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UNITED STATES DISTRICT COURT			
NORTHERN DISTRIC	CT OF CALIFORNIA		
DORINDA VASSIGH, SAMANTHA LEWIN, RICHARD DRAEGER, TRACEY HECHLER and MARK KORABELNIKOV, individually and on behalf of all others similarly situated,  Plaintiffs,	Case No. 3:14-cv-05127-HSG  SECOND AMENDED CLASS ACTION COMPLAINT		
v.	JURY TRIAL DEMANDED		
BAI BRANDS LLC	The Honorable Haywood S. Gilliam, Jr.		
Defendant.			
	L. Timothy Fisher (State Bar No. 191626) Annick M. Persinger (State Bar No. 272996) Yeremey Krivoshey (State Bar No. 295032) 1990 North California Boulevard, Suite 940 Walnut Creek, CA 94596 Telephone: (925) 300-4455 Facsimile: (925) 407-2700 E-Mail: Itfisher@bursor.com     apersinger@bursor.com     ykrivoshey@bursor.com  LEE LITIGATION GROUP, PLLC C.K. Lee (Pro Hac Vice) 30 East 39th Street, Second Floor New York, NY 10016 Tel.: 212-465-1188 Fax: 212-465-1181 E-Mail: cklee@leelitigation.com     diana@leelitigation.com     diana@leelitigation.com  Attorneys for Plaintiffs  UNITED STATES I  NORTHERN DISTRIC  DORINDA VASSIGH, SAMANTHA LEWIN, RICHARD DRAEGER, TRACEY HECHLER and MARK KORABELNIKOV, individually and on behalf of all others similarly situated,  Plaintiffs,  v.  BAI BRANDS LLC		

SECOND AMENDED CLASS ACTION COMPLAINT CASE NO. 3:14-CV-05127-HSG

Plaintiffs Dorinda Vassigh, Samantha Lewin, Richard Draeger, Tracey Hechler, and Mark Korabelnikov ("Plaintiffs") bring this action on behalf of themselves and all others similarly situated against Defendant Bai Brands LLC ("Bai Brands" or "Defendant"). Plaintiffs make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to the allegations specifically pertaining to themselves, which are based on personal knowledge.

#### **INTRODUCTION**

- 1. Bai Brands' marketing campaign takes advantage of high consumer demand for antioxidants by touting the antioxidant content in its Bai5 Antioxidant Infusions beverages in precisely the manner the Food and Drug Administration ("FDA") sought to prohibit by establishing the antioxidant labeling requirements set forth in 21 C.F.R. § 101.54(g). Bai Brands has plastered misleading antioxidant messaging on every square inch of its Bai5 Antioxidant Infusions beverage labels, including the bottle's cap. The simple truth is, however, that Bai5 Antioxidant Infusions does not have even a single nutrient that the FDA recognizes and approves of for labeling statements using the term "antioxidant." Because the antioxidant statements on Antioxidant Infusions' labels are unauthorized and misleading nutrient content claims proscribed by the FDA, Bai5 Antioxidant Infusions is misbranded and improperly labeled in violation of the Food Drug and Cosmetics Act, and corresponding state laws as described herein. Accordingly, Bai Brands has sold misbranded products using misleading advertising to thousands, if not millions, of consumers, who relied on Defendant's advertising and were injured as a result.
- 2. Plaintiffs Vassigh, Lewin, Draeger, Hechler and Korabelnikov purchased numerous bottles of Bai5 Antioxidant Infusions based on Defendant's misleading advertising on the labels of the product.
- 3. Plaintiffs Vassigh, Lewin, and Draeger assert claims on behalf of themselves and a California class of purchasers of Bai5 Antioxidant Infusions<sup>1</sup> for violation of the California Unfair

<sup>&</sup>lt;sup>1</sup> Bai5 Antioxidant Infusions comes in the following flavors: Brasilia Blueberry, Jamaica Blue Berry, Malawi Mango, Molokai Coconut, Ipanema Pomegranate, Sumutra Dragonfruit, Costa Rica Clementine, Tanzania Lemonade Tea, Congo Pear, Panama Peach, Limu Lemon. The term "Bai5 Antioxidant Infusions" encompasses all of these flavors.

Competition Law ("UCL") and for violation of the California False Advertising Law ("FAL"). Plaintiffs Vassigh and Lewin also assert claims on behalf of themselves and a California class of purchasers of Bai5 Antioxidant Infusions for violation of the California Consumer Legal Remedies Act ("CLRA").

- 4. Plaintiff Hechler asserts claims on behalf of herself and a New York class of purchasers of Bai5 Antioxidant Infusions for violation of the New York General Business Law § 349 ("NYBGL").
- 5. Plaintiff Korabelnikov asserts claims on behalf of himself and a Pennsylvania class of purchasers of Bai5 Antioxidant Infusions for violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL").

### **PARTIES**

Plaintiff Dorinda Vassigh is a citizen of California, residing in San Francisco. From 6. the spring of 2013 until the summer of 2014, Ms. Vassigh purchased Bai5 Antioxidant Infusions, including Bai5 Antioxidant Infusions: Molokai Coconut, about once a month. Ms. Vassigh purchased bottles of Bai5 Antioxidant Infusions from multiple retail stores, including Whole Foods and 26<sup>th</sup> & Guerrero Market in San Francisco, California. Ms. Vassigh purchased bottles of Bai5 Antioxidant Infusions relying on statements on the bottles' labels that characterize the level of antioxidants in the beverage, such as "Antioxidant Packed" and "Antioxidant Packed Beverage," as discussed below. Ms. Vassigh would not have purchased Bai5 Antioxidant Infusions, or would have paid significantly less for the products, had she known that these statements were unauthorized, and that Defendant misbranded the products and mischaracterized the level, amount, and nature of the nutrients and antioxidants inside. Ms. Vassigh was misled by the representations that the products were "Antioxidant Packed" and that the products were an "Antioxidant Packed Beverage" because such claims imply that the purported antioxidants in the beverages are sources of real nutrition, like Vitamins A, C, D, and E, and deceived her into believing that Bai5 is a source of nutritional antioxidants. Whereas antioxidant nutrients, such as Vitamin C, are "absorbed 100 percent by body up to a certain level," the purported antioxidants in beverages such as Bai5 are

"poorly absorbed by the body, usually less than five percent, and most of what does get absorbed in to the blood stream is rapidly metabolized in the intestines and liver and excreted from the body." Thus, Defendant's antioxidant advertising was highly misleading for the additional reason that it implied that the purported antioxidants in Bai5 were equivalent to or superior to nutritional sources of antioxidants, such as Vitamin C, when, in fact, such antioxidants do not readily get absorbed by the human body. Ms. Vassigh suffered injury in fact and lost money as a result of Bai Brands' deceptive, misleading, unfair and fraudulent practices described herein. Further, should Ms. Vassigh encounter any Bai5 Antioxidant Infusions products in the future, she could not rely on the truthfulness of the labels' statements characterizing the nature and level of antioxidants in the beverages, absent corrective advertising or the addition of antioxidant nutrients with established RDIs to the beverages. However, Ms. Vassigh would still be willing to purchase the current formulation of Bai5 Antioxidant Infusions, absent the price premium, so long as Defendant engages in corrective advertising.

7. Plaintiff Samantha Lewin is a citizen of California, residing in San Francisco.

Within the past two years, Ms. Lewin purchased Bai5 Antioxidant Infusions, including Bai5

Antioxidant Infusions: Molokai Coconut and Bai5 Antioxidant Infusions: Ipanema Pomegranate from multiple retail stores in California, including Walgreens, and online at Amazon.com. Ms.

Lewin purchased bottles of Bai5 Antioxidant Infusions relying on statements on the bottles' labels that characterize the level of antioxidants in the beverage, such as "Antioxidant Packed" and "Antioxidant Packed Beverage," as discussed below. Ms. Lewin would not have purchased Bai5 Antioxidant Infusions, or would have paid significantly less for the products, had she known that these statements were unauthorized, and that Defendant misbranded the products and mischaracterized the level, amount, and nature of the nutrients and antioxidants inside. Ms. Lewin was misled by the representations that the products were "Antioxidant Packed" and that the products were an "Antioxidant Packed Beverage" because such claims imply that the purported

<sup>&</sup>lt;sup>2</sup> David Stauth, *Studies Force New View on Biology of Flavonoids*, EurekAlert!, March 5, 2007, available at http://www.eurekalert.org/pub\_releases/2007-03/osu-sfn030507.php (last accessed on September 14, 2015).

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antioxidants in the beverages are sources of real nutrition, like Vitamins A, C, D, and E, and deceived her into believing that Bai5 is a source of nutritional antioxidants. Whereas antioxidant nutrients, such as Vitamin C, are "absorbed 100 percent by body up to a certain level," the purported antioxidants in beverages such as Bai5 are "poorly absorbed by the body, usually less than five percent, and most of what does get absorbed in to the blood stream is rapidly metabolized in the intestines and liver and excreted from the body." Thus, Defendant's antioxidant advertising was highly misleading for the additional reason that it implied that the purported antioxidants in Bai5 were equivalent to or superior to nutritional sources of antioxidants, such as Vitamin C, when, in fact, such antioxidants do not readily get absorbed by the human body. Ms. Lewin suffered injury in fact and lost money as a result of Bai Brands' deceptive, misleading, unfair and fraudulent practices described herein. Further, should Ms. Lewin encounter any Bai5 Antioxidant Infusions products in the future, she could not rely on the truthfulness of the labels' statements characterizing the nature and level of antioxidants in the beverages, absent corrective advertising or the addition of antioxidant nutrients with established RDIs to the beverages. However, Ms. Vassigh would still be willing to purchase the current formulation of Bai5 Antioxidant Infusions, absent the price premium, so long as Defendant engages in corrective advertising.

8. Plaintiff Richard Draeger is a citizen of California, residing in Sacramento County. Within the one year period from approximately October 2013 to approximately October 2014, Mr. Draeger purchased bottles of different flavored Bai5 Antioxidant Infusions, including but not limited to, Bai5 Antioxidant Infusion: Ipanema Pomegranate, from retail stores such as Costco located throughout Sacramento, California. Mr. Draeger purchased bottles of Bai5 Antioxidant Infusions relying on statements on the bottles' labels that characterize the level of antioxidants in the beverage, such as "Antioxidant Packed" and "Antioxidant Packed Beverage," as discussed below. Mr. Draeger would not have purchased Bai5 Antioxidant Infusions, or would have paid significantly less for the products, had he known that these statements were unauthorized, and that Defendant misbranded the products and mischaracterized the level, amount, and nature of the

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27 28 nutrients and antioxidants inside. Mr. Draeger was misled by the representations that the products were "Antioxidant Packed" and that the products were an "Antioxidant Packed Beverage" because such claims imply that the purported antioxidants in the beverages are sources of real nutrition, like Vitamins A, C, D, and E, and deceived him into believing that Bai5 is a source of nutritional antioxidants. Whereas antioxidant nutrients, such as Vitamin C, are "absorbed 100 percent by body up to a certain level," the purported antioxidant in beverages such as Bai5 are "poorly absorbed by the body, usually less than five percent, and most of what does get absorbed in to the blood stream is rapidly metabolized in the intestines and liver and excreted from the body." Thus, Defendant's antioxidant advertising was highly misleading for the additional reason that it implied that the purported antioxidants in Bai5 were equivalent to or superior to nutritional sources of antioxidants, such as Vitamin C, when, in fact, such antioxidants do not readily get absorbed by the human body. Mr. Draeger suffered injury in fact and lost money as a result of Bai Brands' deceptive, misleading, unfair and fraudulent practices described herein. Further, should Mr. Draeger encounter any Bai5 Antioxidant Infusions products in the future, he could not rely on the truthfulness of the labels' statements characterizing the nature and level of antioxidants in the beverages, absent corrective advertising or the addition of antioxidant nutrients with established RDIs to the beverages. However, Mr. Draeger would still be willing to purchase the current formulation of Bai5 Antioxidant Infusions, absent the price premium, so long as Defendant engages in corrective advertising.

