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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ALEX KHASIN, individually and on behalf of all others similarly situated,

Plaintiff,

v.

R. C. BIGELOW, INC.,

Defendant.

Case No. 3:12-cv-02204-JSW

AMENDED CLASS ACTION AND REPRESENTATIVE ACTION

FOURTH AMENDED COMPLAINT FOR DAMAGES, EQUITABLE AND INJUNCTIVE RELIEF

JURY TRIAL DEMANDED

Plaintiff, through his undersigned attorneys, brings this lawsuit against Defendant as to his own acts upon personal knowledge and as to all other matters upon information and belief. In order to remedy the harm arising from Defendant's illegal conduct, which has resulted in unjust profits, Plaintiff brings this action on behalf of a class of all persons in California who, since May 2, 2008 to the present (the "Class Period"), purchased Defendant's Green tea products for personal or household use ("Misbranded Food Products").

INTRODUCTION

1. Every day, millions of Americans purchase and consume packaged foods. In order

to protect these consumers, identical federal and California laws require truthful, accurate information on the labels of packaged foods. This case is about a company that flouts those laws even after companies with identical products with similar claims on their labels received warning letters from the FDA notifying those companies that their products were misbranded. The Defendant was and is fully aware of these laws as well as FDA guidance documents on the subjects, and the aforementioned warning letters. The law is clear: misbranded food cannot legally be manufactured, held, advertised, distributed or sold. Misbranded food is worthless as a matter of law, and purchasers of misbranded food are entitled to a refund of their purchase price or other relief and compensation as determined by this Court.

2. Defendant R. C. Bigelow, Inc. (hereinafter "Bigelow" or "Defendant") is a tea company based in Fairfield, Connecticut. It markets the green tea products involved in this litigation.

3. Bigelow recognizes that health claims drive sales. It actively promotes the presence of antioxidants in its tea products and the alleged health benefits from using these products. In a recent press release Bigelow stated:

> It is widely accepted in the medical and nutrition communities that all teas…, have health benefits deriving from polyphenols, the powerful antioxidants found in tea that help control free radicals (the unstable compounds that destroy cells).
>
> Research has shown polyphenols have many health benefits including fighting the effects of aging, and reducing the risk for some cancers, high cholesterol and high blood pressure. Polyphenols can bolster the immune system to better resist flu, other virus and bacteria, strengthen capillaries and prevent infection. New research studies are continually being conducted in order to better understand how tea polyphenols work to support good health and possibly to prevent and treat many health conditions.
>
> http://admin.specialtyfood.com/fileManager/65609Bigelow-Superfruit_Teasdocx_(1).pdf

4. Bigelow also makes unlawful health claims, nutrient content claims, and antioxidant claims directly on packages of the Misbranded Food Products. For example, upon information and belief Defendant has sold at least the following green tea products in the Class Period:

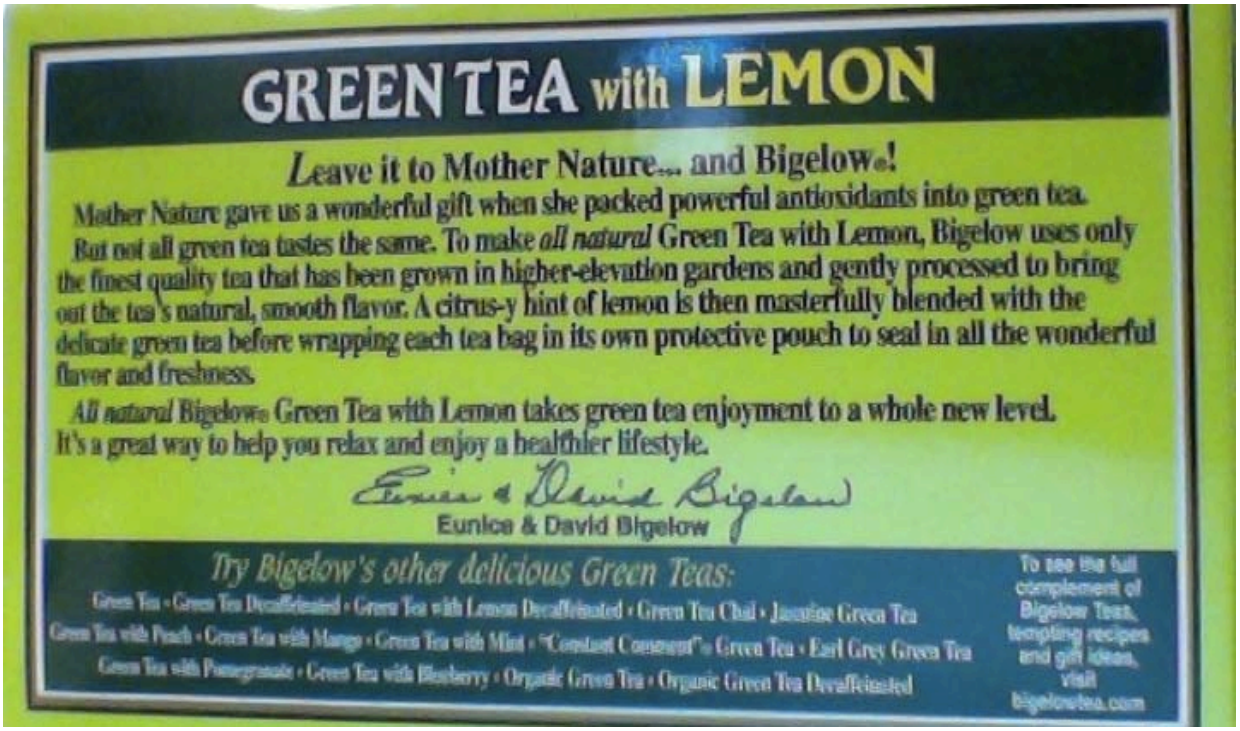
Green Tea

Green Tea Decaffeinated
Green Tea with Mint
Green Tea with Lemon
Green Tea with Lemon Decaffeinated
Green Tea with Pomegranate
Green Tea with Pomegranate Decaffeinated
Green Tea with Pomegranate (Iced Tea)
Green Tea with Peach
Green Tea with Wild Blueberry and Acai
Green Tea with Wild Blueberry and Acai Decaffeinated
Green Tea with Mango

The package front panel of each green tea product listed in this paragraph, including Bigelow's Green Tea with Lemon, purchased by Plaintiff and shown below, bears the statement "*Healthy Antioxidants.*" Attached hereto as Exhibit 1 is a compilation of pictures of Bigelow green tea products showing that each product has the same unlawful antioxidant claim on the front of the package. Such claims have been repeatedly targeted by the FDA as unlawful for tea and other food products. Upon information and belief, the back panel of all green tea products, including Bigelow's Green Tea with Lemon, purchased by Plaintiff and shown below, boasts, "*Mother Nature gave us a wonderful gift when she packed powerful antioxidants into green tea…*" This same claim appears on the other green tea products as well. Such claims have been repeatedly targeted by the FDA as unlawful for tea and other food products.

FRONT OF PACKAGE

BACK OF PACKAGE



5. Statements similar to those appearing on the packages of the Bigelow Green Tea with Lemon purchased by Plaintiff also appear on each of the other Misbranded Food Products manufactured and sold by the Defendant. Said products are of a single kind (tea). The only difference is flavor. These other Bigelow products share the same size and shape packaging. Unlawful nutrient content claims, antioxidant claims, and health claims appear on the labels of each of these Misbranded Food Products.

6. The Misbranded Food Products are a single product: tea. These products share the same size and shape packaging. The only difference is flavor. The same unlawful antioxidant claims, nutrient content claims, and/or health claims appear on the labels of each of these other products.

7. During various times during the Class Period, Plaintiff read the nutrient content claims regarding the presence of beneficial antioxidants and the health claims appearing on Defendant's labels as specified above and relied on this information in making his decisions to purchase Defendant's tea products. Plaintiff paid a premium for Defendant's products with the purported health benefits. Had Plaintiff known the truth, that the products did not in fact contain recognized and accepted nutritional and healthful value, Plaintiff would not have paid such a premium or would not have bought the products at all.

8. If a manufacturer is going to make a claim on a food label, the label must meet certain legal requirements that help consumers make informed choices and ensure that they are not misled. As described more fully below, Defendant has made, and continues to make, false and deceptive claims in violation of federal and California laws that govern the types of representations that can be made on food labels. These laws recognize that reasonable consumers are likely to choose products claiming to have a health or nutritional benefit over otherwise similar food products that do not claim such benefits.

9. Under California law, which is identical to federal law, a number of the Defendant's food labeling practices are unlawful because they are deceptive and misleading to consumers. These include:

a. Making unlawful nutrient content claims on the labels of food products that fail to meet the minimum nutritional requirements legally required for the nutrient content claims being made;

b. Making unlawful antioxidant claims on the labels of food products that fail to meet the minimum nutritional requirements legally required for the antioxidant claims being made;

c. Making unlawful and unapproved health claims about their products that are prohibited by law; and

10. These practices are not only illegal but they mislead consumers and deprive them of the information they require to make informed purchasing decisions. Thus, for example, a mother who reads labels because she wants to purchase healthy foods for her family would be misled by Defendant's practices and labeling.

11. California and federal laws have placed numerous requirements on food companies that are designed to ensure that the claims that companies make about their products to consumers are truthful, accurate and backed by acceptable forms of scientific proof. When a company such as Bigelow makes unlawful nutrient content, antioxidant, or health claims that are prohibited by regulation, consumers such as Plaintiff are misled.

12. Identical federal and California laws regulate the content of labels on packaged food. The requirements of the federal Food Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA") were adopted by the California legislature in the Sherman Food Drug & Cosmetic Law, California Health & Safety Code § 109875 *et seq.* (the "Sherman Law"). Under both the Sherman Law and FDCA section 403(a), food is "misbranded" if "its labeling is false or misleading in any particular," or if it does not contain certain information on its label or in its labeling. 21 U.S.C. § 343(a).

13. Under the FDCA, the term "false" has its usual meaning of "untruthful," while the term "misleading" is a term of art. Misbranding reaches not only false claims, but also those claims that might be technically true, but still misleading. If any one representation in the labeling is misleading, then the entire food is misbranded, and no other statement in the labeling can cure a misleading statement. "Misleading" is judged in reference to "the ignorant, the

unthinking and the credulous who, when making a purchase, do not stop to analyze." *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951). Under the FDCA, it is not necessary to prove that anyone was actually misled.

14. On August 23, 2010, the FDA sent a warning letter to Unilever, the parent company of Lipton Tea, one of Bigelow's biggest competitors, informing Unilever of Lipton Tea's failure to comply with the FDCA and its regulations (the "FDA Warning Letter," is attached hereto as Exhibit 2 and made a part hereof by reference) for remarkably similar nutrient content claims to those Bigelow is presently making on its product labels. The FDA Warning Letter to Unilever stated, in pertinent part:

> **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 CFR 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 CFR 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: "[t]ea 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 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 "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.
>
> http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm224509.htm.

