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September 29, 2011

VIA FEDERAL EXPRESS

Rob Genzel, Jr.
Food & Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
Office of Compliance (HFS-608)
Division of Enforcement
College Park, MD 20740-3835

**Re: GIB, LLC and Brazilian Blowout
Our File No.: 3302-7009**

Dear Mr. Genzel:

This office represents GIB, LLC (“GIB”), and we write in response to Michael W. Roosevelt’s August 22, 2011 letter regarding GIB’s compliance with the U.S. Food and Drug Administration’s (“FDA”) regulations and specifically, the Federal Food, Drug, and Cosmetic Act (the “Act”). GIB takes the FDA’s warning and correspondence very seriously and welcomes this opportunity to discuss Mr. Roosevelt’s letter. We hope that this letter clarifies that GIB’s Brazilian Blowout Acai Professional Smoothing Solution (“Brazilian Blowout”) is neither misbranded nor adulterated within the meaning of the Act and that GIB is not in violation of the Act. As discussed more fully below, GIB has taken several affirmative steps to ensure its full compliance with all pertinent FDA regulations, as well as the Act.

By way of factual background, Brazilian Blowout is not available for purchase by the general public. *See* August 22, 2011 Letter, at 2. GIB only sells Brazilian Blowout to certified stylists, salons and contracted distributors that sell to certified stylists and salons. Further, GIB has repeatedly declined to sell the product to members of the general public. The application and use of the product is by certified stylists only, a small segment of the general population.

If after your review of this letter, the FDA continues to believe that GIB is not in compliance with its legal obligations, we are requesting that you contact us immediately so that we can arrange a time to speak by phone or in person to discuss what steps GIB may take to achieve full compliance and address any outstanding concerns. GIB is committed to ensuring that its products comply with all applicable legal and regulatory standards and seeks to partner with the FDA to achieve this result.

I. BRAZILIAN BLOWOUT DOES NOT CONTAIN A “DELETERIOUS SUBSTANCE” THAT IS INJURIOUS AND THUS, IS NOT ADULTERATED.

As discussed in the August 22, 2011 letter, a party that introduces an “adulterated” cosmetic into interstate commerce violates the Act. 21 U.S.C. § 331(a). A cosmetic is “adulterated” within the meaning of the Act if “it bears or contains a deleterious substance that may render it injurious to users under the conditions of use prescribed in...[its] labeling.” 21 U.S.C. § 361(a). Neither the Act nor its implementing regulations define the term “deleterious.” The Merriam-Webster Dictionary provides that the term means “harmful often in a subtle or unexpected way.” The FDA has alleged that “Brazilian Blowout [contains a deleterious substance because it] contains methylene glycol...which, under the conditions of use prescribed in the labeling, releases formaldehyde when hair treated with the product is heated...” August 22, 2011 Letter, at 1. However, GIB believes this contention to be arbitrary and overbroad given the lack of statutory definition for “deleterious.” It is GIB’s position that the factual premise for this claim is inaccurate. Moreover, when Brazilian Blowout is used as prescribed in its labeling, no substance in the product may render Brazilian Blowout injurious to users.

The FDA begins with the inaccurate premise that methylene glycol and formaldehyde are synonymous. This contention is neither accurate nor supported by the scientific community or the FDA’s own regulatory practices. Methylene glycol and formaldehyde are two chemically distinct substances. First, methylene glycol is a liquid alcohol, while formaldehyde is a gaseous aldehyde. Second, the Chemical Abstracts Service (“CAS”), an authoritative and comprehensive source of chemical information utilized by the FDA and other government agencies¹, has deemed the two substances chemically distinct. More specifically, the CAS has assigned separate CAS Numbers² to methylene glycol (82115-62-6) and to formaldehyde (50-00-0). The State of California’s designated experts, Dr. Yashavanth Kamath and Dr. Dewey Jackson Northington, Jr. confirmed this point in their recent depositions.³ Excerpts of the relevant portions of Dr. Kamath’s and Dr. Northington’s deposition transcripts are enclosed for your review as Exhibits B and C, respectively. See Ex. B at 10:5-12, 31:17-23, 109:15-18; 110:6-18; 121:7-13, 139:4-25, Ex. 1 (Dr. Kamath’s CV), Ex. C at 9:16-23, 22:23-23:6, 36:6-18, Ex. 3 (Dr. Northington’s CV).

