Congress of the United States
Washington, D.C. 20515

May 6, 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:

We are writing to express our deep concern regarding the continued use of formaldehyde-containing hair straighteners in the United States, and we ask that the Food and Drug Administration take immediate action to protect workers and consumers.

As Rep. Blumenauer brought to your attention in a letter dated October 5, 2010, last fall the Oregon Health and Science University's Center for Research on Occupational and Environmental Toxicology (CROET) received complaints from Oregon hair stylists about the keratin hair-straightening products Brazilian Blowout Solution and Acai Professional Smoothing Solution that, while in use, were causing stylists to experience acute reaction such as nose bleeds, breathing problems and eye irritation. Testing by the Oregon Occupational Safety and Health Division (Oregon OSHA) and CROET confirmed that the two different formulations contained between 4.85% and 10.6% formaldehyde. Some of the highest formaldehyde levels were found in the Acai Professional Smoothing Solution, which was labeled "formaldehyde-free". Other hair straightening products that were tested contained levels of formaldehyde above the 0.1 percent threshold of the OSHA Formaldehyde Standard. [1]

Subsequent air monitoring of salons by federal Occupational Safety and Health Administration (OSHA) led 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.

Formaldehyde exposure in salons is a serious concern to the health and safety of salon workers and consumers. The Environmental Protection Agency (EPA) has classified

[1] Oregon OSHA and CROET 2011. Keratin-Based Hair Smoothing Products and the Presence of Formaldehyde. Available: http://www.orosha.org/pdf/Final_Hair_Smoothing_Report.pdf

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formaldehyde as a probable carcinogen and the International Agency for Research on Cancer (IARC) has identified it as a known human carcinogen for cancer of the nose and throat. Recently, the National Academy of Sciences confirmed the EPA's determination that formaldehyde causes cancer in humans.[2] 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.[3]

The Cosmetic Ingredient Review (CIR), the industry-funded body tasked with reviewing the safety of ingredients in cosmetics has reaffirmed its 2005 conclusion that formaldehyde levels in cosmetics should not exceed 0.2%. However, the CIR has no authority to take any enforceable action against manufacturers who exceed the recommended level.

It is clear that the FDA needs to take decisive action. An investigation by the Environmental Working Group revealed that FDA has received 47 complaints from salon workers and clients who experience adverse reactions and injuries (including hair loss, blisters, burning eyes, noses and throats, headaches and vomiting) as the result of giving or receiving hair straightening treatments.[4]

As a result of the risks posed by these types of salon treatments, six countries have recalled the use of formaldehyde-based straighteners.[5] However, the FDA has yet to issue a voluntary recall and as a result these dangerous products are still available and used on a daily basis in salons across the United States. We respectfully request that the FDA take immediate action by:

- Issuing a voluntary recall of the Brazilian Blowout Solution and Acai Professional Smoothing Solution and other brands that have high levels of formaldehyde based on testing information already available.
- Continuing to conduct testing of hair straighteners available on the market to determine formaldehyde levels.
- Requiring warning labels for hair straighteners that contain formaldehyde.

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[2] 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

[3] 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.
Mackar, 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

[4] Environmental Working Group 2011. Flat-Out Risky. Available: http://www.ewg.org/hair-straighteners/

[5] Australia, Ireland, Canada, France, Germany and Cyprus.

- Investigating the labeling practices of companies marketing their products as formaldehyde-free.
- Reviewing whether to ban formaldehyde and formaldehyde-releasing chemicals from these products given the significant health hazard they pose.

Finally, it has been more than five months since the November 26, 2010 response to Rep. Blumenauer's letter stated that, "FDA is currently investigating whether or not Brazilian Blowout is marketed directly to consumers. If so, failure to comply with the ingredient declaration requirement would constitute misbranding." Further delay in this determination will continue to endanger the health of salon workers and consumers. We urge you to take action against GIB LLC, the makers of Brazilian Blowout, for misbranding their products under its authority under the Food, Drug and Cosmetics Act.

Thank you for your assistance and cooperation in responding to this request. Should you have any questions, please have your staff contact Jonathan Rucks in Rep. Schakowsky's office at 202-225-2111 or jonathan.rucks@mail.house.gov.

