



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

AUG 17 2013

Thomas H. Clarke, Jr.  
Ropers Majeski Kohn Bentley PC  
75 Broadway  
Suite 202  
San Francisco, CA 94111

Dear Mr. Clarke:

This responds to your correspondence, dated April 30, 2013 and e-mails dated May 14, 2013 and May 29, 2013 on behalf of your client, GIB LLC (GIB) dba Brazilian Blowout. The information you submitted responds to the Food and Drug Administration's (FDA) response letter dated April 19, 2013. In your letter, you describe a number of steps GIB has taken and/or will take in response to FDA's Warning Letter concerning the labeling of GIB's Brazilian Blowout Acai Professional Smoothing Solution (Brazilian Blowout). Our letter addresses your submissions, to include e-mail correspondence, and also reflects our review of product labeling that FDA reviewed in August 2013.

We recognize GIB's changes to Brazilian Blowout's labeling, including a warning statement and revisions to the instructions for use. While we appreciate the steps the firm has taken to address the issues outlined in FDA's previous letters, we continue to have concerns related to the labeling and marketing of the Brazilian Blowout product. Those concerns are outlined below.

In your letter, you state that FDA's jurisdiction over the labeling of GIB LLC's smoothing solutions is questionable because they are sold for professional use only, citing the Fair Packaging and Labeling Act (FPLA) in support of this assertion. We would like to clarify that requirements for cosmetics and cosmetic labeling are also set out in the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act); see, for example, sections 601 and 602. Regulations applicable to warning statements required on cosmetic product labels are found at 21 CFR 740.1(a) and 740.2. The fact that the products are marketed for professional use does not exempt a product from the labeling requirements specified in the Act.

GIB LLC's existing caution statement on the label continues to be inadequate as it does not provide adequate warning to ensure safe use of the product. Specifically, the current warning statement fails to: