



POLICY & ACTION FROM CONSUMER REPORTS

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

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**Comments of Consumers Union to the
Food and Drug Administration on the Draft Guidance for Industry;
Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended
Maximum Level
Docket No. FDA-2014-D-2275**

Prepared by
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Consumers Union, the policy and mobilization arm of Consumer Reports,¹ welcomes the opportunity to comment on the draft guidance for industry released by the Food and Drug Administration (FDA) on a recommended maximum level of lead in cosmetic lip products and externally applied cosmetics. We commend FDA for proposing a recommended maximum level. However, the proposed limit of 10 parts per million (ppm) is too high to adequately protect the health of the public, and should be decreased to at most 5 ppm—or significantly lower—for the reasons laid out below.

Data clearly demonstrate harmful health effects associated with lead exposure. The Centers for Disease Control and Prevention's (CDC) Agency for Toxic Substances and Disease Registry (ASTDR) has an extensive toxicological profile on lead.² Both the CDC³ and Environmental Protection Agency (EPA)⁴ have stated that no amount of blood lead level is safe

¹ Consumers Union is the policy and mobilization arm of Consumer Reports, an independent, nonprofit organization that works side by side with consumers to create a fairer, safer, and healthier world. As the world's largest independent product-testing organization, Consumer Reports uses its more than 50 labs, auto test center, and survey research center to rate thousands of products and services annually. Founded in 1936, Consumer Reports has over 7 million subscribers to its magazine, website, and other publications.

² CDC. 2007. Toxicological Profile for Lead. At: www.atsdr.cdc.gov/toxprofiles/tp.asp?id=96&tid=22.

³ CDC. 2012. What Do Parents Need to Know to Protect their Children? At: www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm.

⁴ Environmental Protection Agency (EPA). 2017. Basic Information About Lead in Drinking Water. At: www.epa.gov/ground-water-and-drinking-water/basic-information-about-lead-drinking-water.

for children. They also agree that exposure should be minimized or prevented to the extent possible.

In 2006, FDA recommended a maximum lead level of 0.1 ppm for candy that small children were likely to consume.⁵ As part of its rationale for setting the 0.1 ppm lead level, FDA stated that it was consistent with “FDA’s longstanding goal of reducing lead levels in the food supply *to reduce consumers’ lead exposure to the lowest level that can be practicably obtained*”⁶ (emphasis added).

FDA should use this same principle when setting lead levels for cosmetic lip products and externally applied cosmetics. Small children could all too easily be exposed to lead when playing with contaminated cosmetics.

Between 2007 and 2013, FDA surveyed 479 cosmetic lip products and 206 externally applied cosmetics (e.g., eye shadow, blush, face and body lotion, mascara, foundation, body powder, compact powder, shaving cream, and face paints), and tested them for lead. Of the 479 cosmetic lip products, all but two of them had levels below 5 ppm; and those two higher values were 7.0 ppm and 7.19 ppm.⁷ In other words, none of the cosmetic lip products had levels that exceeded 10 ppm and over 99.5% (477 of 479) of the cosmetic lip products could meet a 5 ppm level. For the 206 externally applied cosmetics, only 21 of them had lead levels exceeding 5 ppm.⁸ Most of the lead levels above 5 ppm were found in eye shadow and blushes, with 13 of 53 eye shadow samples, and 6 of 47 blush samples testing above 5 ppm. In other words, some 90% (185 of 206) of the externally applied cosmetics had lead levels lower than 5 ppm.

If FDA applies the same goal of trying “to reduce consumers’ lead exposure to the lowest level that can be practicably obtained” when setting lead levels for cosmetic lip products and externally applied cosmetics, it should recommend a maximum limit for lead that is lower than 10 ppm. If a limit of 10 ppm were recommended, the draft guidance would provide virtually no incentive for cosmetic lip product makers to try to reduce lead levels in their products. An alternative recommended limit of 5 ppm could provide a slight incentive for better control of lead levels in cosmetics, since 2 of 479 cosmetic lip products surveyed by FDA had lead levels exceeding 5 ppm. However—particularly given CDC and EPA recognition of no safe blood lead level for children—an even lower recommended limit could be justified, and could provide a more robust incentive for industry to reduce lead levels in their products.

Finally, it should be noted that under Proposition 65, the California Office of Environmental Health Hazard Assessment (OEHHA), determined that a safe-harbor Maximum

⁵ Food and Drug Administration (FDA). 2006. Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy. At: www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetals/NaturalToxinsPesticides/ucm077904.htm.

⁶ *Id.*

⁷ See Tables in FDA. 2016. Limiting Lead in Lipstick and Other Cosmetics. At: www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm137224.htm.

⁸ See Tables in FDA. 2016. FDA’s Testing of Cosmetics for Arsenic, Cadmium, Chromium, Cobalt, Lead, Mercury, and Nickel Content. At: <http://www.fda.gov/Cosmetics/ProductsIngredients/PotentialContaminants/ucm452836.htm>

Allowable Dose Level (MADL) for lead should be 0.5 micrograms per day, based on work with candy contaminated with lead.⁹ This analysis concluded that a limit of 5 ppm for lead levels in lipstick could be sufficient to result in levels below the MADL of 0.5 micrograms per day.

In sum, while the FDA's proposed maximum limit for lead of 10 ppm in cosmetic lip products and externally applied cosmetics is a step in the right direction, it does not go far enough. Clearly, a maximum limit of lead in cosmetic lip products of 5 ppm would be easily achievable since over 99.5% of the 479 cosmetic lip products surveyed by FDA met this standard. We urge FDA to decrease the recommended maximum lead level in cosmetic lip products and externally applied cosmetics to at most 5 ppm, or significantly lower as may be necessary to protect the public from the recognized harmful impact of exposure to even very low levels of lead.

Thank you for your consideration of our comments.

Respectfully submitted,

A handwritten signature in black ink that reads "Michael Hansen". The signature is written in a cursive style with a large initial "M".

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