Sincerely,

Rep. Jan Schakowsky

Rep. Ed Markey

Rep. Tammy Baldwin

Rep. Earl Blumenauer

Rep. John Conyers

Rep. Nita Lowey

Rep. Jim Moran

Rep. Barbara Lee

Rep. Judy Chu

Rep. Ted Deutch

Enclosures: 2

cc: 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

EARL BLUMENAUER
THIRD DISTRICT, OREGON

COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEES:
TRADE
SELECT REVENUE MEASURES

COMMITTEE ON BUDGET

Congress of the United States
House of Representatives
Washington, DC 20515-3703

WASHINGTON OFFICE:
2267 RAYBURN BUILDING
WASHINGTON, DC 20515
(202) 225-4811
FAX: (202) 225-8941

DISTRICT OFFICE:
729 N.E. OREGON STREET
SUITE 115
PORTLAND, OR 97232
(503) 231-2300
FAX: (503) 230-5413

website: blumenauer.house.gov

October 5, 2010

The Honorable Dr. Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hamburg:

I am writing with serious concerns about advertising claims made by the company Brazilian Blowout Inc. about its hair straightening product, Acai Professional Smoothing Solution. Recent testing by the Oregon Occupational Safety and Health Administration (OSHA) revealed significant levels of formaldehyde in bottles of Brazilian Blowout Solution labeled "formaldehyde-free."

Using four different commonly-accepted testing methodologies, OSHA in September of this year found levels of formaldehyde in samples of the Brazilian Blowout solution provided by Portland-area hair salons ranging from 6.3 to 10.6 percent.

This finding is troubling. The Environmental Protection Agency lists formaldehyde as a "probable human carcinogen," and numerous federal agencies have issued warnings or restrictions governing the use of formaldehyde. Among others, OSHA has said that if a product used in a workplace contains more than 0.1% formaldehyde, the manufacturer must list the substance on the label and address safe work practices on a material safety data sheet accompanying the product.

Already, media have reported that both salon workers and patrons in my district have suffered ill effects while using the improperly labeled solution, including burning eyes, chest pains and nosebleeds.

Given the significant human health hazards associated with formaldehyde exposure, my concern is that Brazilian Blowout's "formaldehyde-free" label may violate the law by deceptively marketing the product and by exposing consumers to a hazardous chemical without their knowledge. News reports indicate these products have already misled consumers in my district and led to injury.

I write to call your attention to this situation to ensure that my constituents and employees and patrons of hair salons across the country are protected from unwitting exposure to a hazardous chemical. I respectfully request that the Food and Drug Administration investigate this issue and provide my office with answers to the following questions:

1. Please clarify if the "formaldehyde-free" label on Brazilian Blowout's "Acai Professional Smoothing Solution" constitutes misbranding under the FDA's standards, taking into account the tests and conclusions issued by OHSA.

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2. If so, please provide my office with a description of the manner in which Brazilian Blowout violates these standards. If not, please provide an explanation for why a "formaldehyde-free" label is acceptable in this case and discuss modifications to current law that would more accurately label this product.

3. Please also clarify whether the safety information enclosed in packages of Brazilian Blowout Solution identifies the proper safety measures that users must take, given the chemical content and likely use of the product.

4. In the event that this product is found to be misbranded or to have inadequate safety information, please provide an explanation of whether or not you believe a recall to be warranted in this case.

Makers of products that thousands of Americans use on a regular basis have an obligation to properly disclose the hazardous chemical content of those products, and to ensure that users are armed with the proper safety information.

Thank you for your attention and I look forward to your reply.

Sincerely,

Earl Blumenauer

EARL BLUMENAUER
Member of Congress

ATTACHED: Oregon OSHA Findings

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

The Honorable Earl Blumenauer
House of Representatives
Washington, D.C. 20515-3703

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Dear Mr. Blumenauer:

Thank you for your letter of October 5, 2010, in which you expressed concern about the safety and labeling of a hair straightening product, Brazilian Blowout. The Food and Drug Administration (FDA or the Agency) shares your concerns and is actively investigating Brazilian Blowout and other similar products on the market.

The Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) grants FDA the authority to regulate cosmetics. Under the Act, cosmetics must be neither adulterated nor misbranded [sections 601 and 602 of the FD&C Act (21 *United States Code* (U.S.C.) 361, 362)]. For example, cosmetics must be safe under their labeled and customary conditions of use, and their labeling must not be misleading. The Act does not require cosmetic products or ingredients, except for certain color additives, to receive premarket approval from FDA. Firms and individuals who market cosmetics, however, have a legal responsibility to ensure that their product is in compliance with all applicable requirements.

In addition to the labeling requirements in the FD&C Act, FDA further regulates cosmetic labeling under the authority of the Fair Packaging and Labeling Act (FPLA) [Public Law 89-755]. Under the FPLA and FDA regulations, the label of a cosmetic marketed to consumers is required to contain, among other things, the identity of the product and a list of its ingredients. Cosmetic products marketed solely to professionals for use in salons are not required to have labeling listing the product's ingredients because the FPLA applies only to consumer commodities. Nevertheless, the ingredient declaration requirement applies to a professional use cosmetic if the product is also marketed to consumers. FDA is currently investigating whether or not Brazilian Blowout is marketed directly to consumers. If so, failure to comply with the ingredient declaration requirement would constitute misbranding.