¹ Pursuant to 21 C.F.R. §§ 720 *et seq.*, the FDA requires the disclosure of CAS Numbers when a party files a voluntary cosmetic product ingredient statement. Specifically, FDA Form 2512a (Cosmetic Product Ingredient Statement) requires the disclosure of a cosmetic’s ingredients and the ingredients’ corresponding CAS Numbers. A copy of Form 2512a is enclosed for your reference as Exhibit A.

² CAS Numbers are unique numerical identifiers assigned by the CAS to every chemical described in scientific literature, enjoying wide acceptance and use in science and in the government. In fact, in California pursuant to Proposition 65, the Governor’s List identifies the subject chemicals by CAS Number and CAS Number based reporting is required. Yet, methylene glycol has a different CAS Number and cannot be reported under formaldehyde’s CAS Number.

³ The State of California also mistakenly contends that Brazilian Blowout contains formaldehyde.

Additionally, independent testing has revealed that Brazilian Blowout off-gases only trace amounts of naturally occurring formaldehyde, indicating that there is no need or requirement for Brazilian Blowout to list formaldehyde as a product ingredient. When rumors began to circulate that Brazilian Blowout contained formaldehyde, GIB representatives hired independent laboratories to measure the purported levels of formaldehyde in Brazilian Blowout. A copy of these test results are enclosed for your review as Exhibits D and E. This impartial testing revealed only trace levels— **0.0115%** —of formaldehyde in Brazilian Blowout. Ex. D at 1. Formaldehyde, however, is an ever-present, naturally occurring chemical and is also present in thousands of products used by consumers everyday, including, but not limited to, various fabrics, plywood, carpet backings, and ceiling tiles. See Health Science Associates Industrial Hygiene Air Sampling and Evaluation at 1, enclosed at Exhibit F. Thus, like carbon dioxide, negligible amounts of formaldehyde will inevitably be found in any product, including in Brazilian Blowout.

Further, contrary to the FDA's allegations, Brazilian Blowout does not contain harmful levels of methylene glycol. The August 22, 2011 correspondence did not address the testing method used by FDA in analyzing a sample of Brazilian Blowout. GIB believes that the FDA's conclusion that Brazilian Blowout contains methylene glycol levels ranging from 8.7 to 10.4 percent to be based on a method of testing that does not fairly measure the levels (and creates formaldehyde in the process). Further, GIB is unaware of any toxicological studies that demonstrate that methylene glycol is harmful to human health.

The proper testing method for determining formaldehyde levels is the NMR Spectroscopy (13C-NMR) testing method. To date, no governmental agency has employed this method. Instead, various agencies have relied on the inferior HPLC testing method. The HPLC method, however, cannot distinguish between methylene glycol and formaldehyde and, rather than measuring actual formaldehyde that is present, the HPLC test measures the potential building blocks within methylene glycol that could create formaldehyde in a laboratory process, but do not actually do so. To make matters worse, HPLC cannot distinguish between formaldehyde originating from the product sample versus that originating from the reactive agent used in the HPLC process. It also relies upon the use of a catalyst, which would not be present in a normal salon (non-laboratory) setting, which, by definition, is employed to increase and expedite the production of formaldehyde. The result is that the HPLC testing method produces results that exaggerate the amount of formaldehyde present in a product. Dr. Kamath and Dr. Northington, the State of California's designated experts, also confirmed this point in their recent depositions. Ex. B at 121:14-122:1, 125:15-126:9, Ex. C at 33:6-35:12, 41:4-42:20; 48:19-49:16, Ex. 5 at 1. Accordingly, the HPLC testing of Brazilian Blowout is neither an accurate nor a valid means of evaluating the product's legal compliance.

In contrast to the HPLC testing method, the NMR Spectroscopy method is able to differentiate between methylene glycol and formaldehyde. Indeed, when the NMR Spectroscopy method was used to test Brazilian Blowout, it established that only trace amounts of

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formaldehyde are present in the product. *See* Exs. D, E. The high levels of methylene glycol found by the FDA are inconsistent with the proper NMR Spectroscopy method of testing that GIB has conducted. We have included hereto as Exhibit G a copy of a recent response to the Cosmetic Ingredient Review provided by Dr. James F. Haw, University of Southern California chemist, which directly addresses the testing methodology issues and the methylene glycol/formaldehyde chemical distinctions.

You should also be aware that Federal Occupational Safety and Health Administration has reached similar conclusions. In writings to the California Occupational Safety and Health Administration and the California Attorney General, the head of the Federal Occupational Safety and Health Administration testing laboratory, Dr. Warren Hendricks, has explained the differences between methylene glycol and formaldehyde and commented upon the current dispute, in pertinent part, as follows.