9. Plaintiff Tracey Hechler is a citizen of New York, residing in Westchester County. Within the one year period from approximately May 2013 to approximately May 2014, Ms. Hechler purchased bottles of different flavored Bai5 Antioxidant Infusions, including Bai5 Antioxidant Infusion: Malawi Mango and Bai5 Antioxidant Infusion: Molokai Coconut, from retail stores such as Target and restaurants located in Queens County and Westchester County. Ms. Hechler purchased bottles of Bai5 Antioxidant Infusions relying on statements on the bottles' labels that characterize the level of antioxidants in the beverage, such as "Antioxidant Packed" and

Id.

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"Antioxidant Packed Beverage," as discussed below. Ms. Hechler would not have purchased Bai5 Antioxidant Infusions, or would have paid significantly less for the products, had she known that these statements were unauthorized, and that Defendant misbranded the products and mischaracterized the level, amount, and nature of the nutrients and antioxidants inside. Ms. Hechler was misled by the representations that the products were "Antioxidant Packed" and that the products were an "Antioxidant Packed Beverage" because such claims imply that the purported antioxidants in the beverages are sources of real nutrition, like Vitamins A, C, D, and E, and deceived her into believing that Bai5 is a source of nutritional antioxidants. Whereas antioxidant nutrients, such as Vitamin C, are "absorbed 100 percent by body up to a certain level," the purported antioxidant in beverages such as Bai5 are "poorly absorbed by the body, usually less than five percent, and most of what does get absorbed in to the blood stream is rapidly metabolized in the intestines and liver and excreted from the body." Thus, Defendant's antioxidant advertising was highly misleading for the additional reason that it implied that the purported antioxidants in Bai5 were equivalent to or superior to nutritional sources of antioxidants, such as Vitamin C, when, in fact, such antioxidants do not readily get absorbed by the human body. Ms. Hechler suffered injury in fact and lost money as a result of Bai Brands' deceptive, misleading, unfair and fraudulent practices described herein. Further, should Ms. Hechler encounter any Bai5 Antioxidant Infusions products in the future, she could not rely on the truthfulness of the labels' statements characterizing the nature and level of antioxidants in the beverages, absent corrective advertising or the addition of antioxidant nutrients with established RDIs to the beverages. However, Ms. Hechler would still be willing to purchase the current formulation of Bai5 Antioxidant Infusions, absent the price premium, so long as Defendant engages in corrective advertising.

10. Plaintiff Korabelnikov is a citizen of Pennsylvania, residing in Allegheny County. Within the 12-month period from approximately October 2013 to approximately October 2014, Mr. Korabelnikov purchased bottles of different flavored Bai5 Antioxidant Infusions from retail stores such as Costco located throughout Queens County and Westchester County. Mr. Korabelnikoc

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purchased bottles of Bai5 Antioxidant Infusions relying on statements on the bottles' labels that
characterize the level of antioxidants in the beverage, such as "Antioxidant Packed" and
"Antioxidant Packed Beverage," as discussed below. Mr. Korabelnikov would not have purchased
Bai5 Antioxidant Infusions, or would have paid significantly less for the products, had he known
that these statements were unauthorized, and that Defendant misbranded the products and
mischaracterized the level, amount, and nature of the nutrients and antioxidants inside. Mr.
Korabelnikov was misled by the representations that the products were "Antioxidant Packed" and
that the products were an "Antioxidant Packed Beverage" because such claims imply that the
purported antioxidants in the beverages are sources of real nutrition, like Vitamins A, C, D, and E,
and deceived him into believing that Bai5 is a source of nutritional antioxidants. Whereas
antioxidant nutrients, such as Vitamin C, are "absorbed 100 percent by body up to a certain level,"
the purported antioxidant in beverages such as Bai5 are "poorly absorbed by the body, usually less
than five percent, and most of what does get absorbed in to the blood stream is rapidly metabolized
in the intestines and liver and excreted from the body." Thus, Defendant's antioxidant advertising
was highly misleading for the additional reason that it implied that the purported antioxidants in
Bai5 were equivalent to or superior to nutritional sources of antioxidants, such as Vitamin C, when,
in fact, such antioxidants do not readily get absorbed by the human body. Mr. Korabelnikov
suffered injury in fact and lost money as a result of Bai Brands' deceptive, misleading, unfair and
fraudulent practices described herein. Further, should Mr. Korabelnikov encounter any Bai5
Antioxidant Infusions products in the future, he could not rely on the truthfulness of the labels'
statements characterizing the nature and level of antioxidants in the beverages, absent corrective
advertising or the addition of antioxidant nutrients with established RDIs to the beverages.
However, Mr. Korabelnikov would still be willing to purchase the current formulation of Bai5
Antioxidant Infusions, absent the price premium, so long as Defendant engages in corrective
advertising.

<sup>6</sup> <u>Id.</u>

11. Defendant Bai Brands LLC is a New Jersey corporation located at 1800 E. State Street, Suite 153, Hamilton, New Jersey 08609. Bai Brands manufactures, advertises, sells, distributes, and markets Bai5 Antioxidant Infusions as alleged herein nationwide, including in California, New York, and Pennsylvania.

### **JURISDICTION AND VENUE**

- 12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d)(2)(A) because this case is a class action where the aggregate claims of all members of the proposed class are in excess of \$5,000,000, exclusive of interests and costs, and Plaintiffs, as well as most members of the proposed class, are citizens of states different from the states of Defendant.

  Defendant has sold hundreds of thousands, if not millions, of bottles of Bai5 Antioxidant Infusions.
- 13. Pursuant to 28 U.S.C. § 1391, this Court is the proper venue for this action because a substantial part of the events, omissions and acts giving rise to the claims herein occurred in this District. Defendant distributed, advertised, and sold Bai5 Antioxidant Infusions, which is the subject of the present complaint, in California and in this District. Moreover, Plaintiffs Vassigh and Lewin read the product's label and purchased Bai5 Antioxidant Infusions in this District.

## FACTS COMMON TO ALL CAUSES OF ACTION

#### Bai Brands' Unlawful Characterization of Antioxidants

14. Bai Brands' marketing campaign for Bai5 Antioxidant Infusions advertises one basic promise: consumers should buy Bai5 Antioxidant Infusions because it is packed with beneficial antioxidants, full stop. Defendant's advertising flies in the face of identical California, New York, Pennsylvania and federal laws that bar manufacturers from spouting "antioxidant" claims without including antioxidant nutrients, like Vitamin C, in their beverages to back up their advertising. Since Antioxidant Infusions does not include the antioxidant nutrients identified by the FDA as a source of real nutrition, Bai Brands' labeling and advertising deceives consumers into believing that all antioxidants are created equal and that Antioxidant Infusions beverages are a source of nutritional antioxidants.

- 15. Specifically, by law, Defendant must disclose on the labels of Bai5 Antioxidant Infusions precisely which *nutrients* have antioxidant properties. Further, each of these nutrients must have established Reference Daily Intake ("RDI") standards set by the FDA to prevent manufacturers from claiming that any obscure fruit or vegetable, or in this case, Defendant's "Superfruit," is a nutritional source of antioxidants.
- 16. Bai5 Antioxidant Infusions claims to be an "Antioxidant Packed" beverage, but does not contain even a single nutrient with an established RDI. Indeed, Antioxidant Infusion beverages are a type of tea, and the FDA considers tea a food of no nutritional significance. As such, Defendant's labels are misbranded and misleading.
- 17. Almost every written word and graphic on the labels of Bai5 Antioxidant Infusions, including the bottles' caps, makes promises about and characterizes the antioxidants inside.

  Although Bai5 Antioxidant Infusions comes in several flavors, including Brasilia Blueberry,
  Jamaica Blue Berry, Malawi Mango, Molokai Coconut, Ipanema Pomegranate, Sumutra

  Dragonfruit, Costa Rica Clementine, Tanzania Lemonade Tea, Congo Pear, Panama Peach, Limu

  Lemon, each and every one of these various flavors bears identical graphics and substantially identical statements concerning antioxidants. Each of the labels for each of the flavors of Bai5

  Antioxidant Infusions contains the same misleading and unlawful common message concerning antioxidants. As shown in the picture below, the only difference between the flavors is a different fruit pictured on the front label, and a different respective fruit flavor listed in the ingredients.<sup>7</sup>

<sup>&</sup>lt;sup>7</sup> For the purposes of this Complaint, any statements made or graphics shown of any of the various flavors Bai5 Antioxidant Infusions that concern antioxidants apply to all flavors of Bai5 Antioxidant Infusions.



18. The name "**Bai5 Antioxidant Infusions**" appears in bold, large letters on the front of the label. On the bottom, the label states "Superfruit Infused, Antioxidant Packed."



- 19. Bai Brands' antioxidant advertising does not stop with the product's name, but is rather the entire platform behind its multimillion dollar marketing campaign. Bai Brands characterizes antioxidants on the labels of Bai5 Antioxidant Infusions through statements such as:
  - "Antioxidant Packed"
  - "Antioxidant Packed Beverage"
- 20. The twist-off cap of Bai5 Antioxidant Infusions' bottles bears the following statement, "Superfruit Infused. Antioxidant Packed." Images of the twist-off cap are reproduced below:





21. The side of Bai5 Antioxidant Infusions' labels state "Meet Our Superfruit" in large bold letters, and show a picture of "The Superfruit" directly below. The "Superfruit" is in fact the outside skin of coffee fruit. Underneath the picture, the label states:

You've probably met the inside of coffeefruit, what your everyday cup'o joe is made from. But we'd like to introduce you to the outside; coffee's secret superfruit.

Can something made with coffeefruit taste fruity and refreshing? Of Course, just because it says "coffee" doesn't mean it tastes like it.

We infuse the antioxidant power of the superfruit, add a splash of exotic fruit juices and voila! You have 100% natural, free-radical crushing, Bai 5.

