



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

September 3, 2015

Thomas H. Clarke, Jr., Esq.
Ropers Majeski Kohn Bentley PC
1001 Marshall Street
Suite 500
Redwood City, CA 94063-2052

Dear Mr. Clarke:

This responds to your written correspondence and the accompanying photos of the most recent labeling of the 34 oz. and 12 oz. bottles of Brazilian Blowout smoothing solution dated April 22, 2014, on behalf of your client, GIB LLC (GIB) dba Brazilian Blowout. The information you submitted further responds to the Food and Drug Administration's (FDA) Warning Letter of August 22, 2011. In this correspondence, you stated that you believe that the new labeling of the products as demonstrated from the photos of the 34 oz. and 12 oz. of Brazilian Blowout product conforms to our continued concerns of adequate warning statements for these products.

We note the current labeling of your products as follows:

The instructions read as follows on your products (34 oz. and 12 oz. weight configurations):

- *"On average, five full pumps is sufficient for one treatment. Shake well before using."*
- *"On average, three pumps is enough for one treatment. Shake well before using."*

The safety disclaimer reads as follows on your products (both weight configurations noted above):

- *"The Brazilian Blowout Professional Smoothing Treatment must be performed by certified, professional stylists only. Stylists should wear protective gloves when performing this treatment. Both stylists and client should wear protective eyewear for optimal protection. If the Brazilian Blowout Professional Solution comes into contact with skin, wash immediately. If ingested, or in contact with eyes, call a physician. If you are nursing or pregnant, do not use this product. Do not use this product on children, pregnant women, chemically sensitive clients, the elderly and clients with respiratory conditions. Keep out of reach of children."*