



March 13, 2006

BY ELECTRONIC MAIL

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

Re: Docket No. 2005D-0481; FDA Draft Guidance – Lead in Candy Likely to Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy

The National Confectioners Association would like to take this opportunity to communicate our support of the draft Guidance for Industry on lead in candy. The NCA represents more than 700 companies that manufacture and market the vast majority of sugar and chocolate candy produced in the U.S. The safety and wholesomeness of candy products are a top priority for the American confectionery industry.

NCA member companies rely on the FDA's expertise in establishing appropriate lead levels for all consumer food products and packaging materials that come into contact with food, based on consumer safety and manufacturing feasibility. This draft guidance sets an allowable lead level in candy based on sound science and principles of risk assessment.

The draft guidance provides a maximum lead level of 0.1 parts per million (ppm) in candy likely to be consumed frequently by small children. This represents an 80% reduction from the existing 0.5 ppm maximum lead level and would be the most stringent lead standard for candy in the world. The draft guidance applies to Mexican-style candy, sugar based candy and chocolate candy sold in the United States, regardless of country of origin, if such candy is likely to be frequently consumed by small children.

In the draft guidance, FDA states that a maximum lead level of 0.1 ppm is "achievable under good manufacturing practices and would not pose a significant risk to small children for adverse effects." FDA has set a provisional total tolerable intake level (PTTIL) for lead by children under the age of six of 6 micrograms per day. This draft guidance will ensure that any lead exposure from candy is well within the PTTIL.

Furthermore, by establishing a uniform national standard, the FDA will ensure product safety and provide a regulatory framework in which enforcement agencies at the federal, local and state level may work together. To this end, the NCA encourages FDA to strengthen the enforcement policy for the guidance. Any foods marketed in the U.S. that contain unsafe levels of lead are adulterated and should be removed from U.S. store shelves. FDA should take enforcement action against candy with lead levels that exceed 0.1 ppm, if frequent consumption of



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candy products by small children can be anticipated,. To clarify the regulatory significance of this guidance, NCA requests that FDA include the following language in the final guidance, “While this guidance is not a regulation, the agency intends to use this guidance to inform its interpretation of the Act, including for purposes of enforcement.” FDA can provide greater leadership to federal, local and state enforcement agencies by elaborating in the final guidance the steps FDA will pursue to assure that all such candy adheres to the guidance.

The National Confectioners Association supports the rigorous standard proposed by FDA, and we believe it will ensure the continued safety of all candy products purchased in the U.S. While we strongly endorse FDA’s guidance, we urge the Agency to revise certain unnecessary and unsupported statements regarding the production of chili powder in the December 2005 draft “Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children” (the “Supporting Document”). In the Supporting Document’s discussion of Mexican-style candy with chili as an ingredient (Section IV.c.i), FDA states its belief that a chili powder lead concentration of 0.2 ppm or less is achievable “by sourcing chili made from effectively washed chili peppers, which were handled, e.g., dried, under good agricultural practices”.

We agree with FDA that analytical data from industry comparing lead levels in washed and unwashed chili “suggest that Mexican-style candy manufacturers could significantly reduce lead levels in their candy products by ensuring that their chili ingredients are sourced from suppliers that effectively wash the peppers before they are ground”. However, the range of analytical data on chili powder in the record does not support FDA’s assertion that a maximum lead level of 0.2 ppm or less is achievable. On the contrary, the analytical data in the record demonstrates that 0.2 ppm is not feasible as a ceiling for lead in chili powder made from washed peppers. There is similarly no support for the Agency’s assumption that not placing peppers on the ground for initial drying will, when coupled with washing, result in a level of lead reduction better than washing alone.

Washing is the key lead reduction step. Obtaining tarps or locating alternative surfaces for laying out of peppers would impose a burden on the many small Mexican chili producers who commonly lay their peppers on the ground for initial drying. This burden is unwarranted since there is no evidence showing lead reduction benefits from avoidance of ground drying so long as the peppers are washed. Therefore, we respectfully request that FDA revise the discussion of ground drying in Section IVc.i to eliminate the suggestions that (1) ground drying has an adverse impact on the lead content of chili powder made from washed peppers and (2) such drying method is therefore incompatible with good agricultural practices for growing and handling of chili peppers.

Although 0.2 ppm is an unrealistic maximum for lead in chili powder made from washed peppers, the analytical data in the record on chili powder made from washed peppers show that



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actual lead levels after appropriate washing are low enough to ensure that chili-containing candies will consistently meet the proposed 0.1 ppm standard for lead in candy frequently consumed by small children. On this basis, NCA respectfully requests that the Supporting Document emphasize the utility of appropriate washing of peppers in achieving optimal lead reduction and avoid statements about the achievability of 0.2 ppm or any other specific concentration of lead in chili powder made from washed peppers.

Ultimately, the goal of the guidance is to regulate lead in candy, rather than in individual ingredients. Therefore, if the relevant products containing chili powder as an ingredient can adhere to the guidance through the use of powder made from washed peppers, there is no need to identify a maximum lead concentration for chili powder or other ingredients, either in the guidance itself or in a Supporting Document whose stated purpose is merely to “further present the background and rationale for FDA’s recommended maximum level” in the relevant candy products. Since candy manufacturers must meet the 0.1 ppm lead limit for their finished products, it is in their interest to audit all of their ingredient suppliers *vis-à-vis* control of lead and confirm supplier use of GMPs so that the candy products, as formulated will meet the guidance’s stringent lead standard.

Other than the changes requested above regarding the Supporting Document, NCA urges FDA to finalize the draft guidance without modification. We also urge the FDA to remain vigilant on this important food safety issue by keeping this a Priority A item in the Center for Food Safety and Applied Nutrition’s FY 2006 Program Priorities and by implementing a final guidance in 2006.

Sincerely,

Larry Graham
President
National Confectioners Association

cc: Honorable Andrew C. von Eschenbach, Acting Commissioner of FDA
Robert Brackett, Ph.D., Director, Center for Food Safety and Applied Nutrition, FDA