A picture of the side label is reproduced below:



22. The name of Bai5 Antioxidant Infusions instructs consumers that they are purchasing a beverage "infused" with antioxidants. Bai Brands markets the antioxidant characteristics of Bai5 Antioxidant Infusions as the primary reasons for purchasing the products. In turn, consumers rely on Bai Brands' characterization of antioxidants in Bai5 Antioxidant Infusions when purchasing the products.

## <u>Bai Brands Is Misbranded Under Identical California, New York, Pennsylvania And Federal</u> Laws

- 23. Identical federal and California laws regulate the content of labels on packaged food. The requirements of the federal Food, Drug & Cosmetic Act ("FDCA") were adopted by the California legislature in the Sherman Food Drug & Cosmetic Law (the "Sherman Law"). Under California law "[a]ny food is misbranded if its labeling does not conform with the requirements for nutrient content or health claims as set forth in Section 403(r) [21 U.S.C. Sec. 343(r)] of the federal act and the regulations adopted pursuant thereto." California Health & Safety Code § 110670.
- 24. Similarly, New York and Pennsylvania laws also adopt by reference the regulatory requirements under the FDCA. New York's Agriculture and Marketing Law provides in language that mirrors the FDCA, that food shall be deemed misbranded "[i]f its labeling is false or misleading in any particular." N.Y. Agm. Law § 201(1). Moreover, Part 259.1 of Title 1 of the New York Codes, Rules and Regulations of the State of New York (1 N.Y.C.R.R. § 259.1), incorporates by reference the regulatory requirements for food labeling under the FDCA:

"For the purpose of the enforcement of article 17 of the Agriculture and Markets Law, and except where in conflict with the statutes of this State or with rules and regulations promulgated by the commissioner, the commissioner hereby adopts the current regulations as they appear in title 21 of the *Code of Federal Regulations* (revised as of April 1, 2013) ... in the area of food packaging and labeling as follows: ... (3) Part 101 of title 21 of the *Code of Federal Regulations*, containing the Federal definitions and standards for *Food Labeling* (including Appendices) ..."

25. Likewise, Section 5729 of Pennsylvania's Food Safety Act states that "[a] food shall be misbranded: (1) If its labeling is false or misleading in any way" and incorporates FDCA regulations by reference. Under 3 Pa. C.S.A. § 5733 (f), "All regulations and supplements thereto or revisions thereof adopted under the Federal acts which relate to food on, before or after the effective date of this subchapter are adopted as regulations in this Commonwealth and shall remain in effect unless subsequently modified or superseded by regulations promulgated by the secretary."

26. Nutrient content claims using the term "antioxidant" must comply with the requirements listed in 21 C.F.R. 101.54(g). Under 21 C.F.R. § 101.54(g), a nutrient content claim that characterizes the level of antioxidant nutrients present in a food may only be used if: "(1) An RDI (Reference Daily Intake) has been established for each of the nutrients; (2) The nutrients that are the subject of the claim have recognized antioxidant activity ...; (3) The level of each nutrient that is the subject of the claim is sufficient to qualify for the [type of claim made]; and (4) The names of the nutrients that are the subject of the claim are included as part of the claim (e.g., 'high in antioxidant vitamins C and E'). Alternatively, when used as part of a nutrient content claim, the term 'antioxidant' or 'antioxidants' (as in 'high in antioxidants') may be linked by a symbol (e.g. an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label followed by the name or names of the nutrients with recognized antioxidant activity." The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 C.F.R. 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

27. The regulations regarding antioxidant nutrient content claims have been made clear by prior FDA actions targeting similar or identical claims. For example, on August 23, 2010, the FDA sent Unilever, Inc. a warning letter that specifically identified unauthorized antioxidant nutrient content claims that Unilever made on Lipton Green Tea's label and on its website. In the letter, the FDA explained that the statement "LIPTON Tea is made from tea leaves rich in naturally protective antioxidants," did not comply with 21 C.F.R. 101.54(g) because it did not "include the nutrients that are the subject of the claim or use a symbol to link the term 'antioxidant' to those nutrients." Accordingly, the FDA determined that the claim misbranded Lipton Green Tea under section 403(r)(2)(A)(i) of the Act. Likewise, the FDA concluded that the statement "packed with protective FLAVONOID ANTIOXIDANTS" did not comply with 21 C.F.R. 101.54(g) because no RDI has been established for flavonoids. Because the statements were unauthorized nutrient content claims, the FDA concluded that Lipton Green Tea was misbranded. <sup>8</sup>

<sup>&</sup>lt;sup>8</sup> See 8/23/2010 FDA Warning Letter to Unilever, Inc. attached hereto as Exhibit A.

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Inc. warning Redco that its green tea products violated the FDCA. The FDA determined that Redco's green tea label bore the following unauthorized nutrient content claim:

One of the antioxidants known as EGCG (Epigallocatechin gallate) is abundantly found in tea leaves.

In another example, on February 22, 2010, the FDA sent a letter to Redco Foods,

The FDA determined that the claim did not comply with 21 C.F.R. 101.54(g)(1) because no RDI has been established for EGCG.<sup>9</sup>

29. The FDA has explained that violations of 21 C.F.R. 101.54(g) occur even where a nutrient with an established RDI is present in a food bearing a label using the term "antioxidant" if the nutrient with the established RDI does not account for 100% of the claimed antioxidant value. On August 30, 2010, the FDA sent a letter to the Dr. Pepper Snapple Group, manufacturers of Canada Dry Sparkling Green Tea Ginger Ale, warning that its labels were misbranded pursuant to 21 C.F.R. 101.54(g). The FDA explained:

The nutrient content claim for your Sparkling Green Tea Ginger Ale product of "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\* .... \*\*Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" identifies Vitamin C as a nutrient associated with the antioxidant claim. Vitamin C is a nutrient that is a recognized source of antioxidants. Your Nutrition Facts panel declares Vitamin C at 100% of the Daily Reference Value (DRV), which accounts for 60 mg of the claimed 200 mg of antioxidants. According to the nutrient content claim on your product label, the remainder 140 mg of antioxidants must be derived from green tea or green tea flavonoids, which are not nutrients with recognized antioxidant activity under 21 CFR § 101.54(g)(2). Therefore, the claim "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\* .... \*\*Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" does not meet the requirements of 21 CFR 101.54(g) and misbrands your product under section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)).

30. Of particular relevance here, the labels of Bai5 Antioxidant Infusions claim that the products' "Antioxidant Blend" consists of "Organic Coffeefruit & White Tea Extract." On April 20, 2011, the FDA sent a letter to Diaspora Tea & Herb Co., LLC, the manufacturer of Rishi brand teas, warning the company that its White Tea products were misbranded. The FDA determined that the following label claim was an unauthorized nutrient content claim pursuant to 21 C.F.R.

<sup>&</sup>lt;sup>9</sup> See 2/22/2010 FDA Warning Letter to Redco Foods, Inc. attached hereto as Exhibit B.
<sup>10</sup> See 8/30/2010 FDA Warning Letter to Dr Pepper Snapple Group, attached hereto as Exhibit C.

101.54(g)(1) because "White Tea" does not have an established RDI: "White Tea...contain[s] high concentrations of ...antioxidant polyphenols (tea catechins)..." (Omissions and alterations in original).

31. The FDA further clarified the requirements of 21 C.F.R. 101.54(g) in compliance guides concerning the use of the term "antioxidant" on food labels. In a June 2008 "Guidance for Industry" document, the FDA made the requirements of 21 C.F.R. 101.54(g) perfectly clear:

Does the label claim have to include the name of the nutrient that is an antioxidant, or can the claim simply say "antioxidants?"

The names of the nutrients that are the antioxidants must appear in the claim. For example, "high in antioxidant vitamins C and E."  $^{12}$ 

- 32. Here, Bai Brands' entire marketing campaign for Bai5 Antioxidant Infusions is centered on the characterization of antioxidants in the products and the use of nutrient content claims using the term "antioxidant." However, the labels of Bai5 Antioxidant Infusions do not state which recognized antioxidant nutrients, if any, are the subject of their antioxidant claims. There is no symbol that refers to another symbol somewhere else on the label followed by the name or names of the nutrients with recognized antioxidant activity. For this reason alone, Antioxidant Infusions beverages are misbranded in violation of parallel state and federal laws.
- 33. Bai5 Antioxidant Infusions also does not contain a single nutrient with an established RDI, much less an antioxidant nutrient with an established RDI. Bai5 Antioxidant Infusions' label specifically states that the product is "Not a significant source of...vitamin A, vitamin C, calcium, and iron." Just below the "Nutritional Facts" portion of Bai5 Antioxidant

 $<sup>^{11}</sup>$  See 4/20/2011 FDA Warning Letter to Diaspora Tea & Herb Co., LLC attached hereto as Exhibit D.

D.
<sup>12</sup> Guidance for Industry: Food Labeling; Nutrient Content Claims; Definition for "High Potency" and Definition for Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods, at 5 (June 2008). Available at

http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-1995-N-0400-GDL.pdf

13 If Bai5 Antioxidant Infusions in fact contains any nutrients with an established RDI, such information is calculated in the property of the

information is solely within Defendant's possession and consumers cannot reasonably obtain such information. Further, if Defendant's antioxidant claims in fact refer to any nutrients with an established RDI, the identity of such nutrients is solely within Defendant's possession and consumers cannot reasonably obtain such information. This information is material to Plaintiffs and the Class, and the withholding of such information is misleading and misbrands the products.

Infusions' labels, the label states "Bai 5 Proprietary Antioxidant Blend: Organic Coffeefruit & White Tea Extract." Organic Coffeefruit and White Tea Extract are not "nutrients" within the scope 21 C.F.R. 101.54(g), and, even if they were, they do not have established RDI's as required by law. In fact, the FDA has determined that tea is a "food[] of no nutritional significance." The fact that Bai5 Antioxidant Infusions do not contain an antioxidant nutrient with an established RDI, provides an additional reason that Antioxidant Infusions are misbranded in violation of parallel state and federal laws.

## Consumers Are Misled By Bai Brands' Unlawful Antioxidant Marketing

- 34. Bai Brands' antioxidant advertising is a calculated ruse to capitalize on consumers demand for products with antioxidants.<sup>15</sup> However, identical federal, California, New York, and Pennsylvania law bans such advertising because it is misleading.
- 35. The FDA specifically proposed paragraph (g) to 21 C.F.R. 101.54 to "ensure that consumers are not confused or misled" by nutrient content claims using the term "antioxidants." The FDA's proposal to add a regulation to standardize nutrient content claims using the term "antioxidants" followed an informal FDA survey that found that claims like "high in antioxidants" often referred "to a variety of nutrients and other dietary ingredients that are present in widely varying amounts." The FDA concluded that such inconsistent use of antioxidant nutrient content claims "lead to consumer confusion."
  - 36. The FDA noted that part of the confusion stems from the fact that:

The term 'antioxidants' is unique in comparison to the names of other nutrients associated with nutrient content claims. Unlike previously approved nutrient content claims that characterize the level of a particular nutrient (e.g., 'low sodium'), a term such as 'high in antioxidants' ties a claim (i.e., 'high') to a class of nutrients that share a specific characteristic (i.e., they are antioxidants) whose very name indicates a metabolic function.