The MSDS for Brazilian Blowout is somewhat misleading. **The MSDS correctly states that the product does not contain a large amount of free formaldehyde.** Anhydrous formaldehyde gas dissolves in water and exists as an equilibrium mixture of the monohydrate, methylene glycol, and a series of low molecular weight hydrate polymers. **These solutions contain only small amounts of the unhydrated monomer, formaldehyde. This allows those who commercialize these solutions to legally state that the solutions contain very low levels of free formaldehyde.** A copy of Dr. Hendrick's statement is enclosed hereto as part of Exhibit H; *see* Ex. H, Ex. 19 at 3 (emphasis added).⁴

Further, Dr. Hendricks went on to conclude that:

Some experts maintain that because formalin solutions are known [to] contain less than 0.1% free formaldehyde,

⁴ Dr. Hendrick's email was an exhibit in Robert Barish's deposition, which occurred in litigation between the State of California and GIB. A copy of Mr. Barish's deposition transcript and pertinent exhibits are enclosed for your review as Exhibit H. Mr. Barish is a Senior Safety Engineer for the California Occupational Safety and Health Administration's Research and Standards Development Unit. Ex. H at 22:9-25:10. In his deposition, Mr. Barish testified repeatedly that he consulted with Dr. Hendricks about the differences between methylene glycol and formaldehyde *because he did not understand the distinction between the two* and that he relied on and did not dispute Dr. Hendrick's statements that Brazilian Blowout contains only trace amounts of formaldehyde. *See, e.g., id.* at 69:17-70:7, 107:13-15, 110:6-115:4, Ex. 19. Query – if Cal OSHA chemists are unclear on the distinctions between formaldehyde and methylene glycol, and if the Fed OSHA agrees that there *is* a chemical distinction, how could any of GIB's beliefs that there is *not* formaldehyde (but instead a different chemical, methylene glycol) be unreasonable *or* misleading?

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analytical methods that give relatively high formaldehyde results must be in error. While this is technically true, this position does not acknowledge that personal exposure to any released formaldehyde can occur when conditions favoring the existence of methylene glycol no longer exist.
Id.

Dr. Hendricks has also noted that “because methylene glycol is the actual chemical species present, Formalin solutions in equilibrium are recognized to contain less than 0.1% free formaldehyde.” Ex. H, Ex. 19 at 3.

In light of the substantial scientific support for GIB’s position that Brazilian Blowout does not contain formaldehyde, but rather methylene glycol, and that the amounts of free formaldehyde in the actual product is very small, GIB believes that the weight of scientific knowledge is on its side in this controversy. Seemingly, the federal government’s own lab appears to concur in GIB’s favor. As such, GIB firmly believes that its product is not dangerous and that the HPLC results that have shown higher formaldehyde content are not scientifically supportable or valid. GIB would welcome the opportunity to speak with you or a representative in your office so that these discrepancies can be resolved.

Further, while Mr. Roosevelt’s letter does not indicate whether the FDA has relied on testing or information provided by the Oregon Occupational Safety and Health Administration, GIB wishes to explain at this juncture that the Oregon Occupational Safety and Health Administration’s testing of and information regarding Brazilian Blowout is flawed and does not establish that Brazilian Blowout is harmful or misleading. A copy of the Oregon Safety and Health Administration’s report regarding Brazilian Blowout is attached hereto as Exhibit I. More specifically, the Oregon Occupational Safety and Health Administration failed to follow established protocols when it tested Brazilian Blowout. For reasons unexplained, the Oregon Occupational Safety and Health Administration altered the established testing procedure to inflate the detectable presence of formaldehyde in the air. While the federal Short Term Exposure Limit (STEL) standard for formaldehyde is 2 parts per millions based upon a 15-minute exposure, the Oregon Occupational Safety and Health Administration employed a 26-minute exposure to achieve a STEL finding of only 1.88 parts per million. Ex. I at 25. In other words, the Oregon Occupational Safety and Health Administration nearly doubled the proper exposure, and still its testing yielded a reading below the federal Occupational Safety and Health Administration standard. *See id.* at 29. Despite using flawed testing protocols, the Oregon Occupational Safety and Health Administration’s test results are consistent with GIB’s air testing that demonstrates that Brazilian Blowout is within tolerance. Indeed, the Oregon Occupational Safety and Health Administration acknowledged this point in its own report! *Id.* To date, GIB is not aware of a single test demonstrating that when Brazilian Blowout is used as directed the product off-gasses an amount of formaldehyde that is above applicable limits.