15. As shown above, the front panel on many Bigelow green tea products contains the statement "*Healthy Antioxidants*." The back panel touts the "*packed powerful antioxidants into green tea*." As determined by the FDA in the Unilever/Lipton warning letter, such health claims are in violation of 21 U.S.C. § 352(f)(1), and therefore the products are misbranded.

16. Defendant has made, and continues to make, food label claims that are prohibited by California and federal law. Under California and federal law, Defendant's Misbranded Food Products cannot legally be manufactured, advertised, distributed, held or sold. Defendant's false and misleading labeling practices stem from its global marketing strategy. Thus, the violations and misrepresentations are similar across product labels and product lines. Defendant's violations of law are numerous and include: (1) the illegal advertising, marketing, distribution, delivery and

sale of Defendant's Misbranded Food Products to consumers and (2) the utilization of unlawful antioxidant claims, nutrient content claims, and health claims on its product labels.

PARTIES

17. Plaintiff Alex Khasin is a resident of Walnut Creek, California who purchased Misbranded Food Products in California since May 2, 2008, four (4) years prior to the filing of the original complaint.

18. Defendant, R. C. Bigelow, Inc. is a Connecticut corporation with its principle place of business in Fairfield, Connecticut. Bigelow is one of the largest tea producers in the country with sales in the hundreds of millions of dollars over the Class Period.

19. Bigelow is a leading producer of retail specialty green tea products. Bigelow sells its Misbranded Food Products to consumers through grocery stores andother retail stores throughout California.

JURISDICTION AND VENUE

20. This Court has original jurisdiction over this action under 28 U.S.C. § 1332(d) because this is a class action in which: (1) there are over 100 members in the proposed class; (2) members of the proposed class have a different citizenship from Defendant; and (3) the claims of the proposed class members exceed $5,000,000 in the aggregate.

21. Alternatively, the Court has jurisdiction over all claims alleged herein pursuant to 28 U.S.C. § 1332, because the matter in controversy exceeds the sum or value of $75,000, and is between citizens of different states.

22. The Court has personal jurisdiction over Defendant because a substantial portion of the wrongdoing alleged in this Fourth Amended Complaint occurred in California, Defendant is authorized to do business in California, has sufficient minimum contacts with California, and otherwise intentionally avails itself of the markets in California through the promotion, marketing and sale of merchandise, sufficient to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

23. Because a substantial part of the events or omissions giving rise to these claims occurred in this District and because the Court has personal jurisdiction over Defendant, venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (b).

FACTUAL ALLEGATIONS

A. Identical California and Federal Laws Regulate Food Labeling

24. Food manufacturers are required to comply with federal and state laws and regulations that govern the labeling of food products. First and foremost among these is the FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101.

25. Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements as its own and indicated that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food regulations of this state." California Health & Safety Code § 110100.

26. In addition to its blanket adoption of federal labeling requirements, California has also enacted a number of laws and regulations that adopt and incorporate specific enumerated federal food laws and regulations. For example, food products are misbranded under California Health & Safety Code § 110660 if their labeling is false and misleading in one or more particulars; are misbranded under California Health & Safety Code § 110665 if their labeling fails to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q) and regulations adopted thereto; are misbranded under California Health & Safety Code § 110670 if their labeling fails to conform with the requirements for nutrient content and health claims set forth in 21 U.S.C. § 343(r) and regulations adopted thereto; are misbranded under California Health & Safety Code § 110705 if words, statements and other information required by the Sherman Law to appear on their labeling are either missing or not sufficiently conspicuous; are misbranded under California Health & Safety Code § 110735 if they are represented as having special dietary uses but fail to bear labeling that adequately informs consumers of their value for that use; and are misbranded under California Health & Safety Code § 110740 if they contain

artificial flavoring, artificial coloring and chemical preservatives but fail to adequately disclose that fact on their labeling.

B. FDA Enforcement History

27. In recent years the FDA has become increasingly concerned that food manufacturers were disregarding food labeling regulations. To address this concern, the FDA elected to take steps to inform the food industry of its concerns and to place the industry on notice that food labeling compliance was an area of enforcement priority.

28. In October 2009, the FDA issued a *Guidance For Industry: Letter Regarding Point Of Purchase Food Labeling* to address its concerns about front of package labels ("2009 FOP Guidance"). The 2009 FOP Guidance advised the food industry:

> FDA's research has found that with FOP labeling, people are less likely to check the Nutrition Facts label on the information panel of foods (usually, the back or side of the package). It is thus essential that both the criteria and symbols used in front-of-package and shelf-labeling systems be nutritionally sound, well-designed to help consumers make informed and healthy food choices, and not be false or misleading. The agency is currently analyzing FOP labels that appear to be misleading. The agency is also looking for symbols that either expressly or by implication are nutrient content claims. We are assessing the criteria established by food manufacturers for such symbols and comparing them to our regulatory criteria.
>
> It is important to note that nutrition-related FOP and shelf labeling, while currently voluntary, is subject to the provisions of the Federal Food, Drug, and Cosmetic Act that prohibit false or misleading claims and restrict nutrient content claims to those defined in FDA regulations. Therefore, FOP and shelf labeling that is used in a manner that is false or misleading misbrands the products it accompanies. Similarly, a food that bears FOP or shelf labeling with a nutrient content claim that does not comply with the regulatory criteria for the claim as defined in Title 21 Code of Federal Regulations (CFR) 101.13 and Subpart D of Part 101 is misbranded. We will consider enforcement actions against clear violations of these established labeling requirements. . .
>
> … Accurate food labeling information can assist consumers in making healthy nutritional choices. FDA intends to monitor and evaluate the various FOP labeling systems and their effect on consumers' food choices and perceptions. FDA recommends that manufacturers and distributors of food products that include FOP labeling ensure that the label statements are consistent with FDA laws and regulations. FDA will proceed with enforcement action against products that bear FOP labeling that are explicit or implied nutrient content claims and that are not consistent with current nutrient content claim requirements. FDA will also proceed

with enforcement action where such FOP labeling or labeling systems are used in a manner that is false or misleading.

The 2009 FOP Guidance recommended that "manufacturers and distributors of food products that include FOP labeling ensure that the label statements are consistent with FDA law and regulations" and specifically advised the food industry that it would "proceed with enforcement action where such FOP labeling or labeling systems are used in a manner that is false or misleading."

29. Despite the issuance of the 2009 FOP Guidance, Defendant did not remove the unlawful and misleading food labeling claims from its Misbranded Food Products.

30. On March 3, 2010, the FDA issued an "Open Letter to Industry from [FDA Commissioner] Dr. Hamburg" (hereinafter, "Open Letter"). The Open Letter reiterated the FDA's concern regarding false and misleading labeling by food manufacturers. In pertinent part the letter stated:

> In the early 1990s, the Food and Drug Administration (FDA) and the food industry worked together to create a uniform national system of nutrition labeling, which includes the now-iconic Nutrition Facts panel on most food packages. Our citizens appreciate that effort, and many use this nutrition information to make food choices. Today, ready access to reliable information about the calorie and nutrient content of food is even more important, given the prevalence of obesity and diet-related diseases in the United States. This need is highlighted by the announcement recently by the First Lady of a coordinated national campaign to reduce the incidence of obesity among our citizens, particularly our children. With that in mind, I have made improving the scientific accuracy and usefulness of food labeling one of my priorities as Commissioner of Food and Drugs. The latest focus in this area, of course, is on information provided on the principal display panel of food packages and commonly referred to as "front-of-pack" labeling. The use of front-of-pack nutrition symbols and other claims has grown tremendously in recent years, and it is clear to me as a working mother that such information can be helpful to busy shoppers who are often pressed for time in making their food selections. …
>
> As we move forward in those areas, I must note, however, that there is one area in which more progress is needed. As you will recall, we recently expressed concern, in a "Dear Industry" letter, about the number and variety of label claims that may not help consumers distinguish healthy food choices from less healthy ones and, indeed, may be false or misleading.
>
> At that time, we urged food manufacturers to examine their product labels in the context of the provisions of the Federal Food, Drug, and Cosmetic Act that prohibit false or misleading claims and restrict nutrient content claims to those defined in FDA regulations. As a result, some manufacturers have revised their labels to bring them into line with the goals of the Nutrition Labeling and Education Act of 1990. Unfortunately, however, we continue to see products

> marketed with labeling that violates established labeling standards.
>
> To address these concerns, FDA is notifying a number of manufacturers that their labels are in violation of the law and subject to legal proceedings to remove misbranded products from the marketplace. While the warning letters that convey our regulatory intentions do not attempt to cover all products with violative labels, they do cover a range of concerns about how false or misleading labels can undermine the intention of Congress to provide consumers with labeling information that enables consumers to make informed and healthy food choices
>
> . . . .
>
> These examples and others that are cited in our warning letters are not indicative of the labeling practices of the food industry as a whole. In my conversations with industry leaders, I sense a strong desire within the industry for a level playing field and a commitment to producing safe, healthy products. That reinforces my belief that FDA should provide as clear and consistent guidance as possible about food labeling claims and nutrition information in general, and specifically about how the growing use of front-of-pack calorie and nutrient information can best help consumers construct healthy diets.
>
> I will close with the hope that these warning letters will give food manufacturers further clarification about what is expected of them as they review their current labeling. I am confident that our past cooperative efforts on nutrition information and claims in food labeling will continue as we jointly develop a practical, science-based front-of-pack regime that we can all use to help consumers choose healthier foods and healthier diets.

31. Notwithstanding the Open Letter, Defendant continued to utilize unlawful food labeling claims despite the express guidance of the FDA in the Open Letter.

32. In addition to its guidance to industry, the FDA has sent warning letters to industry, including many of Defendant's peer/competitor food manufacturers for the same types of unlawful nutrient content claims described above.

33. In these letters dealing with unlawful nutrient content claims, the FDA indicated that, as a result of the same type of claims utilized by the Defendant, products were in "violation of the Federal Food, Drug, and Cosmetic Act … and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR § 101)" and "misbranded within the meaning of section 403(r)(1)(A) because the product label bears a nutrient content claim but does not meet the requirements to make the claim." These warning letters were not isolated as the FDA has issued numerous warning letters to other companies for the same type of food labeling claims at issue in this case; the same being released as public records discoverable and downloadable from the internet.

34. The FDA stated that the agency not only expected companies that received warning letters to correct their labeling practices but also anticipated that other firms would examine their food labels to ensure that they are in full compliance with food labeling requirements and make changes where necessary. Defendant did not change the labels on its Misbranded Food Products in response to the warning letters sent to other companies of which Defendant was aware.

35. Defendant also continued to ignore the FDA's Guidance for Industry, A Food Labeling Guide which details the FDA's guidance on how to make food labeling claims. Defendant continues to utilize unlawful claims on the labels of its Misbranded Food Products. As such, Defendant's Misbranded Food Products continue to run afoul of FDA guidance as well as California and federal law.