<sup>&</sup>lt;sup>14</sup> FDA Food Labeling Guide, at p. 64 available at

http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf

According to a consumer survey by Bossa Nova, half of adults rank antioxidants as the top nutrient they are most concerned about adding to their diets – ahead of calcium, fiber and iron. See New Survey Finds Antioxidants #1 Nutrient Concern Amongst Consumers, PR Newswire. http://www.prnewswire.com/news-releases/new-survey-finds-antioxidants-1-nutrient-concernamongst-consumers-106440093.html.

<sup>&</sup>lt;sup>16</sup> Food Labeling; Nutrient Content Claims: Definition of "Antioxidant" for Use in Nutrient Content Claims, 21 C.F.R. Part 101, Federal Register Vol. 60 No. 249, pp. 67184-67194, at 67189 (Dec. 28, 1995). Available at http://www.gpo.gov/fdsys/pkg/FR-1995-12-28/pdf/95-31194.pdf

- 37. Accordingly, because the use of the term "antioxidant" implies health benefits, the FDA specifically sought to curtail the use of antioxidant statements related to food products that do not contain nutrients recommended for the daily diet. In the FDA's view, consumers are misled and confused when products like Bai5 Antioxidant Infusions are advertised as "packed" with antioxidants, "high in" antioxidants, a source of "many" antioxidants, or "infused" with antioxidants when those products do not contain an essential nutrient with recognized antioxidant activity that also has an established RDI. For example, the statement that Bai5 beverages are "Antioxidant Packed" misleadingly suggests that the beverages provide superior antioxidant content than foods and beverages with antioxidant nutrients like vitamin C that have antioxidant properties as well as nutritional value. Contrary to Bai Brands' labeling statements that tout the antioxidant content of its tea beverages, the FDA has determined that antioxidant vitamins, rather than teas like Antioxidant Infusions, are the superior method for incorporating antioxidants in the daily diet. In other words, the inclusion of the magic word "antioxidant" on Antioxidant Infusions beverage labels deceives consumers into believing that Antioxidant Infusions beverages provides more antioxidants and is superior to foods that contain the requisite amount of real nutrients that the FDA has determined provide antioxidants and are essential to daily human nutrition. 17
- 38. The science backs the FDA's position that statements characterizing the level of antioxidants in a product are not misleading only when such products contain antioxidant nutrients, such as Vitamins A, C, or E. Studies show that antioxidant nutrients and purported antioxidants that are not nutrients are processed entirely differently by the human body. Whereas antioxidant nutrients, such as Vitamin C, are "absorbed 100 percent by body up to a certain level," purported

<sup>&</sup>lt;sup>17</sup> As Navindra P. Seeram, PhD, an assistant professor at the Bioactive Botanical Research Laboratory at the University of Rhode Island explained, "'Because modern-day consumers are constantly bombarded with information, they may naturally look for product comparisons based on quantifiable levels and values,' ... 'Unfortunately, this has led to a misuse in the term 'antioxidants' in products, including whole foods, beverages, and supplements that are touted against each other based on 'antioxidant levels' derived from a vast array of laboratory-based assays, which has led to considerable consumer confusion.'" Palmer, Sharon, *Dietary Antioxidants* – *Do Foods and Supplements With High Antioxidant Values Guarantee Better Health?* Vol. 15 No. 4 P. 42 (Apr. 2013) *available at http://www.todaysdietitian.com/newarchives/040113p42.shtml*.

antioxidant in beverages such as Bai5 are "poorly absorbed by the body, usually less than five percent, and most of what does get absorbed in to the blood stream is rapidly metabolized in the intestines and liver and excreted from the body." For these reasons, Dr. Balz Frei, the director and endowed chair of the Linus Pauling Institute at Oregon State University has concluded that non-nutrient antioxidants such as those found in Bai5 are "ineffectual as antioxidants in the human body." Accordingly, it is misleading to characterize the level of antioxidants in Bai5 Antioxidant Infusions because even "high" levels of non-nutrient antioxidant are hardly absorbed by the human body and are, instead, "metabolized in the intestines and liver and excreted from the body."

- 39. Medical professionals likewise agree with the FDA concerning consumer confusion. For example, Jeffrey B. Blumberg, PhD, a professor and the director of the Antioxidants Research Laboratory at Tufts University explained that the one "problem" with the "Antioxidant Message" that products are "high or rich in antioxidants" is that it deceives consumers by "making people think it's no longer the vitamins, minerals, or fiber but only the phytochemicals that promote health ... But the reason plant foods are good for you is because of *everything* they contain. There's synergy for all of these ingredients synergies between ingredients in one food and between multiple foods."<sup>20</sup>
- 40. The Harvard School of Public Health has also opined that it is critical to differentiate between different types of antioxidants, as the FDA has done through its requirement that manufacturers list nutrients with established RDI's any time they make nutrient content claims using the term "antioxidant." The Harvard School of Public Health Nutrition Source, an online publication of the School of Public Health, instructs that "using the term 'antioxidant' to refer to substances is misleading. It is really a chemical property, namely, the ability to act as an electron

<sup>&</sup>lt;sup>18</sup> David Stauth, *Studies Force New View on Biology of Flavonoids*, EurekAlert!, March 5, 2007, available at http://www.eurekalert.org/pub\_releases/2007-03/osu-sfn030507.php (last accessed on September 14, 2015).

<sup>19</sup> *Id*.

<sup>&</sup>lt;sup>20</sup> That's why the Dietary Guidelines for Americans recommends we consume a diversity of fruits, vegetables, and whole grains." Palmer, Sharon, Dietary Antioxidants – Do Foods and Supplements With High Antioxidant Values Guarantee Better Health? Vol. 15 No. 4 P. 42 (Apr. 2013) (emphasis added) available at

donor. Some substances that act as antioxidants in one situation may be prooxidants—electron grabbers—in a different chemical milieu. Another big misconception is that antioxidants are interchangeable. They aren't. Each one has unique chemical behaviors and biological properties. They almost certainly evolved as parts of elaborate networks, with each different substance (or family of substances) playing slightly different roles. This means that no single substance can do the work of the whole crowd."<sup>21</sup>

- 41. The FDA's and Dr. Blumberg's conclusions about consumer confusion are well founded, as a "recent study conducted by researchers at the University of Houston found that simply placing a healthy euphemism [like antioxidant] on a food package made people believe it was healthier than others that made no obvious health claims." Here, Bai5 Antioxidant Infusions misleads consumers into believing that the products are superior because they have been "packed" with antioxidants, even though the products do not contain a single nutrient essential for human nutrition, with recognized antioxidant activity, and with an established RDI.
- 42. Defendant has made, and continues to make, unlawful and misleading claims on the food labels of Bai5 Antioxidant Infusions that are prohibited by identical federal, California, New York, and Pennsylvania laws and which render these products misbranded. Under federal, California, New York, and Pennsylvania law, Bai5 Antioxidant Infusions cannot legally be manufactured, advertised, distributed, held, or sold.

## CLASS REPRESENTATION ALLEGATIONS

- 43. Plaintiffs Vassigh, Lewin and Draeger seek to represent a class defined as all persons in California who purchased Bai5 Antioxidant Infusions, excluding those that made such purchase for purpose of resale (the "California Class").
- 44. Plaintiff Hechler seeks to represent a class defined as all persons in New York who purchased Bai5 Antioxidant Infusions, excluding those that made such purchase for purpose of resale (the "New York Class").

<sup>22</sup> See Healthy Labels Magic Words Regardless of Food Inside (June 19, 2014) available at http://guardianlv.com/2014/06/healthy-labels-magic-words-regardless-of-the-food-inside/

<sup>&</sup>lt;sup>21</sup> Antioxidants: Beyond the Hype, Harvard School of Public Health Source, available at http://www.hsph.harvard.edu/nutritionsource/antioxidants/

- 45. Plaintiff Korabelnikov seeks to represent a class defined as all persons in Pennsylvania who purchased Bai5 Antioxidant Infusions, excluding those that made such purchase for purpose of resale (the "Pennsylvania Class").
- 46. Collectively, members of the California Class, the New York Class, and the Pennsylvania Class may be collectively referred to as the "Class."
- 47. Defendant sells hundreds of thousands of bottles of Bai5 Antioxidant Infusions.

  Bai5 Antioxidant Infusions is available in major supermarkets across California, New York, and Pennsylvania. Accordingly, members of the Class are so numerous that their individual joinder herein is impracticable. The precise number of Class members and their identities are unknown to Plaintiffs at this time but may be determined through discovery. Class members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant, third party retailers, and vendors.
- 48. Common questions of law and fact exist as to all Class members and predominate over questions affecting only individual Class members. Common legal and factual questions include, but are not limited to whether Bai5 Antioxidant Infusions is misbranded, and whether the labeling, marketing and promotion of Bai5 Antioxidant Infusions is false and misleading.
- 49. The claims of the named Plaintiffs are typical of the claims of the Class in that the named Plaintiffs were exposed to Defendant's false, misleading and misbranded labels, purchased Bai5 Antioxidant Infusions, and suffered losses as a result of those purchases.
- 50. Plaintiffs are adequate representatives of the Class because their interests do not conflict with the interests of the Class members they seek to represent, they have retained competent counsel experienced in prosecuting class actions, and they intend to prosecute this action vigorously. The interests of Class members will be fairly and adequately protected by Plaintiffs and their counsel.
- 51. The class mechanism is superior to other available means for the fair and efficient adjudication of the claims of the Class members. Each individual Class member may lack the resources to undergo the burden and expense of individual prosecution of the complex and

extensive litigation necessary to establish Defendant's liability. Individualized litigation increases the delay and expense to all parties and multiplies the burden on the judicial system presented by the complex legal and factual issues of this case. Individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on the issue of Defendant's liability. Class treatment of the liability issues will ensure that all claims and claimants are before this Court for consistent adjudication of the liability issues.

## **COUNT I**

## <u>Violation Of California's Consumers Legal Remedies Act,</u> <u>California Civil Code §§ 1750, et seq.</u>

- 52. Plaintiffs Vassigh and Lewin hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.
- 53. Plaintiffs Vassigh and Lewin bring this claim individually and on behalf of the members of the proposed California Class against Defendant.
- 54. Plaintiffs Vassigh and Lewin and California Class members are consumers who purchased Bai5 Antioxidant Infusions for personal, family or household purposes. Plaintiffs and the California Class members are "consumers" as that term is defined by the CLRA in Cal. Civ. Code § 1761(d). Plaintiffs Vassigh and Lewin and the California Class members are not sophisticated experts with independent knowledge of the character, effectiveness, nature, level, or amount of antioxidants found Bai5 Antioxidant Infusions or coffeefruit or white tea extracts.
- 55. Bai5 Antioxidant Infusions beverages that Plaintiffs and other California Class members purchased from Defendant were "goods" within the meaning of Cal. Civ. Code § 1761(a).
- 56. Defendant's actions, representations, and conduct have violated, and continue to violate the CLRA, because they extend to transactions that intended to result, or which have resulted in, the sale of goods to consumers.

