

National Healthy Nail and Beauty Salon Alliance



The Campaign for Safe Cosmetics
www.SafeCosmetics.org

September 23, 2011

Dr. Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Hamburg:

On behalf of the National Healthy Nail and Beauty Salon Alliance and the Campaign for Safe Cosmetics we want to thank the FDA for issuing a warning letter to GIB, LLC/Brazilian Blowout (hereafter referred to as Brazilian Blowout) alerting the company that the agency has found the Brazilian Blowout treatment to be adulterated and misbranded. We respectfully request that the agency make Brazilian Blowout's response public, and alert interested parties, including our organizations, upon receipt of such a response.

If no response is received, we urge the FDA to take immediate action by issuing a voluntary recall of Brazilian Blowout's products and filing an injunction against the company.

Despite the FDA's warning letter, Brazilian Blowout continues to make misleading claims about its products. In a letter to stylists and salon owners co-signed by the CEO and co-founder of Brazilian Blowout and dated August 24, 2011, (two days after FDA's warning letter was overnighted to the company) the company claims "to date, all OSHA and independent air-quality tests conducted on the Brazilian Blowout Professional Smoothing Solution, as well as others in this category, have yielded results **well below** even the most stringent of OSHA standards (AL, PEL, STEL)".¹ [emphasis added]

As OSHA notes in its September 22, 2011 letter to Brazilian Blowout this statement is misleading and contradicts OSHA's previous findings that workers using Brazilian Blowout Acai Professional Smoothing Solution "were exposed to formaldehyde levels that **exceeded** OSHA's 15 minute short term exposure limits [STEL] of 2 ppm."² [emphasis added]

Salon workers and consumers need accurate information about potential exposures to toxic chemicals in order to make informed decisions to protect their health, such as not purchasing a product that may release formaldehyde at levels exceeding federal standards.

We are concerned that the more time elapses, the greater the risk for salon workers and their customers who continue to use Brazilian Blowout's products. The misleading information the company is sending to stylists and salon owners only obfuscates well-founded safety concerns, and results in continued use of this dangerous product.

Indeed, investigations into the dangers of the Brazilian Blowout treatment have been building for almost a year. Last September the Oregon Occupational Safety and Health Division (Oregon OSHA) revealed that the two formulations contained between 4.85% and 10.6% formaldehyde.

Since Oregon OSHA released their results, six countries have recalled the use of formaldehyde-based straighteners³ and air monitoring of salons by federal Occupational Safety and Health Administration (OSHA) caused the agency to issue a Hazard Alert warning salons not to use formaldehyde-based hair straighteners, and outlined strict requirements salons must follow if they want to continue their use. Soon after, the Campaign for Safe Cosmetics and the Alliance called on the FDA to recall the products.⁴

In March 2011, the Cosmetics Ingredient Review, the industry-funded panel of scientists tasked with reviewing the safety of cosmetic products in the U.S., declared that it could not conclude that formaldehyde exposure from these types of products is safe.⁵

This was followed by a letter to FDA sent by 10 members of Congress expressing their deep concern regarding formaldehyde-containing hair-straighteners and asking the agency to take immediate action to protect workers and consumers including issuing a voluntary recall of this and similar products.⁶

In addition, the California Attorney General has requested an injunction against Brazilian Blowout, seeking to require health warnings on the products, which is the first enforcement action the state has taken under the California Safe Cosmetics Act. The injunction notes that levels of formaldehyde emitted by the smoothing solution exceed Proposition 65 safe exposure limits "by up to a factor of more than eight for salon workers."⁷

Over the past two years, the Food and Drug Administration has received over 47 complaints of adverse reactions and injuries from salon workers and clients who used Brazilian-style straightening treatments.⁸ Numerous other salon workers have made complaints to state governments about health impacts related to use of Brazilian Blowout and similar products. Examples of the harm caused by Brazilian Blowout include: sore throat, dizziness, difficulty breathing, hair loss, blisters, bloody nose, rashes, itching, welting, vomiting, chest pain, burning in the eyes, throat and lungs.

