

March 7, 2012

Linda M. Katz, M.D., M.P.H.
Director, Office of Cosmetics and Colors
Chief Medical Officer
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway HFS-009
College Park, MD 20740-3835

Re: Request for Status Update on Docket Number FDA-2011-P-0276-0001/CP

Dear Dr. Katz:

The Environmental Working Group submits the following in response to the letter you sent on Sept. 6, 2011, regarding the status of EWG's citizen petition (Docket No. FDA-2011-P-0276-0001/CP). The petition urges the U.S. Food and Drug Administration to address the dangers associated with formaldehyde-laced hair straighteners. According to your letter, the FDA has not made a decision on the petition due to competing priorities.¹ In light of recent developments, principally California's settlement with the maker of "Brazilian Blowout," EWG respectfully requests another update and calls on the FDA to exercise greater leadership in dealing with this important matter of cosmetic safety. The public's interest demands it.

EWG's petition identifies more than a dozen hair straighteners² that contain or release unsafe levels of formaldehyde, a known carcinogen.³ The petition also highlights how makers of these products misrepresent or hide information about their formaldehyde content, exposing salon workers and consumers to significant health risks.⁴ National media outlets have reported on these deceptive practices for months.⁵ The U.S. Occupational Health and Safety Administration issued a national hazard alert advisory to salon workers nearly a year ago.⁶ Even the industry-funded Cosmetic Ingredient Review concluded that formaldehyde is unsafe for use in hair straighteners when used with flat irons, as is customarily done with these products.⁷ Yet, short of a warning letter sent to Brazilian Blowout in September,⁸ the FDA has done little else to address the issue.

In January, California Attorney General Kamala Harris negotiated a settlement with the maker of Brazilian Blowout, requiring the company to provide health warnings on its product's packaging and website, revamp deceptive marketing practices, and pay hefty civil fines.⁹ EWG applauds California's effort to confront the dangers posed by Brazilian Blowout. However, the product is hardly the only hair straightener posing a risk to public health because of its formaldehyde content. The FDA must move ahead with action against formaldehyde-based hair straighteners in the interest of public health.

For those reasons, EWG renews its call on the FDA to address our petition, which asks the Administration to: (1) investigate companies engaged in deceptive marketing of hair straighteners that contain formaldehyde; (2) study whether to ban formaldehyde in hair straighteners; and (3) require a warning label on hair straighteners that contain or release

formaldehyde during the application process.¹⁰ EWG's position is that formaldehyde must be banned from these products to protect public health. Although the FDA's onerous environmental assessment regulations for petitioners, 21 C.F.R. §§ 10.30, 25.30, required EWG to limit its request to a review of whether a ban is appropriate, we ask the FDA to do everything within its authority to protect consumers from this known carcinogen.

I look forward to hearing from you with an update. Thank you very much.

Sincerely,



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¹ Letter from Lisa Katz, Dir., Office of Cosmetics & Colors, Ctr. For Food Safety & Applied Nutrition, U.S. Food & Drug Admin., to Thomas Cluderay, Assistant Gen. Counsel, Env'tl. Working Group (Sept. 6, 2011) (on file with Env'tl. Working Group).

² Citizen Petition for Regulatory Action to Address Safety Concerns Surrounding Keratin Hair-Straighteners that Contain Formaldehyde and Formaldehyde Releasing Chemicals as Ingredients, Docket No. FDA-2011-P-0276-0001/CP, at 14-22 (Apr. 8, 2011), amended Sept. 7, 2011 [hereinafter EWG Petition].

³ See U.S. Agency for Toxic Substances & Disease Registry, ToxFAQs for Formaldehyde, <http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=219&tid=39#bookmark06> (last visited Mar. 7, 2012); see also Int'l Agency for Research on Cancer, IARC Monographs of Evaluation of Carcinogenic Risks to Humans: Formaldehyde, 2-Butoxyethanol and 1-tert-Butoxypropan-2-ol 39 (2006), <http://monographs.iarc.fr/ENG/Monographs/vol88/mono88.pdf>.

⁴ EWG Petition, supra note 2, at 14-22.

⁵ E.g., Press Release, ABC News, Brazilian Blowout Hair Treatment Takes Heat from FDA (Sept. 8, 2011) http://abcnews.go.com/Health/Wellness/brazilian-blowout-fda-warns-formaldehyde-false-labeling/story?id=14471900#.Tz52IjhBS_E.

⁶ Press Release, U.S. Occupational Safety & Health Admin., Hazard Alert Update: Hair Smoothing Products that Release Formaldehyde (Sept. 22, 2011), http://www.osha.gov/SLTC/formaldehyde/hazard_alert.html.

⁷ See Cosmetic Ingredient Rev., Cosmetic Ingredient Review: Final Amended Report on Formaldehyde and Methylene Glycol as Used in Cosmetics 3 (Sept. 26, 2011), http://www.cir-safety.org/sites/default/files/120_final_formy.pdf.

⁸ Warning Letter from Michael W. Roosevelt, Acting Dir., Office of Compliance, Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., to Mike Brady, CEO, GIB, LLC d/b/a Brazilian Blowout (Aug. 22, 2011), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm270809.htm>.

⁹ See Consent Judgment Resolving the People's Claims Against GIB, LLC, No. 4657, Judicial Council Coordination Proceeding, at 4-7, 11 (Cal. Super. Ct. Jan. 5, 2012), http://ag.ca.gov/cms_attachments/press/pdfs/n2617_consent_judgement.pdf?.

¹⁰ EWG Petition, supra note 2, at 3.