- 57. Defendant's antioxidant nutrient content claims including, "Antioxidant Packed" and "Antioxidant Packed Beverage" as discussed above characterize the level of antioxidants in Bai5 Antioxidant Infusions and violate federal and California law because (1) there are no nutrients with RDIs in Bai5 Antioxidant Infusions, and (2) the antioxidant nutrient content claims do not include the nutrients that are subject of the claims or use a symbol to link the term "antioxidant" to those nutrients. Because Defendant's nutrient content claims do not comply with 21 C.F.R. § 101.54(g), Defendant sold misbranded products in California during the Class Period.
- 58. California's Consumers Legal Remedies Act, Cal. Civ. Code § 1770(a)(5), prohibits "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he or she does not have." By engaging in the conduct set forth herein, Defendant violated and continues to violate Section 1770(a)(5) of the CLRA, because Defendant's conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices, in that it misrepresents the particular characteristics, benefits and quantities of the goods.
- 59. Cal. Civ. Code § 1770(a)(7) prohibits representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another. By engaging in the conduct set forth herein, Defendant violated and continues to violate Section 1770(a)(7) of the CLRA, because Defendant's conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices, in that it misrepresents the particular standard, quality or grade of the goods.
- 60. Cal. Civ. Code § 1770(a)(9) further prohibits "[a]dvertising goods or services with intent not to sell them as advertised." By engaging in the conduct set forth herein, Defendant violated and continues to violate Section 1770(a)(9), because Defendant's conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices, in that it advertises goods with the intent not to sell the goods as advertised.
- 61. Plaintiffs Vassigh and Lewin and the California Class members are not sophisticated experts about the character, effectiveness, nature, level, or amount of antioxidants

found in Bai5 Antioxidant Infusions or coffeefruit or white tea extracts. Plaintiffs and the California Class acted reasonably when they purchased Bai5 Antioxidant Infusions based on their belief that Defendant's representations were true and lawful.

- 62. Plaintiffs Vassigh and Lewin and the California Class suffered injuries caused by Defendant because (a) they would not have purchased Bai5 Antioxidant Infusions on the same terms absent Defendant's illegal and misleading conduct as set forth herein, or if the true facts were known concerning Defendant's representations; (b) they paid a price premium for Bai5 Antioxidant Infusions due to Defendant's misrepresentations and unauthorized nutrient content claims; and (c) Bai5 Antioxidant Infusions did not have the characteristics, benefits, or quantities as promised.
- 63. On or about October 4, 2014, prior to filing this action, a CLRA notice letter was served on Defendant which complies in all respects with California Civil Code § 1782(a). Plaintiff Lewin sent Bai Brands LLC, on behalf of herself and the proposed California Class, a letter via certified mail, return receipt requested, advising Bai Brands that it is in violation of the CLRA and demanding that it cease and desist from such violations and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiff Lewin's letter is attached hereto as Exhibit E.
- 64. Wherefore, Plaintiffs Vassigh and Lewin seek damages, restitution, and injunctive relief for these violations of the CLRA.

#### **COUNT II**

## Violation Of California's Unfair Competition Law,

## California Business & Professions Code §§ 17200, et seq.

- 65. Plaintiffs Vassigh, Lewin and Draeger hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.
- 66. Plaintiffs Vassigh, Lewin and Draeger bring this claim individually and on behalf of the members of the proposed California Class against Defendant.
- 67. Defendant is subject to California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq.* The UCL provides, in pertinent part: "Unfair competition shall mean and

include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising ...."

- 68. Defendant's antioxidant nutrient content claims, including "Antioxidant Packed" and "Antioxidant Packed Beverage" as discussed above characterize the level of antioxidants in Bai5 Antioxidant Infusions and violate federal and California law because (1) there are no nutrients with RDIs in Bai5 Antioxidant Infusions, and (2) the antioxidant nutrient content claims do not include the nutrients that are subject of the claims or use a symbol to link the term "antioxidant" to those nutrients. Because Defendant's nutrient content claims do not comply with 21 C.F.R. § 101.54(g), Defendant sold misbranded products in California during the Class Period.
- 69. Defendant's business practices, described herein, violated the "unlawful" prong of the UCL by violating Section 403(r) of the FDCA [21 U.S.C. 343(r)(1)(a)], California Health & Safety Code § 110670, the CLRA, the FAL and other applicable law as described herein.
- 70. Defendant's business practices, described herein, violated the "unfair" prong of the UCL in that their conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous, as the gravity of the conduct outweighs any alleged benefits. Defendant's advertising is of no benefit to consumers, and has been declared misleading to consumers by the FDA, medical professionals, and research institutions. Creating consumer confusion regarding the properties and benefits of antioxidants is of no benefit to consumers. Defendant's failure to comply with FDCA and parallel California labeling requirements and deceptive advertising concerning the nature and effectiveness of antioxidants in Bai5 Antioxidant Infusions offends the public policy advanced by the Act "to protect the public health" by ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A).
- 71. Defendant violated the "fraudulent" prong of the UCL by misleading Plaintiffs and the Class to believe that the nutrient content claims made about Bai5 Antioxidant Infusions were lawful, authorized claims that met the minimum nutritional requirements for such claims, as described herein.

- 72. Plaintiffs Vassigh, Lewin and Draeger and the California Class members are not sophisticated experts about the character, effectiveness, nature, level, or amount of antioxidants found Bai5 Antioxidant Infusions or coffeefruit or white tea extracts. Plaintiffs Vassigh, Lewin and Draeger and the California Class acted reasonably when they purchased Bai5 Antioxidant Infusions based on their belief that Defendant's representations were true and lawful.
- 73. Plaintiffs Vassigh, Lewin and Draeger and the California Class lost money or property as a result of Defendant's UCL violations because (a) they would not have purchased Bai5 Antioxidant Infusions on the same terms absent Defendant's illegal conduct as set forth herein, or if the true facts were known concerning Defendant's representations; (b) they paid a price premium for Bai5 Antioxidant Infusions due to Defendant's misrepresentations and unauthorized nutrient content claims; and (c) Bai5 Antioxidant Infusions did not have the characteristics, benefits, or quantities as promised.

## **COUNT III**

## <u>Violation Of California's False Advertising Law,</u>

## California Business & Professions Code §§ 17500, et seq.

- 74. Plaintiffs Vassigh, Lewin and Draeger hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint
- 75. Plaintiffs Vassigh, Lewin and Draeger bring this claim individually and on behalf of the members of the proposed California Class against Defendant.
- 76. California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, et seq., makes it "unlawful for any person to make or disseminate or cause to be made or disseminated before the public in this state, ... in any advertising device ... or in any other manner or means whatever, including over the Internet, any statement, concerning ... personal property or services, professional or otherwise, or performance or disposition thereof, which is untrue or misleading and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

- 77. Defendant engaged in a scheme of offering misbranded bottles of Bai5 Antioxidant Infusions for sale to Plaintiffs Vassigh, Lewin and Draeger and the California Class members by way of product packaging, labeling, and other promotional materials. These materials misrepresented and/or omitted the true content and nature of the misbranded bottles of Bai5 Antioxidant Infusions. Defendant's advertisements and inducements were made in California and come within the definition of advertising as contained in Bus. & Prof. Code § 17500, *et seq.* in that the product packaging, labeling, and promotional materials were intended as inducements to purchase Defendant's Bai5 Antioxidant Infusions, and are statements disseminated by Defendant to Plaintiffs Vassigh, Lewin and Draeger and the California Class members. Defendant knew that these statements were unauthorized, inaccurate, and misleading.
- 78. Defendant's antioxidant nutrient content claims, including "Antioxidant Packed" and "Antioxidant Packed Beverage" as discussed above characterize the level of antioxidants in Bai5 Antioxidant Infusions and violate federal and California law because (1) there are no nutrients with RDIs in Bai5 Antioxidant Infusions, and (2) the antioxidant nutrient content claims do not include the nutrients that are subject of the claims or use a symbol to link the term "antioxidant" to those nutrients. Because Defendant's nutrient content claims do not comply with 21 C.F.R. § 101.54(g), Defendant sold misbranded products in California during the Class Period.
- 79. Defendant violated § 17500, *et seq*. by misleading Plaintiffs and the California Class to believe that the nutrient content claims made about Bai5 Antioxidant Infusions were lawful, authorized claims that met the minimum nutritional requirements for such claims, as described herein.
- 80. Defendant knew or should have known, through the exercise of reasonable care that Bai5 Antioxidant Infusions was and continues to be misbranded, and that their representations about the antioxidant nutrient content of Bai5 Antioxidant Infusions were unauthorized, inaccurate, and misleading.
- 81. Plaintiffs Vassigh, Lewin and Draeger and the California Class lost money or property as a result of Defendant's FAL violations because (a) they would not have purchased Bai5

Antioxidant Infusions on the same terms absent Defendant's illegal conduct as set forth herein, or if the true facts were known concerning Defendant's representations; (b) they paid a price premium for Bai5 Antioxidant Infusions due to Defendant's misrepresentations and unauthorized nutrient content claims; and (c) Bai5 Antioxidant Infusions did not have the characteristics, benefits, or quantities as promised.

#### **COUNT IV**

## Violation of New York's Deceptive and Unfair Trade Practices Act, New York General Business Law § 349

- 82. Plaintiff Hechler hereby incorporates by reference the allegations contained in all preceding paragraphs of this complain.
- 83. Plaintiff Hechler brings this claim individually and on behalf of the members of the proposed New York Class against Defendant.
- 84. Any person who has been injured by reason of any violation of the NY GBL § 349 may bring an action in her own name to enjoin such unlawful act or practice, an action to recover her actual damages or fifty dollars, whichever is greater, or both such actions. The court may, in its discretion, increase the award of damages to an amount not to exceed three times the actual damages up to one thousand dollars, if the court finds the defendant willfully or knowingly violated this section. The court may award reasonable attorney's fees to a prevailing plaintiff.
- 85. Defendant's antioxidant nutrient content claims, including "Antioxidant Packed" and "Antioxidant Packed Beverage" as discussed above characterize the level of antioxidants in Bai5 Antioxidant Infusions and violate federal and New York law because (1) there are no nutrients with RDIs in Bai5 Antioxidant Infusions, and (2) the antioxidant nutrient content claims do not include the nutrients that are subject of the claims or use a symbol to link the term "antioxidant" to those nutrients. Because Defendant's nutrient content claims do not comply with 21 C.F.R. § 101.54(g), which has been incorporated by reference under New York state regulations, 1 N.Y.C.R.R. § 259.1, Defendant sold misbranded products in New York during the Class Period. Further, Defendant's labeling and advertising practices are of no benefit to

consumers, and have been declared misleading to consumers by the FDA, medical professionals, and research institutions. Defendant's failure to comply with FDCA and parallel New York labeling requirements and deceptive advertising concerning the nature and effectiveness of antioxidants in Bai5 Antioxidant Infusions offends the public policy advanced by the Act "to protect the public health" by ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). Accordingly, Defendant's practices are unfair, deceptive, misleading and are in violation of N.Y. Agriculture and Markets Law § 201 in that Bai5 Antioxidant Infusions are misbranded.