Please note that, generally, workplace safety, including air quality, is regulated by the Occupational Safety and Health Administration (OSHA). Salons are also subject to state and local authorities, which may specify mandatory safety practices, such as ensuring proper ventilation. Although FDA does not have regulatory authority over the operation of salons, we do have regulatory authority over the safety and labeling of cosmetic products, including chemical hair straighteners.

In your letter, you asked four specific questions. They are restated below, followed by our responses. We have combined our responses to your first two questions because the questions are interrelated.

1. "Please clarify if the 'formaldehyde-free' label on Brazilian Blowout's 'Acai Professional Smoothing Solution' constitutes misbranding under the FDA's standards, taking into account the tests and conclusions issued by OHSA."

2. "If so, please provide my office with a description of the manner in which Brazilian Blowout violates these standards. If not, please provide an explanation for why a 'formaldehyde-free' label is acceptable in this case and discuss modifications to current law that would more accurately label this product."

A product is misbranded if, among other things, its labeling is misleading in any particular [section 602(a) of the FD&C Act (21 U.S.C 362(a))]. Labeling a product as formaldehyde-free when it actually contains formaldehyde as an ingredient would cause a cosmetic product to be misbranded. However, FDA has not yet received and considered all the relevant information to make such a determination for the Brazilian Blowout product. Additionally, labeling is misleading when it fails to reveal facts that are material in light of representations made about the product, or material with respect to consequences that may result from use of the product under conditions prescribed in the labeling or under ordinary conditions of use [section 201(n) of the FD&C Act (21 U.S.C 321(n)); 21 *Code of Federal Regulations* (CFR) 1.21]. For example, directions for the safe use of a product, if that product could be unsafe when used incorrectly, would be a material fact. The failure to include adequate directions, in this example, would be considered misleading and render the product misbranded.

Currently, FDA has limited knowledge about the ingredients in the Brazilian Blowout product because we do not conduct premarket review of cosmetic products, and our laws and regulations do not require ingredient declarations for professional-use cosmetic products. FDA recognizes that there is a possibility that formaldehyde might not actually be an ingredient in the Brazilian Blowout product, but might instead be released by decomposition of another ingredient when heat is applied to the hair during application in the salon. Thus, we are still investigating the contents of this product and working to understand its effects.

FDA is aware of the Oregon OSHA's findings. We have yet to have an opportunity to evaluate the methodology used, but we have requested this information along with the data that Oregon OSHA collected. Our past experience has shown that the measurement of formaldehyde in cosmetic products is not straightforward and that laboratory results require significant interpretation.

Please note that, apart from whether or not the product is labeled properly, the use of formaldehyde as a cosmetic ingredient is not prohibited under FDA's regulations [see 21 CFR 700.11-35]. Formaldehyde can be safely used in some cosmetics to protect against

microbial contamination. Its safety as a cosmetic ingredient depends on a variety of factors, such as its concentration in the final product and how the final product is used. [1]

3. "Please also clarify whether the safety information enclosed in packages of Brazilian Blowout Solution identifies the proper safety measures that users must take, given the chemical content and likely use of the product."

Cosmetic firms are not required to file product inserts or other labeling information with FDA. We have not seen the directions for use of the product or any safety information that the company might have provided to salons and, therefore, we cannot comment about their existence or adequacy. Concerns about air quality within the salon should be directed to the U.S. OSHA, as well as the appropriate state and local authorities.

4. "In the event that this product is found to be misbranded or to have inadequate safety information, please provide an explanation of whether or not you believe a recall to be warranted in this case."

FDA has no authority under the FD&C Act to order a recall of a cosmetic, although we can request that a firm recall a product and monitor the recall to ensure that it is effective. Although FDA can take other regulatory action against products marketed in violation of the FD&C Act and against the firms and individuals who market them, we would need to determine the appropriate steps after a full examination of all the relevant facts. As discussed above, we have yet to complete our investigation of this matter. Furthermore, as a matter of policy, FDA does not discuss or announce in advance its intent to carry out an enforcement action.

FDA has posted information on Brazilian Blowout for the public on our website.[2] We will continue to update this webpage as new information becomes available. Further, if we determine that a health hazard exists, we will advise the industry and the public and will take appropriate action under the authority of the FD&C Act to protect the health and welfare of consumers.

Thank you again for contacting us concerning this matter. If you have further questions or concerns, please let us know.

Sincerely,

Phil Brunelbert for

Kristina Harper
Supervisory Congressional
Affairs Specialist

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[1] *http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm127068.htm#form*
[2] *http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm228898.htm*