Formaldehyde exposure in salons poses hazards to the health and safety of salon workers and consumers. The International Agency for Research on Cancer (IARC) has identified it as a known human carcinogen for cancer of the nose and throat and the Environmental Protection Agency (EPA) has classified formaldehyde as a probable carcinogen. Recently, the National Academy of Sciences confirmed the EPA's determination that formaldehyde causes cancer in humans.⁹ In addition, the National Cancer Institute, the World Health Organization and the National

Toxicology Program have all identified a possible link between formaldehyde exposure and leukemia.¹⁰

Therefore, the justification for investigating hair straightening treatments in addition to Brazilian Blowout products is strong. We call upon the FDA to immediately do the following:

- Continue to conduct testing of hair straighteners available on the market to determine formaldehyde levels.
- Require warning labels for hair straighteners that contain formaldehyde.
- Investigate the labeling practices of companies marketing their products as formaldehyde-free.
- Ban formaldehyde and formaldehyde-releasing chemicals from these products given their deleterious impacts and the significant health hazard they pose.

Again, we are pleased to see the FDA taking action on the Brazilian Blowout by sending the company a warning letter, but we fear Brazilian Blowout is only one example of the danger of this kind of hair straightening treatment. In addition to taking prompt action based on the company's response (or non-response), and sharing this response with the public and interested parties, including our organizations, we urge the agency to further your investigation into keratin hair straightening treatments per our recommendations above.

We would appreciate a response outlining the agency's plans for addressing this serious matter by October 7, 2011.

Sincerely,

Lisa Archer



Director

Campaign for Safe Cosmetics*

Breast Cancer Fund

Jamie Silberberger



Director of Programs and Policy

Women's Voices for the Earth**

Cc:

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Enclosures (2)

*The Campaign for Safe Cosmetics is a coalition effort launched in 2004 to protect the health of consumers and workers by securing the corporate, regulatory and legislative reforms necessary to eliminate dangerous chemicals from cosmetics and personal care products.

Key nonprofit coalition partners in the Campaign include the [Alliance for a Healthy Tomorrow](#) (represented by [Clean Water Action](#) and [Massachusetts Breast Cancer Coalition](#)), the [Breast Cancer Fund](#), [Commonweal](#), [Environmental Working Group](#), [Friends of the Earth](#) and [Women's Voices for the Earth](#). The Breast Cancer Fund, a national 501(c)(3) organization focused on preventing breast cancer by identifying and eliminating the environmental links to the disease, serves as the national coordinator for the Campaign.

**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

¹ Brazilian Blowout letter to salons and stylists, August 24, 2011, and updated on September 19, 2011:

<http://www.brazilianblowout.com/fda>

² http://www.osha.gov/SLTC/formaldehyde/brazilian_blowout_letter.pdf

³ Australia, Ireland, Canada, France, Germany and Cyprus.

⁴ http://www.safecosmetics.org/downloads/Brazilian-Blowout-FDA-Letter_Nov2010.pdf

⁵ http://www.cir-safety.org/staff_files/results.pdf

⁶ http://safecosmetics.org/downloads/Brazilian-Blowout_letter-from-Congress-to-FDA_May2011.pdf

⁷ <http://www.safecosmetics.org/article.php?id=815>

⁸ Environmental Working Group's Citizen Petition For Regulatory Action To Address Safety Concerns Surrounding Keratin Hair-Straighteners That Contain Formaldehyde And Formaldehyde Releasing Chemicals As Ingredients http://static.ewg.org/reports/2011/brazil_blowout/PDF/FDA-Petition.pdf.

⁹ National Academy of Sciences 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Available: http://www.nap.edu/catalog.php?record_id=13142

¹⁰ See: National Cancer Institute 2011. **Formaldehyde and Cancer Risk**. Available: <http://www.cancer.gov/cancertopics/factsheet/Risk/formaldehyde>

Baan, Robert, et al on behalf of the World Health Organization International Agency for Research on Cancer Monograph Working Group (WHO/IARC). A review of human carcinogens—Part F: Chemical agents and related occupations. *The Lancet Oncology*, Volume 10, Issue 12, Pages 1143 - 1144, December 2009.

Mackay, Robin. Expert Panel Recommends Listing Formaldehyde as Known Human Carcinogen. *Environmental Factor*, December 2009. Available: <http://www.niehs.nih.gov/news/newsletter/2009/december/spotlight-expert.cfm>