- 86. The foregoing deceptive acts and practices were directed at consumers.
- 87. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics of Bai5 Antioxidant Infusions to induce consumers to purchase same.
- 88. Plaintiff Hechler and the other New York Class members suffered a loss as a result of Defendant's deceptive and unfair trade acts. Specifically, as a result of Defendant's deceptive and unfair trade acts and practices, Plaintiff Hechler and the other New York Class members suffered monetary losses associated with the purchase of the Bai5 Antioxidant Infusions because (a) they would not have purchased Bai5 Antioxidant Infusions on the same terms absent Defendant's illegal conduct as set forth herein, or if the true facts were known concerning Defendant's representations; (b) they paid a price premium for Bai5 Antioxidant Infusions due to Defendant's misrepresentations and unauthorized nutrient content claims; and (c) Bai5 Antioxidant Infusions did not have the characteristics, benefits, or quantities as promised.

### **COUNT V**

# <u>Violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Law,</u> 73 Penn. Stat. Ann. § 201-1 et seq.

89. Plaintiff Korabelnikov hereby incorporates by reference the allegations contained in all preceding paragraphs of this complain.

- 90. Plaintiff Korabelnikov brings this claim individually and on behalf of the members of the proposed Pennsylvania Class against Defendant.
- 91. This is a claim for violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 P.S. § 201-2(xxi).
- 92. Defendant has violated the UTPCPL because Defendant failed to satisfy the Pennsylvania State requirements under the Pennsylvania Food Safety Act, which incorporates the food labeling requirements under the FDCA by reference.
- 93. At all relevant times material hereto, Defendant conducted trade and commerce within the meaning of the UTPCPL.
- 94. Plaintiff Korabelnikov and the Pennsylvania Class are "persons" as defined and construed under the UTPCPL.
- 95. Defendant's antioxidant nutrient content claims, including "Antioxidant Packed" and "Antioxidant Packed Beverage" as discussed above characterize the level of antioxidants in Bai5 Antioxidant Infusions and violate federal and Pennsylvania law because (1) there are no nutrients with RDIs in Bai5 Antioxidant Infusions, and (2) the antioxidant nutrient content claims do not include the nutrients that are subject of the claims or use a symbol to link the term "antioxidant" to those nutrients. Because Defendant's nutrient content claims do not comply with 21 C.F.R. § 101.54(g), Defendant sold misbranded products in Pennsylvania during the Class Period. Further, Defendant's advertising is of no benefit to consumers, and has been declared misleading to consumers by the FDA, medical professionals, and research institutions. Defendant's failure to comply with FDCA and parallel Pennsylvania labeling requirements and deceptive advertising concerning the nature and effectiveness of antioxidants in Bai5 Antioxidant Infusions offends the public policy advanced by the Act "to protect the public health" by ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). Accordingly, Defendant's advertising is (i) unfair, deceptive and fraudulent, (ii) constitutes an unconscionable trade and business practice and (iii) is false advertising.

- 96. Defendant's conduct as set forth herein constitutes an unconscionable commercial practice comprised of deceptive acts or practices in violation of the UTPCPL, 73 P.S. §§ 201-2 (v) and (xxi), including its practice of misleading consumers in the promotion, marketing, advertising, packaging and labeling of its Bai5 Antioxidant Infusions as described herein. Specifically, Defendant is misbranding its Bai5 Antioxidant Infusions by making unlawful nutrient content claims as to antioxidants.
- 97. Defendant's conduct as set forth herein has been unfair in violation of the CFA because the acts or practices violate established public policy, and because the harm they cause to consumers in Pennsylvania greatly outweighs any benefits associated with those practices.
- 98. As a direct and proximate result of Defendant's statutory violations, Plaintiff Korabelnikov and the Pennsylvania Class members have been injured and suffered actual and ascertainable losses of money as a result of Defendant's unconscionable, deceptive, and/or unfair trade practices.
- 99. As a result of the harm caused by Defendant's violation of Pennsylvania consumer protection law, Plaintiff Korabelnikov and Pennsylvania Class members are entitled to recover compensatory damages, punitive damages, and attorneys' fees as set forth below.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, seek judgment against Defendant, as follows:

- a. For an order certifying the California Class under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs Vassigh, Lewin and Draeger as representatives of the California Class and Plaintiffs' attorneys as Class Counsel to represent the California Class members;
- b. For an order certifying the New York Class under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff Hechler as representative of the New York Class and Plaintiffs' attorneys as Class Counsel to represent the New York Class members;

1	c.	For an order certifying	the Pennsylvania Class under Rule 23 of the Federal Rules of
2		Civil Procedure and nar	ming Plaintiff Korabelnikov as representative of the
3		Pennsylvania Class and	l Plaintiffs' attorneys as Class Counsel to represent the
4		Pennsylvania Class me	mbers;
5	d.	For an order declaring t	that Defendant's conduct violates the statutes referenced
6		herein;	
7	e.	For an order finding in	favor of Plaintiffs and the Class on all counts asserted
8		herein;	
9	f.	For compensatory and j	punitive damages in amounts to be determined by the Court
10		and/or jury;	
11	g.	For prejudgment interes	st on all amounts awarded;
12	h.	For an order of restituti	on and all other forms of equitable monetary relief;
13	i.	For injunctive relief as	pleaded or as the Court may deem proper; and
14	j.	For an order awarding l	Plaintiffs and the Class their reasonable attorneys' fees and
15		expenses and costs of s	uit.
16		DEMA	AND FOR TRIAL BY JURY
17	Plaint	iffs demand a trial by jur	
18			
19	Dated: Septe	ember 18, 2015	Respectfully submitted,
20			BURSOR & FISHER, P.A.
21			By: /s/ Annick Persinger Annick M. Persinger
22			L. Timothy Fisher (State Bar No. 191626)
23			Annick M. Persinger (State Bar No. 272996)
24			Yeremey Krivoshey (State Bar No. 295032) 1990 North California Boulevard, Suite 940
25			Walnut Creek, CA 94596 Telephone: (925) 300-4455
26			Facsimile: (925) 407-2700 E-Mail: ltfisher@bursor.com
27			apersinger@bursor.com ykrivoshey@bursor.com
<b>)</b>			

1 2 3 4 5	LEE LITIGATION GROUP, PLLC C.K. Lee (Pro Hac Vice) 30 East 39th Street, Second Floor New York, NY 10016 Tel.: 212-465-1188 Fax: 212-465-1181 E-Mail: cklee@leelitigation.com diana@leelitigation.com shanshan@leelitigation.com
6	Attorneys for Plaintiffs
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## CLRA Venue Declaration Pursuant to California Civil Code Section 1780(d)

I, Samantha Lewin, declare as follows:

- 1. I am a plaintiff in this action and a citizen of the State of California. I have personal knowledge of the facts stated herein and, if called as a witness, I could and would testify competently thereto.
- 2. The complaint filed in this action is filed in the proper place because Bai Brands LLC sells hundreds of thousands of bottles of its products, including Bai5 Antioxidant Infusions, in this District.
- 3. While living in San Francisco, California, I purchased numerous bottles of Bai5
  Antioxidant Infusions within this District, including Bai5 Antioxidant Infusions: Molokai Coconut and Bai5 Antioxidant Infusions: Ipanema Pomegranate, for my personal use. I purchased Bai5
  Antioxidant Infusions after I read statements on the bottles' labels characterizing the antioxidants inside, such as "Antioxidant Packed Beverage," "Antioxidant Goodness Inside" and "Antioxidant Packed." The representations on the label were substantial factors influencing my decision to purchase Bai5 Antioxidant Infusions. I would not have purchased Bai5 Antioxidant Infusions had I known that the bottles were misbranded and mischaracterized the amounts and nature of the nutrients and antioxidants inside.

SAMANTHA LEWIN

## CLRA Venue Declaration Pursuant to California Civil Code Section 1780(d)

- I, Dorinda Vassigh, declare as follows:
- I am a plaintiff in this action and a citizen of the State of California. I have personal knowledge of the facts stated herein and, if called as a witness, I could and would testify competently thereto.
- The complaint filed in this action is filed in the proper place because Bai Brands
   LLC sells hundreds of thousands of bottles of its products, including Bai5 Antioxidant Infusions, in this District.
- 3. While living in San Francisco, California, I purchased numerous bottles of Bai5
  Antioxidant Infusions within this District, including Bai5 Antioxidant Infusions: Molokai Coconut, for my personal use. I purchased Bai5 Antioxidant Infusions after I read statements on the bottles' labels characterizing the antioxidants inside, such as "Antioxidant Packed Beverage," "Antioxidant Goodness Inside" and "Antioxidant Packed." The representations on the label were substantial factors influencing my decision to purchase Bai5 Antioxidant Infusions. I would not have purchased Bai5 Antioxidant Infusions had I known that the bottles were misbranded and mischaracterized the amounts and nature of the nutrients and antioxidants inside.

I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct, executed on November 4, 2014 at San Francisco, California.

DORÍNDA VASSIGH

# U.S. Food and Drug Administration Protecting and Promoting Your Health

Home Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters Inspections, Compliance, Enforcement, and Criminal Investigations

Unilever United States, Inc. 8/23/10



Public Health Service Food and Drug Administration College Park, MD 20740

August 23,2010

#### **WARNING LETTER**

# CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Michael B. Polk President of Unilever Americas Unilever, Inc. 700 Sylvan Avenue Englewood, NJ 07632-3113

Re: CFSAN-OC-10-24

Dear Mr. Polk:

The Food and Drug Administration (FDA) has reviewed the label for your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product and reviewed your labeling for this product on your websites, www.lipton.com<sup>1</sup> and www.liptont.com<sup>2</sup> in August 2010. Based on our review, we have concluded that this product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at www.fda.gov<sup>3</sup>.

A link to .your website, www.lipton.com<sup>4</sup>. appears on your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product label. This website directs U.S. visitors to another website, www.liptont.com<sup>5</sup>. We have determined that your websites, www.lipton.com<sup>6</sup> and www.liptont.com<sup>7</sup>. are labeling within the meaning of section 201(m) of the Act for your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product.

#### **Unapproved New Drug**

Your website, www.liptont.com<sup>8</sup>. also promotes your Lipton Green Tea 100% Natural Naturally Decaffeinated product for conditions that cause it to be a drug under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)].

For example, your webpage entitled "Tea and Health," subtitled "Heart Health Research" and further subtitled "Cholesterol Research" bears the following claim: "[F]our recent studies in people at risk for coronary disease have shown a significant cholesterol lowering effect from tea or tea flavonoids ... One of these studies, on post-menopausal women, found that total cholesterol was lowered by 8% after drinking 8 cups of green tea daily for 12 weeks ...."

The therapeutic claims on your website establish that the product is a drug because it is intended for use i the cure, mitigation, treatment, or prevention of disease. Your Lipton Green Tea 100% Natural Naturally Decaffeinated product is not generally recognized as safe and effective for the above referenced uses and,

therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C.