36. Despite the FDA's numerous warnings to industry of which Defendant was aware, Defendant has continued to sell products bearing unlawful food labeling claims without meeting the requirements to make them.

37. Plaintiff did not know, and had no reason to know, that the Defendant's Misbranded Food Products were misbranded and bore food labeling claims despite failing to meet the requirements to make those food labeling claims. Similarly, Plaintiff did not, and had no reason to know, that Bigelow's Misbranded Food Products he purchased were misbranded because their labeling was false and misleading.

C. Defendant's Food Products Are Misbranded

38. Pursuant to Section 403 of the FDCA, a claim that characterizes the level of a nutrient in a food is a "nutrient content claim" that must be made in accordance with the regulations that authorize the use of such claims. 21 U.S.C. § 343(r)(1)(A). California expressly adopted the requirements of 21 U.S.C. § 343(r) in § 110670 of the Sherman Law.

39. Nutrient content claims are claims about specific nutrients contained in a product. They are typically made on the front of packaging in a font large enough to be read by the

average consumer. Because these claims are relied upon by consumers when making purchasing decisions, the regulations govern what claims can be made in order to prevent misleading claims.

40. Section 403(r)(1)(A) of the FDCA governs the use of expressed and implied nutrient content claims on labels of food products that are intended for sale for human consumption. *See* 21 C.F.R. § 101.13.

41. 21 C.F.R. § 101.13 provides the general requirements for nutrient content claims, which California has expressly adopted. *See* California Health & Safety Code § 110100. 21 C.F.R. § 101.13 requires that manufacturers include certain disclosures when a nutrient claim is made and, at the same time, the product contains certain levels of unhealthy ingredients, such as fat and sodium. It also sets forth the manner in which that disclosure must be made, as follows:

> (4)(i) The disclosure statement "See nutrition information for ___ content" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, and in a size no less than that required by §101.105(i) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclosure statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch, unless the package complies with §101.2(c)(2), in which case the disclosure statement may be in type of not less than one thirty-second of an inch.
>
> (ii) The disclosure statement shall be immediately adjacent to the nutrient content claim and may have no intervening material other than, if applicable, other information in the statement of identity or any other information that is required to be presented with the claim under this section (e.g., see paragraph (j)(2) of this section) or under a regulation in subpart D of this part (e.g., see §§101.54 and 101.62). If the nutrient content claim appears on more than one panel of the label, the disclosure statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information where it may be omitted.

42. An "expressed nutrient content claim" is defined as any direct statement about the level (or range) of a nutrient in the food (*e.g.*, "low sodium" or "contains 100 calories"). *See* 21 C.F.R. § 101.13(b)(1).

43. An "implied nutrient content claim" is defined as any claim that: (i) describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (*e.g.*, "high in oat bran"); or (ii) suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an

explicit claim or statement about a nutrient (*e.g.*, "healthy, contains 3 grams (g) of fat"). 21 C.F.R. § 101.13(b)(2)(i-ii).

44. These regulations authorize use of a limited number of defined nutrient content claims. In addition to authorizing the use of only a limited set of defined nutrient content terms on food labels, these regulations authorize the use of only certain synonyms for these defined terms. If a nutrient content claim or its synonym is not included in the food labeling regulations it cannot be used on a label. Only those claims, or their synonyms, that are specifically defined in the regulations may be used. All other claims are prohibited. 21 CFR § 101.13(b).

45. Only approved nutrient content claims will be permitted on the food label, and all other nutrient content claims will misbrand a food. It is thus clear which types of claims are prohibited and which types are permitted. Manufacturers are on notice that the use of an unapproved nutrient content claim is prohibited conduct. 58 Fed. Reg. 2302. In addition, 21 U.S.C. § 343(r)(2), whose requirements have been adopted by California, prohibits using unauthorized undefined terms and declares foods that do so to be misbranded.

46. Similarly, the regulations specify absolute and comparative levels at which foods qualify to make these claims for particular nutrients (e.g., low fat . . . more vitamin C) and list synonyms that may be used in lieu of the defined terms. Certain implied nutrient content claims (e.g., "healthy") also are defined. The daily values (DVs) for nutrients that the FDA has established for nutrition labeling purposes have application for nutrient content claims, as well. Claims are defined under current regulations for use with nutrients having established DVs; moreover, relative claims are defined in terms of a difference in the percent DV of a nutrient provided by one food as compared to another. *See e.g.*, 21 C.F.R. §§ 101.13 and 101.54.

1. Defendant Has Made Unlawful and Misleading Nutrient Content Claims

47. Defendant's nutrient content claims on its labels that its green tea has "*packed powerful antioxidants*" are unlawful and misleading.

48. In order to appeal to consumer preferences, Defendant has repeatedly made unlawful nutrient content claims about antioxidants that fail to utilize one of the limited defined

terms. These nutrient content claims are unlawful because they failed to comply with the nutrient content claim provisions in violation of 21 C.F.R. §§ 101.13 and 101.54, which have been incorporated in California's Sherman Law. To the extent that the terms used to describe antioxidants without a recognized daily value or RDI (such as "natural source") are deemed to be a synonym for a defined term like "contain" the claim would still be unlawful because, as these nutrients do not have established daily values, they cannot serve as the basis for a term that has a minimum daily value threshold as the defined terms at issue here do.

49. Defendant's claims concerning unnamed antioxidant nutrients are false because Defendant's use of a defined term is in effect a claim that the products have met the minimum nutritional requirements for the use of the defined term (antioxidants) when they have not.

50. For example, nutrient content claims that Defendant make on the labels of its teas are false and unlawful because they use defined terms such as "*packed powerful antioxidants*" Defendant uses these terms to describe antioxidants and flavonoids that fail to satisfy the minimum nutritional thresholds for these defined terms.

51. An "excellent source" claim requires a nutrient to be present at a level at least 20% of the Daily Value for that nutrient while "contains" and "provides" claims require a nutrient to be present at a level at least 10% of the Daily Value for that nutrient. Defendant's "*packed powerful antioxidants*" claim is an "excellent source" claim requiring 20% DV.

52. Therefore, for example, the claim that mother nature "*packed powerful antioxidants*" into Defendants products is false and unlawful. Defendant's teas do not meet the minimum nutrient level threshold to make such a claim, which is 20% or more of the RDI or the DRV of a nutrient per reference amount customarily consumed. Defendant's teas do not meet the minimum nutrient level threshold to make such a claim, which is 10% or more of the RDI or the DRV of a nutrient per reference amount customarily consumed.

53. Defendant's misuse of defined terms is not limited to the nutrient content claims on one or two products. Defendant's tea related claims are part of a widespread practice of misusing defined nutrient content claims to overstate the nutrient content of its tea products. The

statements regarding antioxidants and the health benefits to be derived from consuming defendant's products appear on each variety of Defendant's Green Tea Products. These other products are substantially similar to the tea products purchased by Plaintiff.

54. FDA enforcement actions targeting identical or similar claims to those made by Defendant have made clear the unlawfulness of such claims. Defendant knew or should have known about these enforcement actions. For example, on March 24, 2011, the FDA sent Jonathan Sprouts, Inc. a warning letter (Exhibit 4) where it specifically targeted a "source" type claim like the one used by Defendant. In that letter the FDA stated:

> Your Organic Clover Sprouts product label bears the claim "Phytoestrogen Source[.]" Your webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals" bears the claim "Alfalfa sprouts are one of our finest food sources of . . . saponin." These claims are nutrient content claims subject to section 403(r)(1)(A) of the Act because they characterize the level of nutrients of a type required to be in nutrition labeling (phytoestrogen and saponin) in your products by use of the term "source." Under section 403(r)(2)(A) of the Act, nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined by regulation. However, FDA has not defined the characterization "source" by regulation. Therefore, this characterization may not be used in nutrient content claims.

55. It is thus clear that a "source" claim like the one utilized by Defendant is unlawful because the "FDA has not defined the characterization 'source' by regulation" and thus such a "characterization may not be used in nutrient content claims."

56. The types of misrepresentations made above would be considered by a reasonable consumer like the Plaintiff when deciding to purchase the products. Plaintiff placed great importance on the claimed presence of "packed *powerful antioxidants*" in choosing Defendant's products over other tea products and alternative beverage products.

57. The nutrient content claims regulations discussed above are intended to ensure that consumers are not misled as to the actual or relative levels of nutrients in food products.

58. Defendant has violated these referenced regulations. Plaintiff relied on Bigelow's nutrient content claims when making his purchase decisions and was misled because he erroneously believed the implicit misrepresentation that the Bigelow products he was purchasing met the minimum nutritional threshold to make such claims. Antioxidant and nutrient content was

important to the Plaintiff in trying to buy "healthy" food products. Plaintiff would not have purchased these products had he known that the Bigelow products did not in fact satisfy such minimum nutritional requirements with regard to the claimed antioxidants and nutrients.

59. For these reasons, Defendant's nutrient content claims are false and misleading and in violation of 21 C.F.R. §§ 101.13 and 101.54 and identical California law, and the products at issue are misbranded as a matter of law. Defendant has violated these referenced regulations. Therefore, Defendant's Misbranded Food Products are misbranded as a matter of California and federal law and cannot be sold or held and thus are legally worthless. Plaintiff and members of the Class who purchased the Defendant's Misbranded Food Products paid an unwarranted premium for the products.

60. Plaintiff was thus misled by the Defendant's unlawful labeling practices and actions into purchasing products he would not have otherwise purchased had he known the truth about those products. Plaintiff had cheaper alternatives.

61. Defendant's claims in this respect are false and misleading and the products are in this respect misbranded under identical California and federal laws.

2. Defendant Has Made Unlawful and Misleading Antioxidant Nutrient Content Claims

62. In addition to Defendant's violation of the general, basic provisions of the Sherman Law as to making a nutrient content claim, Defendant also has violated identical California and federal labeling regulations specific to antioxidants.

63. Federal and California regulations regulate antioxidant claims as a particular type of nutrient content claim. Specifically, 21 C.F.R. § 101.54(g) contains special requirements for nutrient claims that use the term "antioxidant":

(1) the name of the antioxidant must be disclosed;

(2) there must be an established Recommended Daily Intake ("RDI") for that antioxidant, and if not, no "antioxidant" claim can be made about it;

(3) the label claim must include the specific name of the nutrient that is an antioxidant and cannot simply say "antioxidants" (*e.g.*, "high in antioxidant vitamins C and E"),[1] *see* 21 C.F.R. § 101.54(g)(4);

(4) the nutrient that is the subject of the antioxidant claim must also have recognized antioxidant activity, *i.e.*, there must be scientific evidence that after it is eaten and absorbed from the gastrointestinal tract, the substance participates in physiological, biochemical or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions, *see* 21 C.F.R. § 101.54(g)(2);

(5) the antioxidant nutrient must meet the requirements for nutrient content claims in 21 C.F.R. § 101.54(b), (c), or (e) for "High" claims, "Good Source" claims, and "More" claims, respectively. For example, to use a "High" claim, the food would have to contain 20% or more of the Daily Reference Value ("DRV") or RDI per serving. For a "Good Source" claim, the food would have to contain between 10-19% of the DRV or RDI per serving, *see* 21 C.F.R. § 101.54(g)(3); and

(6) the antioxidant nutrient claim must also comply with general nutrient content claim requirements such as those contained in 21 C.F.R. § 101.13(h) that prescribe the circumstances in which a nutrient content claim can be made on the label of products high in fat, saturated fat, cholesterol or sodium.

