

The Campaign for Safe Cosmetics

www.SafeCosmetics.org



Steering Committee

December 4, 2008

Alliance for a Healthy Tomorrow

Linda Katz, M.D., M.P.H.
Director
Office of Cosmetics and Colors

Breast Cancer Fund

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Harvey W. Wiley Federal Building

Commonwealth

5100 Paint Branch Parkway
College Park, MD 20740-3835

Environmental Working Group

Dear Dr. Katz:

Friends of The Earth

I am writing to follow up on our correspondence earlier this year regarding the Food and Drug Administration's planned testing of lipsticks on the market for lead. We have asked your agency repeatedly to make public the results of any testing done to analyze lead in lipstick, including raw data, brand names tested and updates on any actions taken by FDA to ensure that lipsticks no longer contain lead.

Massachusetts Clean Water Fund

Massachusetts Breast Cancer Coalition

The latest information on the progress of this testing that the Campaign for Safe Cosmetics has been able to locate is on the FDA CFSAN/Office of Cosmetics and Colors website (<http://www.cfsan.fda.gov/~dms/cos-pb.html#followup>) on the page entitled *Lipstick and Lead: Questions and Answers* dated December 27, 2007:

Women's Voices for the Earth

“Is FDA following up on the latest reports?”

“Because allegations regarding lead in lipstick surface periodically, and because of the amount of time since FDA last surveyed lipsticks in the marketplace, FDA has decided to allocate the resources necessary to conduct independent testing of a selection of lipstick on the market. FDA has obtained commercial samples of the same lipstick brands cited in the recent report. FDA laboratories have been adapting a previously validated, state-of-the-art method to do the analyses.”

It has been more than a year since FDA publicly stated that it would investigate this matter. FDA has a responsibility to make its test results available to the public in a timely and accessible fashion, and the public deserves to know if commercially available lipsticks contain lead, a potent neurotoxin. As such, we urge you to make public any information you have obtained in your study.

In your November 27, 2007 letter to us, you state regulations in CFR 20.105 © require the FDA “to make available the results of FDA testing or research when the final report is complete and accepted by the agency as authoritative.” The regulation further states: “(d) Access to all raw data, slides, worksheets, and other similar working materials shall

be provided at the same time that the final report is disclosed."

As you are aware, the original tests conducted by the Campaign for Safe Cosmetics found that 39% of lipsticks tested contained no detectable lead levels. Obviously it is possible for manufacturers to make lipstick without lead, and that should be the gold standard which all manufacturers should aim to achieve. We urge FDA to issue a Guidance to Industry with a recommended maximum level of lead in lipstick of less than .02 – the non-detectable level achieved by 39% of the lipsticks tested by the Campaign for Safe Cosmetics. FDA should further urge transparency and data sharing among cosmetics companies so they can learn from each other about how to keep lead and other harmful contaminants out of lipstick.

We believe that we share a common aim with the FDA to ensure that lipstick and other cosmetics sold in the United States are as safe as possible. We request a written update by December 18th, 2008 on the progress of FDA's lead in lipstick study and a date when the public can expect to see a report on the results, including raw data, the brands tested and any actions the agency will take to ensure that consumers can purchase lipstick with confidence —knowing that they won't be exposing themselves or their loved ones to hazardous contaminants like lead. If you prefer to talk by phone, please know that we will make every effort to quickly find a time to discuss these matters. On behalf of the Campaign for Safe Cosmetics, thank you for your prompt attention to this matter.

Sincerely,



Lisa Archer
National Coordinator
The Campaign for Safe Cosmetics
Breast Cancer Fund

Cc: Andrew C. von Eschenback, MD
Commissioner of Food and Drugs
U.S. Food and Drug Administration

Senator Barbara Boxer
Senator Diane Feinstein
Senator John Kerry
Representative Henry Waxman
Representative Tammy Baldwin
Representative Rosa DeLauro
Representative Edward Markey
Representative Jan Schakowsky