

Division of Dockets Management (HFA-305)
Food and Drug Administration
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To Whom it May Concern

Docket Number 2005D – 0481

Thank you for your commitment in trying to reduce exposure of children to lead. We agree with the contents of your draft document for candy manufacturers regarding lead in candy, powdered snack mix, and candy wrappers. However, there are a few points we would like to make to further ensure children's safety.

As Chair of the South Carolina State Lead Advisory Committee which at its last meeting held on February 23rd discussed the FDA document at length, I am pleased to submit our comments and recommendations.

We believe that the FDA document is unclear on vital issues and that more stringent measures are needed, particularly with regard to the recommended maximum level of lead. Some new studies now indicate that blood lead levels below 10 µg/dL can still have an adverse impact on children's IQ scores. This provides further evidence that there is no threshold effect of lead.

The SC Lead Advisory Committee strongly suggests that the FDA remove the statement in the December 2005 draft guidance that says the 0.1 ppm recommended maximum lead level "would not pose a significant risk to small children".¹ There is no physiologic function for lead, therefore any amount of lead has the capacity to harm children.

Although no new directions have come from the Centers for Disease Control and Prevention (CDC) regarding safe lead levels, the SC Lead Advisory Committee believes that there is **NO** safe level for lead in candy likely to be consumed frequently by children.

The Advisory Committee agrees with the recommendation to lower the allowable concentration from 0.5 ppm to 0.1 ppm with due consideration being given to what a detectable level is. However, we also suggest that the FDA should use an enforcement guideline. In 1995, FDA established an enforcement level at 0.5 ppm. By changing it to a **recommendation** that lead in candy does not exceed 0.1 ppm, FDA has effectively removed an enforcement guideline which would imply that FDA will not take any action to reduce a child's risk to candy containing lead.

Thank you for considering these comments and recommendations in preparing the final guidance document.

Sincerely,



2005D-0481

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¹ 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>