64. The antioxidant labeling for Bigelow's Misbranded Food Products promoting these products violate California law: (1) because the names of the antioxidants are not disclosed on the product labels; (2) because there are no RDIs for the antioxidants being touted, including flavonoids and polyphenols; (3) because the claimed antioxidant nutrients fail to meet the requirements for nutrient content claims in 21 C.F.R. § 101.54(b), (c), or (e) for "High" claims, "Good Source" claims, and "More" claims, respectively; and (4) because Defendant lacks

[1] Alternatively, when used as part of a nutrient content claim, the term "antioxidant" or "antioxidants" (such as "high in antioxidants") may be linked by a symbol (such as an asterisk) that refers to the same symbol that appears elsewhere on the same panel of a product label followed by the name or names of the nutrients with the recognized antioxidant activity. If this is done, the list of nutrients must appear in letters of a type size height no smaller than the larger of one half of the type size of the largest nutrient content claim or 1/16 inch.

adequate scientific evidence that the claimed antioxidant nutrients participate in physiological, biochemical, or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions after they are eaten and absorbed from the gastrointestinal tract.

65. For example, as discussed above, the package label of Bigelow Green Tea with Lemon bears the statement "*Healthy Antioxidants.*" The back panel further boasts, "*Mother Nature gave us a wonderful gift when she packed powerful antioxidants into green tea* Similar unlawful statements appear on all Bigelow Green tea products. These same violations were condemned in the FDA Warning Letter to Unilever/Lipton discussed above and attached as Exhibit 2.

66. These same violations were condemned in numerous other warning letters to other tea companies of which Defendant knew or should have known including the April 11, 2011 warning letter to Diaspora Tea & Herb Co., LLC (attached as Exhibit 3) which states in pertinent part:

> Additionally, your website bears nutrient content claims using the term "antioxidant." … 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 is…rich in… antioxidants."; … "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… contain[s] high concentrations of… antioxidant polyphenols (tea catechins)…." ; … "Antioxidant rich…222mg polyphenols per serving!"; … "Antioxidant rich…109mg polyphenols per serving!"
>
> 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.

67. For these reasons, Defendant's antioxidant claims at issue in this Complaint are misleading and in violation of 21 C.F.R. § 101.54 and California law, and the products at issue are misbranded as a matter of law. Misbranded products cannot be legally manufactured, advertised, distributed, held or sold and are legally worthless. Plaintiff and members of the Class who purchased these products paid an unwarranted premium for these products.

68. In addition to the FDA Warning Letters to Unilever and Diaspora Tea & Herb Co., LLC discussed above (Exhibits 2 and 3), the FDA has issued numerous warning letters addressing similar unlawful antioxidant nutrient content claims. *See, e.g.*, FDA warning letter dated February 22, 2010 to Redco Foods, Inc. regarding its misbranded Salada Naturally Decaffeinated Green Tea product because "there are no RDIs for (the antioxidants) grapeskins, rooibos (red tea) and anthocyanins"; FDA warning letter dated February 22, 2010 to Fleminger Inc. regarding its misbranded TeaForHealth products because the admonition "[d]rink high antioxidant green tea" . . . "does not include the nutrients that are the subject of the claim or use a symbol to link the term antioxidant to those nutrients". These warning letters were hardly isolated. Defendant is aware of these FDA warning letters.

69. The types of misrepresentations made above would be considered by a reasonable consumer when deciding to purchase the products. They directly contradict current scientific research, which has concluded: "[T]he evidence today does not support a direct relationship between tea consumption and a physiological AOX [antioxidant] benefit." This conclusion was reported by Dr. Jane Rycroft, Director of Lipton Tea Institute of Tea, in an article published in January, 2011, in which Dr. Rycroft states:

> Only a few scientific publications report an effect of tea on free radical damage in humans using validated biomarkers in well designed human studies. Unfortunately, the results of these studies are at variance and the majority of the studies do not report significant effects . . .
>
> Therefore, despite more than 50 studies convincingly showing that flavonoids possess potent antioxidant activity *in vitro,* the ability of flavonoids to act as an antioxidant *in vivo* [in humans], has not been demonstrated.

> Based on the current scientific consensus that the evidence today does not support a direct relationship between tea consumption and a physiological AOX benefit…
>
> No evidence has been provided to establish that having antioxidant activity/content and/or antioxidant properties is a beneficial physiological effect.

Rycroft, Jane, "The Antioxidant Hypothesis Needs to be Updated," Vol. 1, *Tea Quarterly Tea Science Overview*, Lipton Tea Institute of Tea Research (Jan. 2011), pp. 2-3.

70. This scientific evidence and consensus conclusively establishes the improper nature of the Defendant's antioxidant claims, as they cannot possibly satisfy the legal and regulatory requirement that the nutrient that is the subject of the antioxidant claim must also have recognized antioxidant activity, *i.e.*, there must be substantial scientific evidence that after it is eaten and absorbed from the gastrointestinal tract, the substance participates in physiological, biochemical or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions, *see* 21 C.F.R. § 101.54(g)(2).

71. The antioxidant regulations discussed above are intended to ensure that consumers are not misled as to the actual or relative levels of antioxidants in food products and purported beneficial health benefits from consuming the food product.

72. Plaintiff relied on Defendant's antioxidant and health claims when making his purchase decisions over the last four years and was misled because he erroneously believed the implicit misrepresentation that the Defendant's products he was purchasing met the minimum nutritional threshold to make such claims. Antioxidant and flavonoid content was important to Plaintiff in trying to buy "healthy" food products. Plaintiff would not have purchased these products had she known that the Defendant's products did not in fact satisfy such minimum nutritional requirements with regard to antioxidants and the consumption of defendant's tea did not, in fact, result in the purported health benefits touted by Defendant.

73. For these reasons, Defendant's antioxidant claims at issue in this Complaint are false and misleading and in violation of 21 C.F.R. §§ 101.13 and 101.54 and identical California law, and the products at issue are misbranded as a matter of law. Defendant has violated these referenced regulations. Therefore, Defendant's Misbranded Food Products are misbranded as a matter of California and federal law and cannot be sold or held and thus are legally worthless.

Additionally, Plaintiff was misled and deceived by the actions of the Defendant in violation of California Law.

74. Defendants' claims in this respect are false and misleading and the products are in this respect misbranded under identical California and federal laws, Misbranded products cannot be legally sold and are legally worthless. Plaintiff and members of the Class who purchased these products paid an unwarranted premium for these products.

3. Defendant Has Made Unlawful and Misleading Health Claims

75. Defendant violated identical California and federal law by making numerous unapproved health claims about its products. It has also violated identical California and federal law by making numerous unapproved claims about the ability of its products to cure, mitigate, treat and prevent various diseases that render its products unapproved drugs under California and federal law. Moreover, in promoting the ability of its products to have an effect on certain diseases such as cancer and heart disease among others, Defendant has violated the advertising provisions of the Sherman law.

76. A health claim is a statement expressly or implicitly linking the consumption of a food substance (*e.g.*, ingredient, nutrient, or complete food) to risk of a disease (*e.g.*, cardiovascular disease) or a health-related condition (*e.g.*, hypertension). *See* 21 C.F.R. § 101.14(a)(1), (a)(2), and (a)(5). Only health claims made in accordance with FDCA requirements, or authorized by FDA as qualified health claims, may be included in food labeling. Other express or implied statements that constitute health claims, but that do not meet statutory requirements, are prohibited in labeling foods.

77. 21 C.F.R. § 101.14, which has been expressly adopted by California, provides when and how a manufacturer may make a health claim about its product. A "Health Claim" means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (*e.g.*, a brand name including a term such as "heart"), symbols (*e.g.*, a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims

include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition (*see* 21 CFR § 101.14(a)(1)).

78. Further, health claims are limited to claims about disease risk reduction, and cannot be claims about the diagnosis, cure, mitigation, or treatment of disease. An example of an authorized health claim is: "Three grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the risk of heart disease. This cereal has 2 grams per serving."

79. A claim that a substance may be used in the diagnosis, cure, mitigation, treatment, or prevention of a disease is a drug claim and may not be made for a food. 21 U.S.C. § 321(g)(1)(D).

80. The use of the term "healthy" is not a health claim but rather an implied nutrient content claim about general nutrition that is defined by FDA regulation.

81. 21 C.F.R. § 101.65, which has been adopted by California, sets certain minimum nutritional requirements for making an implied nutrient content claim that a product is healthy. For example, for unspecified foods the food must supply at least 10 percent of the RDI of one or more specified nutrients. Defendants have misrepresented the healthiness of their products while failing to meet the regulatory requirements for making such claims. In general, the term may be used in labeling an individual food product that:

> Qualifies as both low fat and low saturated fat;
>
> Contains 480 mg or less of sodium per reference amount and per labeled serving, and per 50 g (as prepared for typically rehydrated foods) if the food has a reference amount of 30 g or 2 tbsps or less;
>
> Does not exceed the disclosure level for cholesterol (*e.g.*, for most individual food products, 60 mg or less per reference amount and per labeled serving size); *and*
>
> Except for raw fruits and vegetables, certain frozen or canned fruits and vegetables, and enriched cereal-grain products that conform to a standard of identity, provides at least 10% of the daily value (DV) of vitamin A, vitamin C, calcium, iron, protein, *or* fiber per reference amount.

> Where eligibility is based on a nutrient that has been added to the food, such fortification must comply with FDA's fortification policy.

21 C.F.R. § 101.65(d)(2). FDA's regulation on the use of the term healthy also encompasses other, derivative uses of the term health (*e.g.*, healthful, healthier) in food labeling. 21 C.F.R. § 101.65(d).

82. Bigelow has violated the provisions of 21 C.F.R. § 101.14, 21 C.F.R. § 101.65, 21 U.S.C. § 321(g)(1)(D), 21 U.S.C. § 321(m) and 21 U.S.C. § 352(f)(1) on a number of its products. For example, the claim on the green tea package front label: "*Healthy Antioxidants*" and the claim on the package back panel: "*Mother Nature gave us a wonderful gift when she packed powerful antioxidants into green tea….*" is in violation of the aforesaid law.

83. As FDA found in regard to the therapeutic claims made by Unilever/Lipton and Diaspora Tea & Herb Co. discussed above, the therapeutic claims on Bigelow's labels establish that their products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Bigelow's Misbranded Food 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 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 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.

84. As discussed above and as shown in Exhibits 1 and 2, the FDA has conducted reviews of similar products to Bigelow's tea products and concluded that those companies were "in violation of the Federal Food, Drug, and Cosmetic Act … and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101)." FDA found the products to be misbranded stating, "Your 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 … 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)]." *See* Exhibits 1 and 2.