§ 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your Lipton Green Tea 100% Natural Naturally Decaffeinated product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for its intended purposes. Thus, your Lipton Green Tea 100% Natural Naturally Decaffeinated product is misbranded under section 502(f)(1) of the Act in that the labeling for this drug fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)] .

#### **Unauthorized Nutrient Content Claims**

Under section 403(r)(1)(A) of the Act [21 U.S.C. 343(r)(1)(A)], a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFI 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

Your webpage entitled "Tea and Health" and subtitled "Tea Antioxidants" includes the statement, "LIPTON Tea is made from tea leaves rich in naturally protective antioxidants." The term "rich in" is defined in 21 CFI 101.54(b) and may be used to characterize the level of antioxidant nutrients (21 CFR 101.54(g)(3)). However, this claim does not comply with 21 CFR 101.54(g)(4) because it does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients. Thus, this claim misbrands your product under section 403(r)(2)(A)(i) of the Act.

This webpage also states that "tea is a naturally rich source of antioxidants." The term "rich source" characterizes the level of antioxidant nutrients in the product and, therefore, this claim is a nutrient content claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we determined that the term "rich source" could be considered a synonym for a term defined by regulation (e.g., "high" or "good source"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "tea is a naturally rich source of antioxidants" does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients, as required by 21 CFR 101.54(g)(4). Thus, this claim misbrands your product under section 403(r)(2)(A)(i) of the Act.

The product label back panel includes the statement "packed with protective FLAVONOID ANTIOXIDANTS." The term "packed with" characterizes the level of flavonoid antioxidants in the product; therefore, this clair is a nutrient content claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we determined that the term "packed with" could be considered a synonym for a term defined by regulation, nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "packed with FLAVONOID ANTIOXIDANTS" does not comply with 21 CFR 101.54(g)1) because no RDI has been established for flavonoids. Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or

injunction.

6/18/2014

We note that your label contains a chart entitled "Flavonoid Content of selected beverages and foods." The chart appears to compare the amounts of antioxidants in your product with the amount of antioxidants in orange juice, broccoli, cranberry juice and coffee. However, the information provided may be misinterpreted by the consumer because although the chart is labeled, in part, "Flavonoid Content," the y-axis is labeled "AOX"; therefore, the consumer might believe that the chart is stating the total amount of antioxidants rather than specifically measuring the amount of flavonoids in the product.

You should take prompt action to correct these violations. Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Latasha A. Robinson, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/s/

Jennifer A. Thomas Acting Director Office of Compliance Center for Food Safety and Applied Nutrition

cc: FDA New Jersey District

#### **Close Out Letter**

Unilever United States, Inc. - Close Out Letter 5/10/11<sup>9</sup>

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U.S. Department of Health & Human Services

# Links on this page:

1. http://www.lipton.com/

- 2. http://www.liptont.com/
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- 6. http://www.lipton.com/
- 7. http://www.liptont.com/
- 8. http://www.liptont.com/
- 9. /ICECI/EnforcementActions/WarningLetters/2010/ucm267398.htm

# U.S. Food and Drug Administration Protecting and Promoting Your Health

Home Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters Inspections, Compliance, Enforcement, and Criminal Investigations

Redco Foods, Inc. 2/22/10



Public Health Service Food and Drug Administration College Park, MD 20740

FEB 22 2010

#### **WARNING LETTER**

#### **VIA OVERNIGHT MAIL**

Mr. Douglas N. Farrell, General Manager Redco Foods, Inc. One Hansen Island Little Falls, NY 13365

Re: CFSAN-OC-10-10

Dear Mr. Farrell:

The Food and Drug Administration (FDA) has reviewed the label for your "Salada Naturally Decaffeinated Green Tea" product and your website www.greentea.com. Based on our review, we have concluded that your green tea products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at www.fda.gov.

#### **Unapproved New Drug**

Your website, www.greentea.com. promotes your green tea products for conditions that cause them to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. Examples of disease claims that cause your products to be drugs include:

#### On a web page entitled "About Green Tea":

#### "A Steaming Cup of Medicine" Article:

- "And today, scientific [sic] are ... finding that green tea can ... inhibit the cancer process at virtually every stage, regulate cholesterol levels ... and ward off viruses, fungi and food-borne bacteria."
- "[I]t also helps inhibit dental plaque formation, lower the risk of type 2 diabetes ...."

# "The Origins of Tea" Article:

- "By this time, tea was prized as a medicine that could cure digestive disorders ...
- "The tea leaves were also applied externally as a paste to ease the pains of rheumatism."

#### "Is Green Tea a Brain Food?" Article:

• "[R]ecent studies of the effects of green tea's catechins on animal brains are intriguing:

o "\* Less buildup of plaque[.] Finally, mice specially bred to develop Alzheimer's disease developed up to 54% less beta-amyloid buildup in their brains when they were given daily injections of the green tea catechin EGCg.... Beta-amyloid plaques are believed to be a major cause of the brain cell death and dissue [tissue] loss seen in Alzheimer's disease."

The therapeutic claims on your website establish that your green tea products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Your green tea products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201 (p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your green tea products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, your green tea products are misbranded under section 502(f)(1) of the Act in that the labeling for these drugs fails to bear adequat directions for use [21 U.S.C. § 352(f)(1)].

#### **Unauthorized Health Claims**

Your green tea products are further misbranded under section 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] because its labeling bears unauthorized health claims. Your website, www.greentea.com. was reviewed and was found to contain a number of unauthorized health claims, including:

#### "Green Tea and the FDA: Who's Right?" Article:

- "[O]ver the past 25 years, countless studies showing the positive effect of green tea on several important risk factors for cardiovascular disease have been published in scientific journals."
- $\bullet$  "[M]ost studies have shown that green tea reduces certain CVD risk factors with a daily intake of 4-5 cups ...."

The above claims are unauthorized health claims because there is no health claim authorized by regulation or the Act that provides for health claims that characterize the relationship between green tea and cardiovascular disease.

#### **Unauthorized Nutrient Content Claims**

Under section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)], a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFI 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b)). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act  $[21 \text{ U.S.C.} \S 343(r)(2)(A)(i)]$ .

The principal display panel of the product label includes the statement "Fortified with Purple Antioxidants [/ Fortified with Grapeskins, Rooibos (Red Tea), Anthocyanins ..." In the context of the label, the term "antioxidants" refers, in part, to grapeskins, rooibos (red tea), and anthocyanins. The term "fortified" is defined by regulation and may be used to describe the level of certain substances for which an RDI or Daily Reference Value (DRV) has been established [21 CFR 101.54(e)]. However, there are no RDIs or DRVs for grapeskins, rooibos (red tea) or anthocyanins. Therefore, the claim "Fortified with Grapeskins, Rooibos (Red Tea), Anthocyanins" is unauthorized and misbrands your product under section 403(r)(1)(A) of the Act.

In addition, nutrient content claims using the term "antioxidant" may only be made for nutrients for which a Reference Daily Intake (RDI) has been established [21 CFR 101.54(g)(1)]. As noted above, there are no RDIs for grapeskins, rooibos (red tea) or anthocyanins. Therefore, the claim "Fortified with Purple Antioxidants ... Grapeskins. Rooibos (Red Tea), Anthocyanins" is an unauthorized nutrient content claim that causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The label for this product also bears the unauthorized nutrient content claim "One of the antioxidants known as EGCG (Epigallocatechin gallate) is abundantly found in green tea leaves." This claim is a nutrient content claim because "abundantly found" characterizes the level of EGCG in your product [see section 403(r)(1) of the Act (21 U.S.C. § 343(r)(1)) and 21 CFR 101.13(b)]. Even if we determined that the term "abundantly found" could be considered a synonym for a term defined by regulation (e.g., "high" or "good source"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). This claim does not comply with 21 CFR 101.54(g)(1) because no RDI has been established for EGCG. Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

You should take prompt action to correct these violations. Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Kathleen M. Lewis, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/S/

Roberta F. Wagner Director Office of Compliance Center for Food Safety and Applied Nutrition

cc: FDA New York District

Page Last Updated: 03/03/2010

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Letters

# Dr Pepper Snapple Group 8/30/10



Public Health Service Food and Drug Administration College Park, MD 20740

**Animal & Veterinary** 

AUG 30 2010

**WARNING LETTER** 

**CERTIFIED MAIL RETURN RECEIPT REQUESTED** 

Mr. Larry D. Young President and CEO Dr Pepper Snapple Group 5301 Legacy Drive Plano, Texas 75024

Re: CFSAN-OC-10-26

Dear Mr. Young:

The Food and Drug Administration (FDA) has reviewed the label for your Canada Dry Sparkling Green Tea Ginger Ale. We examined the product label and your website at www.canadadry.com in July of 2010. Based on our review, we have concluded that your green tea ginger ale product is in violation of the Federal Food, Drug. and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at www.fda.gov.

Your Sparkling Green Tea Ginger Ale is misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product label bears a nutrient content claim that is not authorized by regulation. Under section 403(r)(2)(A)(i) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Your Sparkling Green Tea Ginger Ale bears the claim, "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\*" with the double asterisk referring to the statement, "\* \*Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" on the principal display panel of the product label. In the context of this label the term "enhanced" is an unauthorized synonym for a "more" nutrient content claim. FDA has defined the nutrient content claim "more" and its authorized synonyms in 21 CFR 101.54(e). "More" nutrient content claims may be used on the label or in the labeling of foods to describe the level of nutrients, provided that (1) the food contains at least 10 percent more of the Reference Daily Intake or Daily Reference Value for the nutrient per reference amount customarily consumed than an appropriate reference food, (2) where the claim is based on nutrients that are added to the food, that the fortification is in accordance with the policy on fortification of foods in 21 CFR 104.20, and (3) the claim bears the required information for relative claims as described in 21 CFR 101.130)(2) and 101.54(e)(1)(iii).

Your Sparkling Green Tea Ginger Ale is a carbonated beverage. The policy on fortification in 21 CFR 104.20(a) states that the FDA does not consider it appropriate to fortify snack foods such as carbonated beverages. Additionally, the label of your product does not state the identity of a reference food and the percentage (or fraction) of the amount of the nutrient(s) in the reference food by which the nutrient(s) in the labeled food differs, as is required for "more" nutrient content claims under 101.130)(2). Therefore, even if the term "enhanced" was an authorized synonym for "more," your product would not meet the requirements for a "more" claim under 21 CFR 101.54(e)(1).

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a Reference Daily Intake (RDI) must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g) (1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant Vitamin C," the product must contain 20 percent or more of the RDI for Vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that

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appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

The nutrient content claim for your Sparkling Green Tea Ginger Ale product of "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\* .... \*\*Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" identifies Vitamin C as a nutrient associated with the antioxidant claim. Vitamin C is a nutrient that is a recognized source of antioxidants. Your Nutrition Facts panel declares Vitamin C at 100% of the Daily Reference Value (DRV), which accounts for 60 mg of the claimed 200 mg of antioxidants. According to the nutrient content claim on your product label, the remainder 140 mg of antioxidants must be derived from green tea or green tea flavonoids, which are not nutrients with recognized antioxidant activity under 21 CFR § 101.54(g)(2). Therefore, the claim "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\* .... \*\*Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" does not meet the requirements of 21 CFR 101.54(g) and misbrands your product under section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)).

