

# The Campaign for Safe Cosmetics

[www.SafeCosmetics.org](http://www.SafeCosmetics.org)



## Steering Committee

February 7, 2012

Alliance for a Healthy Tomorrow

Linda Katz, M.D., M.P.H., Director  
Office of Cosmetics and Colors  
U.S. Food and Drug Administration  
Center for Food Safety and Applied Nutrition

Breast Cancer Fund

Harvey W. Wiley Federal Building  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Commonweal

Environmental Working Group

Dear Dr. Katz,

Friends of The Earth

We were pleased to see that on December 5, 2011, the Office of Cosmetics and Colors posted online the results, including brand names, of a new analysis that found lead in 400 lipsticks tested by your agency. This new report found higher levels of lead in lipstick than previously reported, and adds to our concern about the health risks of lead-containing lipstick -- a product used by millions of women of childbearing age who are unaware that they may be building up their blood lead levels each time they apply lipstick.

Massachusetts Clean Water Fund

Massachusetts Breast Cancer Coalition

As you may know, on January 4, 2012, an advisory committee to the U.S. Centers for Disease Control and Prevention recommended that the CDC shift its policies to focus on aggressive prevention efforts for lead exposure.<sup>1</sup> Based on new information as well as new understanding of old data, the committee's report asserted that there is no safe level of lead for children; that the low-dose effects of lead extend beyond the neurodevelopmental realm into cardiovascular, immunological, and endocrine effects; and that the health effects of lead exposure appear to be irreversible.

Women's Voices for the Earth

The CDC committee's report identifies imported cosmetics as a risk factor for lead exposure in pregnant and lactating women. However, the FDA study on lead in lipstick indicates that lead is also a problem with cosmetics manufactured in the US. The new FDA analysis indicates that the lead in lipstick problem is more widespread than previously reported. Your new analysis found lead levels in lipstick more than twice as high as your previous report. As in previous studies, certain manufacturers consistently have higher lead levels than other brands. The most-contaminated brand, Maybelline Color Sensation made by L'Oreal USA, had lead levels more than 275 times the level found in the least contaminated brands, and more than seven times higher than the average found in all the lipsticks. Clearly, some manufacturers could be doing more to protect women from unnecessary lead exposure.

Many experts agree that there is no safe blood level of lead for children and pregnant women. Lead is a proven neurotoxin that can cause learning, language and behavioral problems such as lowered IQ, reduced school performance and increased aggression. Pregnant women are particularly vulnerable to lead exposure, because lead easily crosses the placenta and enters the fetal brain where it can interfere with normal development.

Lead builds up in the body over time and lead-containing lipstick applied several times a day, every day, can add up to significant exposure levels. Therefore, in the interest of public health, we urge the Office of Cosmetics and Colors to take action to reduce the amount of lead in lipstick.

We are hopeful that the Office of Cosmetics and Colors shares our goal of ensuring that cosmetics sold in America are as safe as they can possibly be. However, we are concerned about misleading statements on your web page entitled, "Lipstick and Lead: Questions and Answers."

<http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm137224.htm>

We first wrote to you about these concerns in January 2010, and we have not heard back from you about the following questions and concerns:

1. Your web page states: "Is there a safety concern about the lead found by FDA in lipsticks? No. FDA has assessed the potential for harm to consumers from use of lipstick containing lead at the levels found in its testing."

FDA has not, to our knowledge, conducted a formal safety assessment of lead in lipstick, nor has the agency publicly released any data or analysis to explain the agency's position that there is no safety concern about lead in lipstick. Upon what assessment or reasoning did FDA base its opinion that lead in lipstick is safe?

2. Your web page states: "Lipstick, as a product intended for topical use, is only ingested incidentally and in very small quantities."

We have searched the literature and have found no scientific studies – not one – to determine the amount of lipstick ingested into the body with the routine use of lipstick. As you are aware, under current regulations, there are no requirements for industry or government to conduct such studies to determine chemical exposure via cosmetics. Upon what research did FDA base its statement that lipstick is ingested only in very small quantities?

3. FDA notes on this web page that "the lead levels that it found are lower than limits recommended by other public health authorities for lead in cosmetics, including lipstick." FDA cites Health Canada's Draft Guidance on Heavy Metal Impurities in Cosmetics and a ruling based on California's Proposition 65 law.

Our concerns about this statement are as follows:

- a. The Health Canada guidance is in draft form and should not be used as a standard by the U.S. FDA since it is not aimed at reducing lead in cosmetics to the lowest levels possible.

- b. The California Proposition 65 law is intended to provide warnings about carcinogens, reproductive toxicants and mutagens, but it does not consider the science on neurotoxicity. Since the concerns about low-level lead exposures are based on the recent science of neurotoxic effects, which is not considered in Prop. 65 rulings, the rulings cannot be used to determine a reliable “safe harbor” level for lead in cosmetics.
4. The Campaign for Safe Cosmetics has repeatedly stated that the lead found in lipstick far exceeds the FDA’s recommended limit of lead in candy of 0.1 ppm. FDA states that this comparison is unfair and “not scientifically valid.” The statement is misleading; the Campaign for Safe Cosmetics is making a logical comparison, not a scientific one, between lipstick and candy – based on FDA’s own reasoning for the candy limit. FDA recommends a maximum allowable lead level of 0.1 ppm in candy not because that level is considered safe, but because FDA determined that level to be the lowest lead level candy manufacturers can feasibly achieve. Using that logic, FDA should set a maximum allowable level of lead in cosmetics, based on the lowest lead levels that cosmetic manufacturers can feasibly achieve.

Based on your recent study, the lowest level of lead that lipstick manufacturers can feasibly achieve is below .026 parts per million, the detection limit for the most sensitive testing method available from studies conducted thus far.

We respectfully request that the Office of Cosmetics and Colors reviews and revises the web page entitled “Lipstick and Lead: Questions and Answers” in light of our concerns.

Lastly, we are pleased to see on your web page that OCC is currently evaluating whether to recommend an upper limit for lead in lipstick. We urge FDA to take this important step to protect consumers from unnecessary lead exposures from lipstick, as requested in a letter dated Nov. 19, 2007 and signed by U.S. Senators John Kerry, Dianne Feinstein and Barbara Boxer.

[http://www.safecosmetics.org/downloads/Kerry-Boxer-Feinstein\\_letter-to-FDA-lipstick.pdf](http://www.safecosmetics.org/downloads/Kerry-Boxer-Feinstein_letter-to-FDA-lipstick.pdf)

We look forward to hearing back from you about this matter.

Sincerely,  
Janet Nudelman

*Founding members of the Campaign for Safe Cosmetics include Alliance for a Healthy Tomorrow, Breast Cancer Fund, Clean Water Fund, Commonweal, Environmental Working Group, Friends of the Earth, Massachusetts Breast Cancer Coalition, National Black Environmental Justice Network, National Environmental Trust and Women's Voices for the Earth. [www.SafeCosmetics.org](http://www.SafeCosmetics.org)*

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<sup>i</sup> January 4, 2012. “Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention,”

Report of the Advisory Committee on Childhood Lead Poisoning Prevention of the Centers of Disease Control and Prevention

[http://www.cdc.gov/nceh/lead/ACCLPP/Final\\_Document\\_010412.pdf](http://www.cdc.gov/nceh/lead/ACCLPP/Final_Document_010412.pdf)