85. The package front panel of Bigelow's Misbranded Food Products claims a level of "*healthy antioxidants*" and "packed powerful antioxidants" but their products do not contain any antioxidant substance or nutrient with an established RDI.

86. Plaintiff saw the health related claims on the packages at various times during the Class Period and relied on the Defendant's health claims which influenced his decision to purchase the Defendant's products. Plaintiff would not have bought the products had he known Defendant's claims were false, misleading, unapproved and that the products were misbranded.

87. Plaintiff and members of the Class were misled into the belief that such claims were legal and had passed regulatory muster and were supported by science capable of securing regulatory acceptance. Because this was not the case, the Plaintiff and members of the Class have been deceived.

88. Defendant's materials and advertisements not only violate regulations adopted by California such as 21 C.F.R. § 101.14, they also violate California Health & Safety Code § 110403 which prohibits the advertisement of products that are represented to have any effect on enumerated conditions, disorders and diseases including cancer and heart diseases unless the claims have federal approval.

89. Defendant's health claims were also improper because of their inadequate nutritional profiles.

90. 21 C.F.R. § 101.14, which has been expressly adopted by California, prohibits manufacturers from making any health claim about products that have inadequate nutrient levels.

91. In addition, 21 C.F.R. § 101.65, which has been adopted by California, sets certain minimum nutritional requirements for making an implied nutrient content claim that a product is healthy. For example, for unspecified foods the food must be low in fat, saturated fat, sodium and cholesterol and supply at least 10 percent of the RDI of one or more specified nutrients.

92. Defendant has misrepresented the healthiness of its products while failing to meet the regulatory thresholds for making such claims either because the products lack minimum nutritional requirements to make such a claim.

93. Defendant Misbranded Food Products violate 21 C.F.R. § 101.14 or 21 C.F.R. § 101.65.

94. Plaintiff saw such health related claims and relied on the Defendant's health claims which influenced his decision to purchase the Defendant's products. Plaintiff would not have bought the products had he known Defendant's products failed to meet the minimum nutritional threshold for such health claims.

95. Plaintiff and members of the Class was misled into the belief that such Defendant's products met the minimum nutritional thresholds for the health claims that were made about them. Because this was not the case, the Plaintiff and members of the Class have been deceived.

96. Plaintiff and members of the Class have been misled by Defendant's unlawful labeling practices and actions into purchasing products they would not have otherwise purchased had they known the truth about these products. Plaintiff and members of the Class who purchased these products paid an unwarranted premium for these products.

97. Defendant's health related claims are false and misleading and the products are in this respect misbranded under identical California and federal laws, Misbranded products cannot be legally sold and thus are legally worthless.

D. Defendant Has Violated California Law

98. The back panel of Bigelow's Misbranded Food Products claims a level of "antioxidants" but their products do not contain any antioxidant substance or nutrient with an established RDI. Bigelow makes various health related benefits to be derived from using its products but, as with the Lipton and Diaspora Tea & Herb Co. products, Bigelow's tea products do not have approval from FDA to make the health related claims. Moreover, the health related claims are in violation of 21 U.S.C. § 352(f)(1) and therefore the products are misbranded.

99. Defendant has manufactured, advertised, distributed and sold products that are misbranded under California law. Misbranded products cannot be legally manufactured, advertised, distributed, sold or held and are legally worthless as a matter of law.

100. Defendant has violated California Health & Safety Code §§ 109885 and 110390 which make it unlawful to disseminate false or misleading food advertisements that include statements on products and product packaging or labeling or any other medium used to directly or indirectly induce the purchase of a food product.

101. Defendant has violated California Health & Safety Code § 110395 which makes it unlawful to manufacture, sell, deliver, hold or offer to sell any misbranded food.

102. Defendant has violated California Health & Safety Code § 110398 which makes it unlawful to deliver or proffer for delivery any food that has been falsely advertised.

103. Defendant has violated California Health & Safety Code § 110660 because its labeling is false and misleading in one or more ways, as follows:

a. They are misbranded under California Health & Safety Code § 110665 because their labeling fails to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q) and the regulations adopted thereto;

b. They are misbranded under California Health & Safety Code § 110670 because their labeling fails to conform with the requirements for nutrient content and health claims set forth in 21 U.S.C. § 343(r) and the regulations adopted thereto; and

c. They are misbranded under California Health & Safety Code § 110705 because words, statements and other information required by the Sherman Law to appear on their labeling either are missing or not sufficiently conspicuous.

104. Defendant has violated California Health & Safety Code § 110760 which makes it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is misbranded.

105. Defendant has violated California Health & Safety Code § 110765 which makes it unlawful for any person to misbrand any food.

106. Defendant has violated California Health & Safety Code § 110770 which makes it unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for deliver any such food.

107. Defendant has violated the standard set by 21 C.F.R. § 101.2, which has been incorporated by reference in the Sherman Law, by failing to include on their product labels the nutritional information required by law.

108. Defendant has violated the standards set by 21 CFR §§ 101.13, and 101.54, which have been adopted by reference in the Sherman Law, by including unauthorized antioxidant claims on their products. Defendant has violated the standards set by 21 CFR §§ 101.14, and 101.65, which have been adopted by reference in the Sherman Law, by including unauthorized health and healthy claims on their products.

E. Plaintiff Purchased Defendant's Misbranded Food Products

109. Plaintiff cares about the nutritional content of food and seeks to maintain a healthy diet.

110. Plaintiff purchased Defendant's Misbranded Food Products at issue in this Fourth Amended Complaint and throughout the Class Period.

111. Plaintiff purchased Defendant's Misbranded Food Products at issue in this FourthAmended Complaint on numerous occasions throughout the Class Period including the following products: Green Tea; Green Tea with Lemon, and Green Tea Naturally Decaffeinated.

112. Plaintiff read the labels on Defendant's Misbranded Food Products, including the antioxidant, nutrient content, and health claims, where applicable, before purchasing them. Plaintiff would have foregone purchasing Defendant's products and bought other products readily available at a lower price.

113. Plaintiff reasonably relied on Defendant's package labeling and packaging and product placement. Plaintiff read the antioxidant, nutrient content and health labeling claims including the "healthy antioxidants," and "packed with powerful antioxidants" claims and based and justified the decision to purchase Defendant's products in substantial part on Defendant's

package labeling including the antioxidant, nutrient content and health labeling claims, and representations related to Defendant's food products before purchasing them.

114. Plaintiff reasonably relied on Defendant's package labeling, packaging, and product placement, and justified the decision to purchase Defendant's Misbranded Food Products in substantial part on Defendant's package labeling as well as product packaging and product placement including the claims, and based and justified the decision to purchase Defendant's products in substantial part on Defendant's package labeling including the antioxidant, nutrient content and health labeling claims including the "healthy antioxidants,"and "packed with powerful antioxidants" claims, and representations related to Defendant's food products before purchasing them.

115. At the point of sale, Plaintiff did not know, and had no reason to know, that Defendant's products were misbranded as set forth herein, and would not have bought the products, or paid a premium for them, had he known the truth about them.

116. At point of sale, Plaintiff did not know, and had no reason to know, that Defendant's antioxidant, nutrient content and health labeling claims including the "healthy antioxidants,"and "packed with powerful antioxidants" claims on the products' labels were unlawful and unauthorized as set forth herein, and would not have bought the products had he known the truth about them.

117. After Plaintiff learned that Defendant's Misbranded Food Products are falsely labeled, he stopped purchasing them.

118. Plaintiff justified the decision to purchase Defendant's products in substantial part on Defendant's false and unlawful representations.

119. As a result of Defendant's misrepresentations, Plaintiff and thousands of others in California purchased the Misbranded Food Products at issue.

120. Defendant's labeling, advertising and marketing as alleged herein are false and misleading and were designed to increase sales of the products at issue. Defendant's misrepresentations are part of an extensive labeling, advertising and marketing campaign, and a

reasonable person would attach importance to Defendant's representations in determining whether to purchase the products at issue.

121. A reasonable person would also attach importance to whether Defendant's products were legally salable, and capable of legal possession, and to Defendant's representations about these issues in determining whether to purchase the products at issue. Plaintiff would not have purchased Defendant's Misbranded Food Products had he known they were not capable of being legally sold or held.

122. These Misbranded Food Products 1) whose essential characteristics had been misrepresented by the Defendant; 2) which had their nutritional and health benefits misrepresented and overstated by the Defendant, and 3) which were misbranded products which could not be resold and whose very possession was illegal; were worthless to the Plaintiff and as a matter of law.

F. All Misbranded Food Products Are Substantially Similar

123. Defendant's Misbranded Food Products, i.e., all greens teas, are substantially similar.

124. The Misbranded Food Products have the same labels, packaging, and sizes.

125. The Misbranded Food Products are the same product, tea. The only difference in the Misbranded Food Products is the flavor of the tea.

CLASS ACTION ALLEGATIONS

126. Plaintiff brings this action as a class action pursuant to Federal Rule of Procedure 23(b)(2) and 23(b)(3) on behalf of the following class:

> All persons in California who purchased Defendant's Green tea products for personal or household use since May 2, 2008 (the "Class").

127. The following persons are expressly excluded from the Class: (1) Defendant and its subsidiaries and affiliates; (2) all persons who make a timely election to be excluded from the proposed Class; (3) governmental entities; and (4) the Court to which this case is assigned and its staff.

128. This action can be maintained as a class action because there is a well-defined community of interest in the litigation and the proposed Class is easily ascertainable.

129. Numerosity: Based upon Defendant's publicly available sales data with respect to the misbranded products at issue, it is estimated that the Class numbers in the thousands, and that joinder of all Class members is impracticable.

130. Common Questions Predominate: This action involves common questions of law and fact applicable to each Class member that predominate over questions that affect only individual Class members. Thus, proof of a common set of facts will establish the right of each Class member to recover. Questions of law and fact common to each Class member include, for example:

a. Whether Defendant engaged in unlawful, unfair or deceptive business practices by failing to properly package and label its Misbranded Food Products sold to consumers;

b. Whether the food products at issue were misbranded or unlawfully packaged and labeled as a matter of law;

c. Whether Defendant made unlawful and misleading antioxidant, nutrient content and health related claims with respect to the food products it sold to consumers;

d. Whether Defendant violated California Bus. & Prof. Code § 17200 *et seq*., California Bus. & Prof. Code § 17500 *et seq*., the Consumer Legal Remedies Act, Cal. Civ. Code § 1750 *et seq*., and the Sherman Law;

e. Whether Plaintiff and the Class are entitled to equitable and/or injunctive relief;

f. Whether Defendant's unlawful, unfair and/or deceptive practices harmed Plaintiff and the Class; and

g. Whether Defendant was unjustly enriched by its deceptive practices.

