcement level." That would not be disturbing, in and of itself, if the guidance being rescinded were being replaced with new enforcement policy. However, the draft guidance and supporting documents make clear that is not the case.

As the draft guidance entitled "Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy" reads, "The 0.1 ppm recommended maximum lead level is not an enforcement guideline. FDA intends to consider several factors in bringing enforcement actions regarding lead in candy..., including the level of lead present and the best available consumption data."

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The 0.1 ppm level is further undermined by the draft guidance's clarification that "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required."

In addition, the supporting document for the guidance takes it one step further by stating, "The draft guidance also rescinds the 0.5 ppm guideline for considering enforcement action and does not announce a new enforcement guideline."

Further to the point, the *Baltimore Sun* (December 23, 2005) quotes Michael Kashtock, "a senior adviser at the FDA," as stating "the guidance doesn't include enforcement because it's too difficult to have a 'one-size-fits-all approach' to various candies" and that "the agency has met with Mexican officials and is hoping to prevent tainted candy from coming across the border." FDA enforcement policy should not be based on "hope."

In sharp contrast, the 1995 enforcement guidance read:

...we 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. We also have regulations that require that ingredients used to manufacture food be safe, which requires that they be of a suitable degree of purity for their intended use. Further, our regulations require that equipment and utensils used in the production of food be designed and used in a manner that precludes contamination of the food with unsafe substances.

The statute clearly anticipates that FDA will set acceptable levels of contaminants, such as lead, in food products, and that, once such levels are established and exceeded, the product is adulterated and subject to enforcement action.

FDA's press release on the new guidance states that the Agency will "[c]ontinue to closely monitor the lead levels in Mexican candy and other domestic and imported candy products, work with our Mexican counterpart regulatory agencies, and take appropriate regulatory action...." Since FDA has apparently now rescinded the 1995 enforcement guidance, I ask that you take immediate action to clarify what the Agency means by "appropriate regulatory action." Further, I ask that you explain both how FDA will take action against manufacturers, importers, and distributors of candy that exceeds 0.1 ppm of lead, whether domestic or imported, and how the Agency will identify the most likely sources of violations and set enforcement priorities. This clarification is essential so we can be assured that you intend to protect our nation's children, particularly Hispanic children and children along the U.S.-Mexico border, from dangerous lead exposure.

As part of that effort, I urge that FDA work in close partnership with the U.S.-Mexico Border Health Commission (USMBHC) to protect the health of children in both the United States and Mexico. I understand FDA will participate in a meeting in El Paso, Texas, on January 26-27,

2006, and urge that the Agency engage in this effort at the highest levels, to assure appropriate involvement of the Mexican government, health agencies, and other key stakeholders.

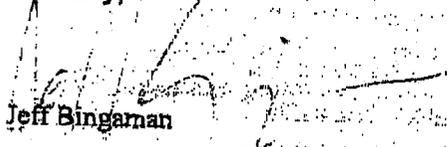
Dr. von Eschenbach, this has been an issue of great importance to many of us along the U.S.-Mexico border for a number of years. In August 2002, for example, the Centers for Disease Control and Prevention (CDC) reported that tests by the State of California revealed up to 21,000 ppm of lead in imported candies and stated that, in California children, approximately 15 percent of cases of elevated blood lead levels (BLLs) were associated with candy produced in Mexico.

At that time, CDC recommended, "Although household paint and resulting contaminated dust and soil are the most common sources of exposure, all sources of lead poisoning should be identified and removed." Unfortunately, FDA has a long history of failing to take action (see, for example, the series of award-winning articles in 2004 by the *Orange County Register*) in matters within its jurisdiction.

We know that elevated BLLs can have, as the California Senate Committee on Health and Human Services has found, "dramatic and devastating effects, particularly on children." The Committee adds, "It affects the liver, kidneys, lungs, spleen, muscles, heart, and central nervous system. At high levels, lead poisoning can cause kidney problems, seizures, coma, miscarriages in pregnant women and low sperm counts in men, and even death. Once eaten, it stays in the bloodstream and bones. Even low levels of lead are harmful and are associated with decreased intelligence, impaired behavioral development, stunted growth, and impaired hearing."

I urge your immediate attention to this important matter. It is crucial for our children that you immediately make public real enforcement policies and ensure appropriate regulatory action in cases where there is failure to comply with the new 0.1 ppm standard. Anything less will fail many of our nation's children and force individual states to take action, as California and Illinois already have done, to protect their children.

Sincerely,


Jeff Bingaman