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Judith G. Dausch, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

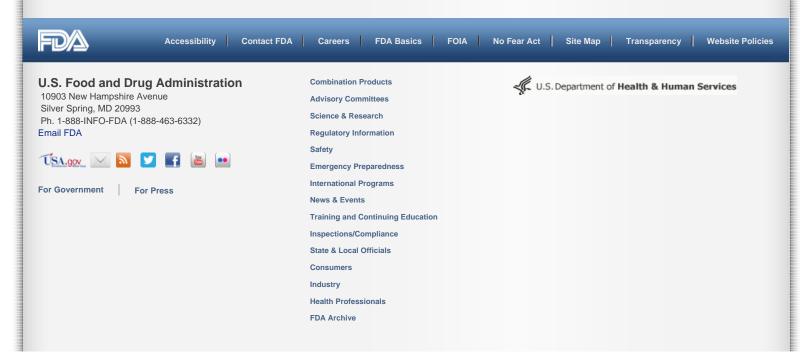
/s/

Jennifer Thomas Acting Director Office of Compliance Center for Food Safety and Applied Nutrition

cc: FDA Dallas District

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.



# Inspections, Compliance, Enforcement, and Criminal Investigations



**Tobacco Products** 



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# **Compliance Actions and Activities Warning Letters** 2014 2013 2012 2011 2010 2009 2008 2007 2006 2005 2004 2003 2002 2001 2000 1999 1998 1997 1996 **Tobacco Retailer Warning**

Letters

### Diaspora Tea & Herb dba Rishi Tea 4/20/11



Public Health Service Food and Drug Administration Minneapolis District Office Central Region 250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 Telephone: (612) 334-4100 FAX: (612) 334-4142

April 20, 2011

#### **WARNING LETTER**

**CERTIFIED MAIL RETURN RECEIPT REQUESTED** 

Refer to MIN 11 - 21

Joshua Kaiser President and Co-owner Diaspora Tea & Herb Co., LLC 427 East Stewart Street Milwaukee, Wisconsin 53207

Dear Mr. Kaiser:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address http://www.rishi-tea.com/store/index.php in January 2011. FDA has determined that your Oolong Tea, Ginger, Organic Botanical, Green Oolong Tea, 100% Premium Tealeaf Powder, and Pu-erh Tea products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1)(B). The therapeutic claims on your website establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Additionally, FDA has determined that your Yerba Maté Shade Grown, Organic Yerba Maté, White Tea, Pu-erh Tea, Green Oolong Tea, 100% Premium Tealeaf Powder, Matcha, 100% Premium Tea Powder, Blueberry Rooibos, Organic Fair Trade Rooibos Blend, Green Rooibos (Green Bush), Organic Fair Trade Botanical, and Super Green, Organic Japanese Green Tea products are also misbranded within the meaning of section 403(r)(1)(A) of the Act, 21 U.S.C. § 343(r)(1)(A). The marketing of these products with these claims violates the Act. You can find copies of the Act through links on FDA's home page at http://www.fda.gov.

### I. Unapproved New Drugs

Examples of disease claims on your website http://www.rishi-tea.com/store/ index.php include:

#### Ginger, Organic Botanical

"[G]inger is used in food and drinks as a preventive medicine against colds [and] flus."

#### Green Oolong Tea, 100% Premium Tealeaf Powder

• "The powerful antioxidants found in tea are believed to help prevent cancer [and] lower cholesterol '

#### Pu-erh Tea

• "Recent research suggests that consuming 5-8 cups of Pu-erh Tea each day can reduce cholesterol and plaque of the arteries."

#### **Oolong Tea**

- "Regular consumption of Oolong Tea is linked to the reduction of plaque in the arteries, reduction of cholesterol and lowering of blood sugar."
- "Oolong Tea is...prized for its cholesterol reducing...."

Your Oolong Tea, Ginger, Organic Botanical, Green Oolong Tea, 100% Premium Tealeaf Powder and Pu-erh

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Tea products are not generally recognized as safe and effective for the above referenced uses and, therefore, are also "new drugs" under section 201(p) of the Act, 21 U.S.C. § 321(p). New drugs may not be legally marketed in the U.S. without prior approval from FDA, as described in section 505(a) of the Act, 21 U.S.C. § 355(a). FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

#### **II. Unauthorized Nutrient Content Claims**

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. Characterizing the level of a nutrient in food labeling of a product without complying with specific requirements pertaining to nutrient content claims for that nutrient misbrands the product under section 403(r)(1)(A) of the Act.

Nutrient content claims that use the defined terms "rich in" or "high" may be used in the labeling of a food only if the food contains 20 percent or more of the daily value (DV) of that nutrient per reference amount customarily consumed (RACC), Title 21, Code of Federal Regulations (21 CFR), 101.54(b)(1). Such claims may not be made about a nutrient for which there is no established DV. However, your website bears "high" and "rich in" nutrient content claims about nutrients for which there are no established DV.

The following are examples of unauthorized "high" and "rich in" nutrient content claims on your website:

#### Pu-erh Tea

• "[R]ich in Tea Polyphenols and Theaflavins...rich in Thearubigin and Theabrownin...."

#### Super Green, Organic Japanese Green Tea

• "Super Green is...high in amino acids...."

#### White Tea

• "White Tea...contain[s] high concentrations of...L-Theanine Amino Acid."

Additionally, your website bears nutrient content claims using the term "antioxidant." Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a Recommended Daily Intake (RDI) must have been established for each of the nutrients that are the subject of the claim, 21 CFR 101.54(g)(1), and these nutrients must have recognized antioxidant activity, 21 CFR 101.54(g)(2). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e), 21 CFR 101.54(g)(3). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity, 21 CFR 101.54(g)(4). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

The following are examples of nutrient content claims on your website that use the term "antioxidant" but do not include the names of the nutrients that are the subject of the claim as required under 21 CFR 101.54(g)(4):

#### Yerba Maté Shade Grown, Organic Yerba Maté

• "Yerba Maté is...rich in... antioxidants."

#### Blueberry Rooibos, Organic Fair Trade Rooibos Blend

• "Antioxidant-rich...."

#### Green Rooibos (Green Bush), Organic Fair Trade Botanical

• "Caffeine-free Green Rooibos...contain[s] high concentrations of antioxidants...."

Additionally, the following are examples of nutrient content claims on your website that use the term "antioxidant," but where the nutrients that are the subject of the claim do not have an established RDI as required under 21 CFR 101.54(g)(1):

#### White Tea

• "White Tea... contain[s] high concentrations of... antioxidant polyphenols (tea catechins)...."

#### Matcha, 100% Premium Tea Powder

• "Antioxidant rich...222mg polyphenols per serving!"

#### Genmai Green Tea, 100% Premium Tealeaf Powder

• "Antioxidant rich...65mg polyphenols per serving!"

#### Green Oolong Tea, 100% Premium Tealeaf Powder

- "Antioxidant rich...109mg polyphenols per serving!"
- "[R]ichest sources of flavonoid antioxidants...."

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your website, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products, 21 U.S.C. §§ 332 and 334. You should take prompt action to correct these violations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these violations and to prevent similar violations. You should include in your response documentation such as revised labels or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

Your reply should be sent to the attention of Compliance Officer Tyra S. Wisecup at the address on the

# Warning Letters > Diaspora Tea & Herb dba Rishi Tea 4/20/11 Case 3:14-cv-05127-HSG Document 50 Filed 09/18/15 Page 53 of 56 Sincerely, /s/ Gerald J. Berg Director Minneapolis District **Close Out Letter** Diaspora Tea & Herb Co., LLC - Close Out Letter 2/3/12 Page Last Updated: 02/10/2012 Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players. Accessibility Contact FDA Careers FDA Basics FOIA No Fear Act Site Map Transparency Website Policies U.S. Food and Drug Administration **Combination Products** U.S. Department of Health & Human Services 10903 New Hampshire Avenue **Advisory Committees** Silver Spring, MD 20993 Science & Research Ph. 1-888-INFO-FDA (1-888-463-6332) **Email FDA Regulatory Information** Safety USA.gov **Emergency Preparedness** International Programs For Government For Press **Training and Continuing Education** Inspections/Compliance State & Local Officials

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# BURSOR FISHER

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September 30, 2014

# Via Certified Mail - Return Receipt Requested

Bai Brands LLC 1800 E. State Street Ste. 153 Hamilton, New Jersey 08609

Re: Demand Letter Pursuant to California Civil Code § 1782, Violation of Magnuson-Moss Act, 15 U.S.C. §§ 2301, et seq., and other applicable laws.

## To Whom It May Concern:

This letter serves as a notice and demand for corrective action on behalf of my client, Samantha Lewin, and all other persons similarly situated, arising from breaches of warranty under the Magnuson-Moss Warranty Act and violations of numerous provisions of California law including the Consumers Legal Remedies Act, Civil Code § 1770, including but not limited to subsections (a)(5), (7), and (9). This letter also serves as notice pursuant to Cal. Com. Code § 2607(3)(a) concerning the breaches of express and implied warranties described herein.

You have participated in the manufacture, marketing, and sale of Bai5 Antioxidant Infusions. Bai5 Antioxidant Infusions labels include unauthorized nutrient content claims in violation of 21 C.F.R. 101.54(g), as well as federal and state law. As a result, Bai5 Antioxidant Infusions products are misbranded.

Ms. Lewin, a resident of California, purchased Bai5 Antioxidant Infusions based on the antioxidant representations on the label. She would not have purchased Bai5 Antioxidant Infusions absent the antioxidant claims on the label.

Ms. Lewin is acting on behalf of a class defined as all persons in California who purchased Bai5 Antioxidant Infusions (hereafter, the "Class").

To cure the defects described above, we demand that you (1) cease and desist from continuing to mislabel Bai5 Antioxidant Infusions; (2) issue an immediate recall on any Bai5 Antioxidant Infusion products bearing misbranded labels; and (3) make full restitution to all California purchasers of Bai5 Antioxidant Infusions of all purchase money obtained from sales thereof.

We further demand that you preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

- 1. All documents concerning the ingredients, formula, and manufacturing process for Bai5 Antioxidant Infusions;
- 2. All communications with the U.S. Food and Drug Administration concerning the product development, manufacturing, marketing and sales of Bai5 Antioxidant Infusions;
- 3. All documents concerning the advertisement, marketing, or sale of Bai5 Antioxidant Infusions; and
- 4. All communications with customers concerning complaints or comments concerning Bai5 Antioxidant Infusions.

We are willing to negotiate to attempt to resolve the demands asserted in this letter. If you wish to enter into such discussions, please contact me immediately. If I do not hear from you promptly, I will conclude that you are not interested in resolving this dispute short of litigation. If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents promptly.

Very truly yours, annie Persinger

Annick M. Persinger