131. Typicality: Plaintiff's claims are typical of the claims of the Class because Plaintiff bought Defendant's Misbranded Food Products during the Class Period. Defendant's unlawful, unfair and/or fraudulent actions concern the same business practices described herein irrespective of where they occurred or were experienced. Plaintiff and the Class sustained similar injuries arising out of Defendant's conduct in violation of California law. The injuries of each

member of the Class were caused directly by Defendant's wrongful conduct. In addition, the factual underpinning of Defendant's misconduct is common to all Class members and represents a common thread of misconduct resulting in injury to all members of the Class. Plaintiff's claims arise from the same practices and course of conduct that give rise to the claims of the Class members and are based on the same legal theories.

132. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class. Neither Plaintiff nor Plaintiff's counsel have any interests that conflict with or are antagonistic to the interests of the Class members. Plaintiff has retained highly competent and experienced class action attorneys to represent his interests and those of the members of the Class. Plaintiff and Plaintiff's counsel have the necessary financial resources to adequately and vigorously litigate this class action, and Plaintiff and his counsel are aware of their fiduciary responsibilities to the Class members and will diligently discharge those duties by vigorously seeking the maximum possible recovery for the Class.

133. Superiority: There is no plain, speedy or adequate remedy other than by maintenance of this class action. The prosecution of individual remedies by members of the Class will tend to establish inconsistent standards of conduct for Defendant and result in the impairment of Class members' rights and the disposition of their interests through actions to which they were not parties. Class action treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently and without the unnecessary duplication of effort and expense that numerous individual actions would engender. Further, as the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation would make it difficult or impossible for individual members of the Class to redress the wrongs done to them, while an important public interest will be served by addressing the matter as a class action. Class treatment of common questions of law and fact would also be superior to multiple individual actions or piecemeal litigation in that class treatment will conserve the resources of the Court and the litigants, and will promote consistency and efficiency of adjudication.

134. The prerequisites to maintaining a class action for injunctive or equitable relief pursuant to Fed. R. Civ. P. 23(b)(2) are met as Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive or equitable relief with respect to the Class as a whole.

135. The prerequisites to maintaining a class action pursuant to Fed. R. Civ. P. 23(b)(3) are met as questions of law or fact common to class members predominate over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

136. Plaintiff and Plaintiff's counsel are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

Business and Professions Code § 17200 *et seq.*
Unlawful Business Acts and Practices

137. Plaintiff incorporates by reference each allegation set forth above.

138. Defendant's conduct constitutes unlawful business acts and practices.

139. Defendant sold Misbranded Food Products nationwide and in California during the Class Period.

140. Defendant is a corporation and, therefore, is a "person" within the meaning of the Sherman Law.

141. Defendant's business practices are unlawful under § 17200 *et seq*. by virtue of Defendant's violations of the advertising provisions of the Sherman Law (Article 3) and the misbranded food provisions of the Sherman Law (Article 6).

142. Defendant's business practices are unlawful under § 17200 *et seq.* by virtue of Defendant's violations of § 17500 *et seq.*, which forbids untrue and misleading advertising.

143. Defendant's business practices are unlawful under § 17200 *et seq.* by virtue of Defendant's violations of the Consumer Legal Remedies Act, Cal. Civil Code § 1750 *et seq.*

144. Defendant sold Plaintiff and the Class Misbranded Food Products that were not capable of being sold or held legally and which were legally worthless. Plaintiff and the Class paid a premium for the Misbranded Food Products.

145. As a result of Defendant's illegal business practices, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and to restore to any Class Member any money paid for the Misbranded Food Products.

146. Defendant's unlawful business acts present a threat and reasonable continued likelihood of injury to Plaintiff and the Class.

147. As a result of Defendant's conduct, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

SECOND CAUSE OF ACTION

Business and Professions Code § 17200 *et seq.* Unfair Business Acts and Practices

148. Plaintiff incorporates by reference each allegation set forth above.

149. Defendant's conduct as set forth herein constitutes unfair business acts and practices.

150. Defendant sold Misbranded Food Products nationwide and in California during the Class Period.

151. Plaintiff and members of the Class suffered a substantial injury by virtue of buying Defendant's Misbranded Food Products that they would not have purchased absent Defendant's illegal conduct as set forth herein.

152. Defendant's deceptive marketing, advertising, packaging and labeling of its Misbranded Food Products and its sale of unsalable Misbranded Food Products that were illegal

to possess were of no benefit to consumers, and the harm to consumers and competition is substantial.

153. Defendant sold Plaintiff and the Class Misbranded Food Products that were not capable of being legally sold or held and that were legally worthless. Plaintiff and the Class paid a premium for the Misbranded Food Products.

154. Plaintiff and the Class who purchased Defendant's Misbranded Food Products had no way of reasonably knowing that the products were misbranded and were not properly marketed, advertised, packaged and labeled, and thus could not have reasonably avoided the injury suffered.

155. The consequences of Defendant's conduct as set forth herein outweigh any justification, motive or reason therefore. Defendant's conduct is and continues to be immoral, unethical, illegal, unscrupulous, contrary to public policy, and is substantially injurious to Plaintiff and the Class.

156. As a result of Defendant's conduct, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

THIRD CAUSE OF ACTION

Business and Professions Code § 17200 *et seq.* Fraudulent Business Acts and Practices

157. Plaintiff incorporates by reference each allegation set forth above.

158. Defendant's conduct as set forth herein constitutes fraudulent business practices under California Business and Professions Code sections § 17200 *et seq.*

159. Defendant sold Misbranded Food products nationwide and in California during the Class Period.

160. Defendant's misleading marketing, advertising, packaging and labeling of the Misbranded Food Products were likely to deceive reasonable consumers, and in fact, Plaintiff and members of the Class were deceived. Defendant has engaged in fraudulent business acts and practices.

161. Defendant's fraud and deception caused Plaintiff and the Class to purchase Defendant's Misbranded Food Products that they would otherwise not have purchased had they known the true nature of those products.

162. Defendant sold Plaintiff and the Class Misbranded Food Products that were not capable of being sold or held legally and that were legally worthless. Plaintiff and the Class paid a premium price for the Misbranded Food Products.

163. As a result of Defendant's conduct as set forth herein, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

FOURTH CAUSE OF ACTION

Business and Professions Code § 17500 *et seq.* Misleading and Deceptive Advertising

164. Plaintiff incorporates by reference each allegation set forth above.

165. Plaintiff asserts this cause of action for violations of California Business and Professions Code § 17500 *et seq.* for misleading and deceptive advertising against Defendant.

166. Defendant sold Misbranded Food Products nationwide and in California during the Class Period.

167. Defendant engaged in a scheme of offering Defendant's Misbranded Food Products for sale to Plaintiff and members of the Class by way of, *inter alia*, product packaging and labeling, and other promotional materials. These materials misrepresented and/or omitted the true contents and nature of Defendant's Misbranded Food Products. Defendant's advertisements and inducements were made within California and come within the definition of advertising as

contained in Business and Professions Code §17500 *et seq.* in that such product packaging and labeling, and promotional materials were intended as inducements to purchase Defendant's Misbranded Food Products and are statements disseminated by Defendant to Plaintiff and the Class that were intended to reach members of the Class. Defendant knew, or in the exercise of reasonable care should have known, that these statements were misleading and deceptive as set forth herein.

168. In furtherance of its plan and scheme, Defendant prepared and distributed within California and nationwide via product packaging and labeling, and other promotional materials, statements that misleadingly and deceptively represented the composition and nature of Defendant's Misbranded Food Products. Plaintiff and the Class necessarily and reasonably relied on Defendant's materials, and were the intended targets of such representations.

169. Defendant's conduct in disseminating misleading and deceptive statements in California and nationwide to Plaintiff and the Class was and is likely to deceive reasonable consumers by obfuscating the true composition and nature of Defendant's Misbranded Food Products in violation of the "misleading prong" of California Business and Professions Code § 17500 *et seq.*

170. As a result of Defendant's violations of the "misleading prong" of California Business and Professions Code § 17500 *et seq.*, Defendant has been unjustly enriched at the expense of Plaintiff and the Class. Misbranded products cannot be legally sold or held and are legally worthless. Plaintiff and the Class paid a premium price for the Misbranded Food Products.

171. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

FIFTH CAUSE OF ACTION

Business and Professions Code § 17500 *et seq.* <u>Untrue Advertising</u>

172. Plaintiff incorporates by reference each allegation set forth above.

173. Plaintiff asserts this cause of action against Defendant for violations of California Business and Professions Code § 17500 *et seq.*, regarding untrue advertising.

174. Defendant sold mislabeled Misbranded Food Products nationwide and in California during the Class Period.

175. Defendant engaged in a scheme of offering Defendant's Misbranded Food Products for sale to Plaintiff and the Class by way of product packaging and labeling, and other promotional materials. These materials misrepresented and/or omitted the true contents and nature of Defendant's Misbranded Food Products. Defendant's advertisements and inducements were made in California and come within the definition of advertising as contained in Business and Professions Code §17500 *et seq.* in that the product packaging and labeling, and promotional materials were intended as inducements to purchase Defendant's Misbranded Food Products, and are statements disseminated by Defendant to Plaintiff and the Class. Defendant knew, or in the exercise of reasonable care should have known, that these statements were untrue.

176. In furtherance of its plan and scheme, Defendant prepared and distributed in California and nationwide via product packaging and labeling, and other promotional materials, statements that falsely advertise the composition of Defendant's Misbranded Food Products, and falsely misrepresented the nature of those products. Plaintiff and the Class were the intended targets of such representations and would reasonably be deceived by Defendant's materials.

177. Defendant's conduct in disseminating untrue advertising throughout California and nationwide deceived Plaintiff and members of the Class by obfuscating the contents, nature and quality of Defendant's Misbranded Food Products in violation of the "untrue prong" of California Business and Professions Code § 17500.

178. As a result of Defendant's violations of the "untrue prong" of California Business and Professions Code § 17500 *et seq.*, Defendant has been unjustly enriched at the expense of Plaintiff and the Class. Misbranded products cannot be legally sold or held and are legally worthless. Plaintiff and the Class paid a premium price for the Misbranded Food Products.

179. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

SIXTH CAUSE OF ACTION

Consumers Legal Remedies Act, Cal. Civ. Code §1750 *et seq.*

180. Plaintiff incorporates by reference each allegation set forth above.

181. This sixth cause of action is brought pursuant to the CLRA.

182. Defendant's acts were and are willful, oppressive and fraudulent, thus supporting an award of punitive damages.

183. Plaintiff and the Class are entitled to actual and punitive damages against Defendant for its violations of the CLRA. In addition, pursuant to Cal. Civ. Code § 1782(a)(2), Plaintiff and the Class are entitled to an order enjoining the above-described acts and practices, providing restitution to Plaintiff and the Class, ordering payment of costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court pursuant to Cal. Civ. Code § 1780.

184. Defendant's actions, representations and conduct have violated, and continue to violate the CLRA, because they extend to transactions that are intended to result, or which have resulted, in the sale of goods or services to consumers.

