

National Healthy Nail Salon Alliance



Linda M. Katz, M.D.,M.P.H., Director
Federal Food and Drug Administration
Office of Cosmetics and Colors
CPK-2 Bldg Room 1025
5100 Paint Branch
College Park, MD 20740

November 8, 2010

Dear Dr. Katz,

The National Healthy Nail Salon Alliance, a coalition dedicated to improving the health and safety of salon workers, and the Campaign for Safe Cosmetics, a coalition working to protect the health of consumers and workers from harmful chemicals in cosmetics, request that the FDA Office of Cosmetics and Colors issue a voluntary recall of Brazilian Blowout Solution and Acai Professional Smoothing Solution, both manufactured by Brazilian Blowout of California. Recent testing results by the Oregon Occupational Safety and Health Division (Oregon OSHA) found that the two different formulations contained between 4.85% and 10.6% formaldehyde.

According to the Cosmetic Ingredient Review, formaldehyde levels in cosmetics should not exceed 0.2%. The EPA has classified formaldehyde as a probable carcinogen and the International Agency for Research on Cancer has identified it as a known human carcinogen. The levels of formaldehyde found in both of these formulations present a real risk of harm to salon workers and consumers and a voluntary recall should be issued immediately.

Subsequent testing by Health Canada found the Brazilian Blowout solution contained 12% formaldehyde; Health Canada immediately responded by issuing a health advisory and took steps to stop distribution of the product to salons in Canada. In addition, the Irish Medicines Board and the Health Service Executive's Environmental Health Service recommended salons stop using Acai Professional Smoothing Solution and issued a recall of the product. Clearly, the problem is pervasive and places salon workers at risk of exposure to high levels of formaldehyde in the workplace. The Food and Drug Administration should warn salons of the dangers of using such treatments and ask Brazilian Blowout to recall these two products in the U.S.

1 of 2

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c/o Women's Voices for the Earth
114 W. Pine Street
Missoula, MT 59802

In addition, under Section 602 of the Food, Drug and Cosmetics Act, a cosmetic is considered to be misbranded if, among other things, it contains false and misleading information. The Acai Professional Smoothing Solution was labeled formaldehyde-free, yet four different testing methods found that the product contained 10.6 percent, 6.3 percent, 10.6 percent, and 10.4 percent of formaldehyde, respectively. The FDA should immediately issue a health advisory and use its statutory authority to ensure Brazilian Blowout does not continue to make false claims and is penalized for misleading salon workers and consumers regarding the formaldehyde content in its products. In closing, we ask that you take immediate action to protect consumers and workers from these unsafe products. We respectfully request a response to this letter no later than November 30, 2010.

Sincerely,

Lisa Archer
National Coordinator
Campaign for Safe Cosmetics
Breast Cancer Fund

Jamie Silberberger
Director of Programs and Policy
Women's Voices for the Earth (WVE)*

* WVE is a co-founder of the National Healthy Nail Salon Alliance along with the National Asian American Pacific Women's Forum and the California Healthy Nail Salon Collaborative

Cc:
Dr. Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner

2 of 2

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