Moreover, another expert retained by the State of California has also confirmed that more independent testing of Brazilian Blowout revealed that any small amounts of formaldehyde off-gassed during a Brazilian Blowout treatment are not harmful to consumers. Specifically, Dr. Francis Offerman testified in deposition as follows:

A: ...If we just start with, so we know what we're talking about, Exhibit 10, and we go to page 9, Table 2, here's your Formaldehyde Lifetime Average Daily Dose micrograms per day. The guidelines being 40, and we see under the low ventilation rate with just a half a capful or one capful, or one and a half, all those three scenarios are over. And then when we go to a medium ventilation scenario rate, then just the medium and long hair capfuls are over. **And then when we go to the high ventilation scenario, they are all under.**

Q: And then what with respect to customers, what was your conclusion because that was stylists that you just spoke to, right?

A: **That's correct. For the customers there's no violation.**

Q: Okay. In any of the scenarios that you looked at, there was no violation for customers?

A: No violation of the Prop 65 labeling law.

A copy of this excerpt from Dr. Offerman's deposition is enclosed for your review as Exhibit J; *see* 39:5-40:2; 132:16-133:10.

In sum, while Brazilian Blowout does contain methylene glycol, it does not contain formaldehyde, a separate chemical. Moreover, independent testing has revealed that consistent with other products used daily by consumers, only trace amounts of formaldehyde are present in Brazilian Blowout, which was and is to be expected as formaldehyde is a naturally occurring substance. *See* Exs. D, E. Again, independent testing has confirmed that the trace amounts of formaldehyde that are released when heat is applied to treated hair are far below the California Occupational Safety and Health Administration's and the federal Occupational Safety and Health Administration's maximum Permissible Exposure Limits and Action Levels, further indicating that Brazilian Blowout does not contain a deleterious substance that would harm users and is not adulterated. Ex. F at 4, Ex. I at 25, 29. Thus, the assertion that Brazilian Blowout is adulterated

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is based on an inaccurate premise and is contrary to the testing results based on the proper testing method to measure formaldehyde content.

II. BRAZILIAN BLOWOUT IS NOT MISBRANDED.

As discussed in the August 22, 2011 letter, a cosmetic is “misbranded” within the meaning of the Act where “its labeling is false or misleading in any particular.” 21 U.S.C. § 362(a). The introduction of a “misbranded” cosmetic into interstate commerce violates the Act. 21 U.S.C. § 331(a). The Act further provides that in determining whether a cosmetic’s labeling or advertising is misleading (and thus “misbranded” within the meaning of the Act)

there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual. 21 U.S.C. § 321(n).

Here, contrary to the FDA’s allegations, Brazilian Blowout’s labeling is not misleading. While GIB does not believe that Brazilian Blowout must display a warning to consumers regarding use of the product, GIB is nonetheless implementing such a notification to assure the FDA of its compliance with the Act.

A. Brazilian Blowout Is Not Misleading Because Formaldehyde Is Not An Active Product Ingredient.

Brazilian Blowout does not contain formaldehyde. As discussed at length above, it contains methylene glycol, a substance that is chemically distinct and not equivalent to formaldehyde. Thus Brazilian Blowout’s label does not list formaldehyde as an active ingredient in the product, nor is it required to. Methylene glycol, however, is accurately listed as a product ingredient on both Brazilian Blowout’s label and material safety data sheet, establishing that the product labeling is not misleading. Photographs of the entire Brazilian Blowout bottle, including the ingredient list appearing on the Brazilian Blowout product itself, are enclosed as Exhibit K for your review. Because Brazilian Blowout does not contain formaldehyde as a product ingredient, GIB is not required to list formaldehyde as an active ingredient on the Brazilian Blowout label, establishing that the product is not misbranded.

In sum, because Brazilian Blowout's label and material safety data sheet accurately disclose that the product contains methylene glycol the product is not misleading. Further, because Brazilian Blowout does *not* contain formaldehyde, neither its label nor its material safety data sheet need list formaldehyde as an active ingredient. The product is therefore neither misleading, nor "misbranded," and GIB has not violated the Act.

B. Brazilian Blowout Need Not Include A Warning Regarding The Product's Use Because When Used Properly It Is Not Harmful; Nonetheless, To Assure The FDA Of Compliance, GIB Has Implemented An Informational Label On Brazilian Blowout Regarding The Product's Use.