185. Defendant sold Misbranded Food Products nationwide and in California during the Class Period.

186. Plaintiff and members of the Class are "consumers" as that term is defined by the CLRA in Cal. Civ. Code §1761(d).

187. Defendant's Misbranded Food Products were and are "goods" within the meaning of Cal. Civ. Code §1761(a).

188. 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 ingredients, characteristics, uses, benefits and quantities of the goods.

189. 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.

190. By engaging in the conduct set forth herein, Defendant violated and continues to violate Section 1770(a)(9) of the CLRA, because Defendant's conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices in that Defendant advertises goods with the intent not to sell the goods as advertised.

191. By engaging in the conduct set forth herein, Defendant has violated and continue to violate Section 1770(a)(16) of the CLRA, because Defendant's conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices in that Defendant represents that a subject of a transaction has been supplied in accordance with a previous representation when they have not.

192. Plaintiff requests that the Court enjoin Defendant from continuing to employ the unlawful methods, acts and practices alleged herein pursuant to Cal. Civ. Code § 1780(a)(2). If Defendant is not restrained from engaging in these practices in the future, Plaintiff and the Class will continue to suffer harm.

193. Pursuant to Section 1782(a) of the CLRA, Plaintiff's counsel served Defendant with notice of Defendant's violations of the CLRA. Plaintiff's counsel served Defendant by certified mail, return receipt requested.

194. Defendant has failed to provide appropriate relief for its violations of the CLRA within 30 days of its receipt of the CLRA demand notice. Accordingly, pursuant to Sections 1780 and 1782(b) of the CLRA, Plaintiff is entitled to recover actual damages, punitive damages, attorneys' fees and costs, and any other relief the Court deems proper.

195. Plaintiff makes certain claims in this Amended Complaint that were not included in the original Complaint filed on May 2, 2012, and were not included in Plaintiff's CLRA demand notice.

196. This cause of action does not currently seek monetary relief and is limited solely to injunctive relief, as to Defendant's violations of the CLRA not included in the original Complaint. Plaintiff intends to amend this Complaint to seek monetary relief in accordance with the CLRA after providing Defendant with notice of Plaintiff's new claims pursuant to Cal. Civ. Code § 1782.

197. At the time of any amendment seeking damages under the CLRA, Plaintiff will demonstrate that the violations of the CLRA by Defendant were willful, oppressive and fraudulent, thus supporting an award of punitive damages.

198. Consequently, Plaintiff and the Class will be entitled to actual and punitive damages against Defendant for its violations of the CLRA. In addition, pursuant to Cal. Civ. Code § 1782(a)(2), Plaintiff and the Class will be entitled to an order enjoining the above-described acts and practices, providing restitution to Plaintiff and the Class, ordering payment of costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court pursuant to Cal. Civ. Code § 1780.

SEVENTH CAUSE OF ACTION

Restitution Based on Unjust Enrichment/Quasi-Contract

199. Plaintiff incorporates by reference each allegation set forth above.

200. As a result of Defendant's unlawful, fraudulent and misleading labeling, advertising, marketing and sales of Defendant's Misbranded Food Products, Defendant was enriched at the expense of Plaintiff and the Class.

201. Defendant sold Misbranded Food Products to Plaintiff and the Class that were not capable of being sold or held legally and which were legally worthless. Plaintiff and the Class paid a premium for the Misbranded Food Products. It would be against equity and good conscience to permit Defendant to retain the ill-gotten benefits Defendant received from Plaintiff

and the Class, in light of the fact that the products were not what Defendant purported them to be. Thus, it would be unjust and inequitable for Defendant to retain the benefit without restitution to Plaintiff and the Class of all monies paid to Defendant for the products at issue.

202. As a direct and proximate result of Defendant's actions, Plaintiff and the Class have suffered damages in an amount to be proven at trial.

JURY DEMAND

Plaintiff hereby demands a trial by jury of his and the Class' claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, and on behalf of the general public, prays for judgment against Defendant as follows:

A. For an order certifying this case as a class action and appointing Plaintiff and his counsel to represent the Class;

B. For an order awarding, as appropriate, damages, restitution or disgorgement to Plaintiff and the Class;

C. For an order requiring Defendant to immediately cease and desist from selling its Misbranded Food Products in violation of law; enjoining Defendant from continuing to market, advertise, distribute, and sell these products in the unlawful manner described herein; and ordering Defendant to engage in corrective action;

D. For all remedies available pursuant to Cal. Civ. Code § 1780;

E. For an order awarding attorneys' fees and costs;

F. For an order awarding punitive damages;

G. For an order awarding pre-and post-judgment interest; and

H. For an order providing such further relief as this Court deems proper.

Dated: August 14, 2015

Respectfully submitted,

s/*J. Price Coleman*

J. Price Coleman (*Pro Hac Vice*)
Coleman Law Firm
1100 Tyler Avenue, Suite 102
Oxford, MS 38655
Telephone: (662) 236-0047
Facsimile: (662) 513-0072
(colemanlawfirmpa@bellsouth.net)

Attorneys for Plaintiff

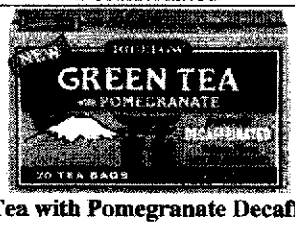
 Green Tea with Wild Blueberry & Acai	 Green Tea with Pomegranate
 Green Tea with Peach	 Green Tea with Lemon
 Green Tea with Mint	 Green Tea with Mango
 Green Tea	 Green Tea with Lemon Decaffeinated
 Green Tea with Wild Blueberry & Acai Decaffeinated	 Green Tea Decaffeinated
 Green Tea with Pomegranate Decaffeinated	 Green Tea with Pomegranate (Iced Tea)

EXHIBIT 1

Inspections, Compliance, Enforcement, and Criminal Investigations

Unilever United States, Inc. 8/23/10

Department of Health and Human Services

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[1] and www.liptont.com[2] 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[3].

A link to .your website, www.lipton.com[4]. appears on your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product label. This website directs U.S. visitors to another website, www.liptont.com[5]. We have determined that your websites, www.lipton.com[6] and www.liptont.com[7]. 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[8]. 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 CFR 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 CFR 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 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 "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.

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[9]

Page Last Updated: 08/09/2011
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page:

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

3. http://www.fda.gov
4. http://www.lipton.com/
5. http://www.liptont.com/
6. http://www.lipton.com/
7. http://www.liptont.com/
8. http://www.liptont.com/
9. /ICECI/EnforcementActions/WarningLetters/2010/ucm267398.htm

Inspections, Compliance, Enforcement, and Criminal Investigations

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

Department of Health and Human Services

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[1] 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[2].

I. Unapproved New Drugs

Examples of disease claims on your website http://www.rishi-tea.com/store/[3] 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 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 t 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 Dail Intake (RDI) must have been established for each of the nutrients that are the subject of the claim, 21 CFI 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 actio 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 letterhead.

Sincerely,

/s/

Gerald J. Berg
Director
Minneapolis District

Close Out Letter

- Diaspora Tea & Herb Co., LLC - Close Out Letter 2/3/12[4]

Page Last Updated: 02/10/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue

Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page:

1. http://www.rishi-tea.com/store/index.php
2. http://www.fda.gov
3. http://www.rishi-tea.com/store/
4. /ICECI/EnforcementActions/WarningLetters/2011/ucm291275.htm

Inspections, Compliance, Enforcement, and Criminal Investigations

Jonathan's Sprouts Inc. 3/24/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District
One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 587-7500
FAX: (781) 587-7556

WARNING LETTER
NWE-13-11W

VIA UNITED PARCEL SERVICE
OVERNIGHT DELIVERY

March 24, 2011

Mr. Robert Sanderson
Owner
Jonathan's Sprouts Inc.
384 Vaughan Hill Road
Rochester, MA 02770

Dear Mr. Sanderson:

The United States Food and Drug Administration (FDA) conducted an inspection of your facility located at 384 Vaughan Hill Road, Rochester, MA, from September 27, 2010 to October 13, 2010. The inspection determined that your firm is a manufacturer and distributor of sprouts. During the inspection, our investigators collected sample labels for your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts. The FDA reviewed your website at http://www.jonathansorganic.com[1], in February 2011 and determined that this website constitutes labeling under section 201(m) of the Federal Food, Drug, and Cosmetic Act (the Act) because the website address appears on the label of your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts. Based on our review of your product labels and website, your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)] and are misbranded within the meaning of section 403 of the Act [21 U.S.C. § 343]. Regulations implementing the food labeling requirements of the Act can be found in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and implementing regulations through links on FDA's Internet home page at http://www.fda.gov[2].

Unapproved New Drug

Your website address www.jonathansorganic.com[3] appears on your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts and Organic Broccoli Sprouts product labels. We have reviewed you website in February 2011 and have determined that your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts and Organic Broccoli Sprouts products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment or prevention of disease. The marketing of these products with these claims violates the Act. Examples of some of the claims observed on your website from the webpage entitled "Sprouts, The Miracle Food! - Rich Vitamins, Minerals and Phytochemicals" and in a brochure entitled "Health Benefits of Sprouts" that can be viewed and downloaded from your website include, but are not limited to the following:

- "[S]prouts are full of phytochemicals . . . that are powerful allies in protecting us from the growth of cancer cells . . . in lowering cholesterol levels . . . ."
- "Mung Bean Sprouts Identified as Potent Anti-tumor Agent"
- "Studies on canavanine . . . in alfalfa, have demonstrated benefit for pancreatic, colon and leukemi cancers."
- "Alfalfa Sprouts High in Cholesterol Lowering Agent"
- "Saponins [substance found in alfalfa sprouts] lower the bad cholesterol . . . . Animal studies prove their benefit in arteriosclerosis and cardiovascular disease."
- "Phytoestrogens [substance in alfalfa, clover, and mung bean sprouts] . . . prevent . . . osteoporosis. They are also helpful in controlling . . . fibrocystic breast tumors."
- "Research into the possible benefits of phytoestrogens has focused on . . . a) Cancer-breast and prostate in particular . . . c) Osteoporosis d) Heart disease (antioxidant activity) Other potential areas of benefit include diabetes . . . ."
- "The cruciferous sprouts: Broccoli, [lists others] . . . Cancer Fighters"
- "Broccoli . . . may fight cancer."
- "Broccoli sprouts are rich in one class of cancer protecting agents."
- "There is strong evidence that just two or three tablespoons of broccoli sprouts a day can help prevent cancer, gastric cancer, and other diseases."
- "[S]ulforaphane [obtained from a substance in broccoli] prevents tumor growth and kills stomach bacteria that lead to ulcers and stomach cancer. In one study, they showed that feeding broccoli sprouts to rats prevented . . . heart disease, and stroke."