Brazilian Blowout poses no harmful consequences to the typical stylist or consumer when the product is used in accordance with its instructions. All of the product ingredients are safe for stylist or consumer use. As discussed above, Brazilian Blowout does not contain formaldehyde, but rather only methylene glycol. At the levels present in Brazilian Blowout, methylene glycol is not harmful to Brazilian Blowout stylists or consumers. This is evidenced by the fact that California law *does not* include methylene glycol as a "hazardous substance" subject to regulation under Proposition 65.⁵ *See* 8 C.C.R. § 339. While the California Department of Public Health has contemplated adding methylene glycol to the Governor's List, which sets forth substances subject to disclosure pursuant to Proposition 65, the Department has declined to do so. Dr. Michael J. DiBartolomeis confirmed this in his recent deposition, explaining that the Department and several other governmental entities have yet to add methylene glycol to the list, ***despite having reviewed this topic and considered it in several different year end reviews.*** (For your review, the pertinent excerpts of Dr. DiBartolomeis's deposition transcript are enclosed as Exhibit L.) Further, Mr. Roosevelt's letter does not cite or refer to any federal authority for the proposition that the presence of methylene glycol in a cosmetic or product somehow renders the cosmetic's or product's use inherently harmful to consumers.

While GIB does not dispute that a trace amount of formaldehyde is off-gassed when hair is heated during the Brazilian Blowout treatment, this small emission does not require GIB to include a label, warning, or other statement on the product regarding its use. Indeed, pursuant to 21 C.F.R. § 740.1(a), a cosmetic is only required to display a warning statement where such a statement is necessary to prevent a health hazard associated with the product.

Independent testing, however, has confirmed that there is no health hazard associated with use of Brazilian Blowout when the product is used properly. *See* Ex. F at 3-4. More specifically, independent testing conducted in October 2010 revealed that the minimal formaldehyde gas that is released during the heating process is far below the Action Levels and Permissible Exposure Limits set by the California Occupational Safety and Health

⁵ Proposition 65 (also known as the Safe Drinking Water and Toxic Enforcement Act of 1986) is codified at California Health and Safety Code §§ 25249 *et seq.*

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Administration. *Id.* While the California Occupational Safety and Health Administration sets the maximum Action Level for formaldehyde gas at 0.5 parts per million, the heating process associated with Brazilian Blowout results in only a small emission of formaldehyde gas ranging between 0.016 and 0.073 parts per million. *Id.* at 4. These levels are also far below the California Occupational Safety and Health Administration's maximum Permissible Exposure Limit of 0.75 parts per million, indicating that there is no need for the product to contain a notification to consumers regarding the product's use. *Id.*; *see also* Ex. J.

Further, to ensure that stylists and consumers do not experience negative consequences from improper product use, product use instructions are included on the product itself (*see* Ex. K) and a separate product instruction sheet is included with all Brazilian Blowout products when purchased. Additionally, Brazilian Blowout's material safety data sheet and a video demonstration regarding how to use and apply the product are available to stylists on the Brazilian Blowout website.⁶ While it is possible that a stylist or consumer could experience some negative side effects from *improper* use of Brazilian Blowout, GIB should not be forced to unnecessarily explain the consequences of improper product use on the product simply because some have chosen to ignore the product's instructions. GIB already includes instructions on how to use the product, as well as warnings regarding the consequences of product misuse, on the on the product itself (*see* Ex. K), in addition to providing detailed instructions about how to use the product to the certified individuals that purchase it.

Although GIB believes that a warning or statement on the Brazilian Blowout product itself is unnecessary, GIB is committed to working with the FDA to achieve full compliance. Accordingly, in an act of good faith and in an effort to alleviate the FDA's concerns, GIB is currently in the process of adding the following informational label regarding product use to the product: "CAUTION This product contains methylene glycol. When heated, this product releases trace amount of formaldehyde. Use in a well-ventilated area and only as directed." A copy of this new informational label is enclosed for your review as Exhibit M. As of October 1, 2011, this informational label will appear on all Brazilian Blowout that GIB packages.

⁶ The material safety data sheet is also available to stylists or consumers upon request.

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We hope that that this response has assured you of GIB's compliance with the Act and relevant regulations. Should you or the FDA continue to have questions or concerns regarding Brazilian Blowout, please contact us directly so that we may discuss how GIB may address any continuing concerns and ensure its full compliance with pertinent legal and regulatory requirements. GIB wants nothing more than to achieve full compliance, and it stands ready and willing to work with the FDA to achieve such compliance. We look forward to your response and working with the FDA to resolve this matter.

Sincerely,

KLINEDINST PC

HARTFORD O. BROWN

Enclosure(s):

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