These products are not generally recognized as safe and effective for the above referenced uses; therefor these 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 United States without prior approval from the 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. In addition, your products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; hence adequate directions cannot be written so a layman can use them safely for their intended uses. Therefore, your products are also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fail to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

Unauthorized Health Claims

Your Organic Alfalfa Sprouts, Organic Mung Bean Sprouts and Organic Clover Sprouts products are misbranded within the meaning of 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] because the labeling bears unauthorized health claims. Your website is referenced on each of the above product labels and was found to contain the following unauthorized health claims on the webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals":

- "[P]hytoestrogens [substance found in alfalfa, clover, and mung bean sprouts] . . . may have desirable effects, for example reduce the risk of breast cancer."

- "Phytoestrogens actually reduce the risk of breast cancer."

These health claims misbrand the products listed above because these health claims have not been authorized either by regulation [see section 403(r)(3)(A)-(B) of the Act [21 U.S.C. § 343(r)(3)(A)-(B)]] or under authority of the health claim notification provision of the Act [see section 403(r)(3)(C) of the Act [21 U.S.C. § 343(r)(3)(C)]]. FDA has not authorized any health claims for phytoestrogens.

Unauthorized Nutrient Content Claims

Your Organic Alfalfa Sprouts, Organic Broccoli Sprouts, Organic Mung Bean Sprouts, and Organic Clover Sprouts products are misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product labels bear nutrient content claims that are not authorized by regulation or fail to meet the terms of authorizing regulations. 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 of a type required to be in the labeling misbrands a product under section 403(r)(1)(A) of the Act. Specifically,

1. Your product labels and labeling bear antioxidant nutrient content claims but fail to comply with the requirements for using such a claim. Nutrient content claims using the term "antioxidant" must comply with, among other requirements, 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 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 antioxidant claims found in your product labeling are nutrient content claims because they characterize the level of antioxidants in your product, but they do not comply with 21 CFR 101.54(g)(4) because they do not include the names of the nutrients that are the subject of the claim or link the nutrients with the claim by use of a symbol. This includes the following claims:

- On your website on the page entitled "Tasty, Nutritious Sprout Recipes: Index": "All Sprouts are . . . HIGH IN ANTIOXIDANTS."

- On your website on the page entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals": "Sprouts also contain an abundance of highly active antioxidants . . . ."

2. In accordance with 21 CFR 101.54(b), the terms "high," "rich in," or "excellent source of" may be used t characterize the level of a nutrient on the label and in the labeling of foods provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed (RACC). Your Organi Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Broccoli Sprouts, and Organic Clover Sprouts products do not meet the requirements to make certain "high" claims that appear in your product labeling. Specifically:

The webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals" found on your website bears the claim "Sprouts . . . Rich in Vitamins, Minerals . . ." However, as stated on your nutrition facts panels, your Organic Alfalfa Sprouts and Organic Clover Sprouts products both contain only 2 percent of the Reference Daily Intake (RDI) for vitamin A and calcium, 10 percent of the RDI for vitamin C, and 4 percent of the RDI for iron. Neither of these products contains vitamins or minerals at levels that are 20 percent or more of the RDI. In addition, as stated on your nutrition facts panels, your Organic Broccoli Sprouts contain 10 percent of the RDI for vitamin A, 60 percent of the RDI for vitamin C, 6 percent of the RDI for Calcium, and 4 percent of the RDI for Iron. Your Organic Mung Bean Sprouts contain 4 percent of the RDI for vitamin A, 20 percent of the RDI for vitamin C, 2 percent of the RDI for Calcium, and 4 percent of the RDI for Iron. Neither of these products contain minerals at 20 percent or more of the RDI.

Although your labels do state that your Organic Broccoli Sprouts and Organic Mung Bean Sprouts contain 2 percent or more of the RDI for vitamin C, the claim uses the plural "Vitamins," implying that more than one vitamin should be present at levels of 20 percent or more of the RDI. Therefore your Organic Alfalfa Sprouts, Organic Clover Sprouts, Organic Broccoli Sprouts, and Organic Mung Bean Sprouts products do not meet the requirements to make "rich in" claims for vitamins and minerals.

- Your webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals" bears the claim "Clover Sprouts High in Phytoestrogens[.]" This claim characterizes the level of nutrients of the type required to be in nutrition labeling (phytoestrogens) in your products by use of the defined term "high." However, because there is no established RDI or DRV for phytoestrogens, this claim does not comply with the requirements for use of the term "high" in 21 CFR 101.54(b).

3. In accordance with 21 CFR 101.54(c), the term "good source" may be used to characterize the level of a nutrient on the label and in the labeling of foods provided that the food contains 10 to 19 percent of the RDI or the DRV per RACC. Your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Broccoli Sprouts, and Organic Clover Sprouts products do not meet the requirements to make the following "good source" claim that appears in your product labeling.

- Your webpage entitled "Tasty, Nutritious Sprout Recipes: Index" bears the nutrient content claim: "They [all sprouts] provide a good source of . . . calcium . . . as well as fiber, iron . . . ." However, as stated on your nutrition facts panels for your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts these products fail to contain at least 10 percent of the RDI for calcium and iron. All of these products, with the exception of your Organic Broccoli Sprouts product, also fail to meet the requirement to bear a good source of fiber claim because, as stated on your nutrition facts panels, they fail to contain at least 10 percent of the DRV for dietary fiber.

4. Your webpage entitled "Tasty, Nutritious Sprout Recipes: Index" bears the nutrient content claim "They [all sprouts] provide a good source of vitamins B . . . and K, phosphorus . . . potassium . . . and thiamin." However, Your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Broccoli Sprouts, and Organic Clover Sprouts products product labels fail to provide information about the levels of vitamin B, vitamin K, phosphorus, potassium, and thiamin in those products as required under 21 CFR 101.9(c)(8)(ii), 101.9(c)(5) and 101.13(n). Therefore, these products are misbranded under section 403(q) and 403(r)(1)(A) of the Act Further, because the nutrient levels are not declared, it is not clear whether the products have the required minimum 10 percent of the RDI or DRV per RACC of these nutrients as required under 21 CFR 101.54(c) for use of the defined term "good source."

5. In accordance with 21 CFR 101.65(c)(2), the phrases "contains the same amount of [nutrient] as a

[food]" and "as much [nutrient] as a [food]" may be used on the label or in the labeling of foods, provided that the amount of the nutrient in the reference food is enough to qualify that food as a "good source" of that nutrient, and the labeled food, on a per serving basis, is an equivalent, good source of that nutrient (e.g., "as much fiber as an apple," "Contains the same amount of Vitamin C as an 8 oz. glass of orange juice."). Your products fail to meet the requirements to make this type of implied nutrient content claim, which is contained in your product labeling. Specifically:

- Your webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals" bears the implied nutrient content claim: "one-half cup of almost any sprouted seed provides as much Vitamin C as six glasses of orange juice." According to your product labels one 85 g serving is equal to a cup of sprouts; therefore, one half of a labeled serving would equal a half cup. As stated on your nutrition facts panels, one half serving of your Organic Alfalfa Sprouts contains 5 percent of the RDI of Vitamin C, one half serving of your Organic Broccoli Sprouts contains 30 percent of the RDI of Vitamin C, one half serving of your Organic Clover Sprouts contains 5 percent of the RDI of Vitamin C and one half serving of your Organic Mung Bean Sprouts contains 10 percent of the RDI of Vitamin C. However, based on the USDA National Nutrient Database,one 8 oz. serving of raw orange juice contains 124 mg of Vitamin C, which is over 200 percent of the RDI. Your Organic Alfalfa Sprouts, Organic Broccoli Sprouts, Organic Clover Sprouts, and Organic Mung Bean Sprouts do not contain as much Vitamin C as a single 8 oz. serving of orange juice and, by extension, do not contain as much Vitamin C as six 8 oz. glasses of orange juice; therefore, these products do not meet the requirements to make this claim.

- Your webpage entitled "Tasty, Nutritious Sprout Recipes: Index" bears the implied nutrient content claim: "By weight, most sprouts contain twice the protein of meat." Your product labels declare an 85 gram serving size. As stated on your nutrition facts panels, 85 grams of your Organic Alfalfa Sprouts contains 3 grams of protein, 85 grams of your Organic Broccoli Sprouts contains 2 grams of protein, 85 grams of your Organic Clover Sprouts contains 3 grams of protein, and 85 grams of your Organic Mung Bean Sprouts contains 3 grams of protein. However, based on the USDA National Nutrient Database, an 85 gram serving of chicken tenders cooked in a conventional oven contains 13.41 grams of protein; an 85 gram serving of beef, bottom sirloin, tri-tip roast, separable lean and fat, trimmed to 0" fat, choice, cooked, roasted contains 21.81 grams of protein; and an 85 gram serving of pork, fresh, loin, sirloin (roasts), boneless, separable lean and fat, cooked, roasted contains 24.22 grams of protein. Your Organic Alfalfa Sprouts, Organic Broccoli Sprouts, Organic Clover Sprouts, and Organic Mung Bean Sprouts do not contain as much protein by weight as chicken, beef or pork, and, by extension, do not contain twice the protein by weight of chicken, beef or pork. Therefore, your products do not meet the requirements to make this claim.

6. In accordance with 21 CFR 101.61(b)(1)(i), the term "sodium free" may be used on the label or in the labeling of foods provided that the food contains less than 5 mg of sodium per RACC and per labeled serving. The webpage entitled "Tasty, Nutritious Sprout Recipes: Index" bears the claim "Sprouts are sodium free." Your Organic Broccoli Sprouts contain 25 mg of sodium per 85 g labeled serving as declared on your nutrition facts panel; therefore, it does not meet the requirements to make a "sodium free" claim.

7. Your Organic Clover Sprouts product label bears the claim "Phytoestrogen Source[.]" Your webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals" bears the claim "Alfalfa sprouts are one of our finest food sources of . . . saponin." These claims are nutrient content claims subject to section 403(r)(1)(A) of the Act because they characterize the level of nutrients of a type required to be in nutrition labeling (phytoestrogen and saponin) in your products by use of the term "source." Under section 403(r)(2)(A) of the Act, nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined by regulation. However, FDA has not defined the characterization "source" by regulation. Therefore, this characterization may not be used in nutrient content claims.

We acknowledge your firm's efforts in addressing the issues raised in the FDA-483 Inspectional Observation that was issued to you on October 13, 2010 and the specific corrections your letter indicates that you have made. Your corrective actions will be further evaluated during our next inspection of your facility and your response will be filed as a part of the inspectional record for this facility. The above violations are not

meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to assure that all of your sprout products are labeled and processed in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We also have the following comments about your product labels:

Your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts are single ingredient foods and therefore are not required to bear an ingredients declaration under section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)]. You have elected to provide ingredients statements on these products. Your ingredients statements on each of these products declare the corresponding type of seed (i.e. "Contents: Organic Alfalfa Seeds"). However, as required by section 403(i)(2) of the Act, your ingredient declaration must use the food's common or usual name, which is the name of the specific kind of sprout (i.e., "Contents: Alfalfa Sprouts").

Your Organic Alfalfa Sprouts, Organic Clover Sprouts, and Organic Broccoli Sprouts product labels contain the statements "Certified Organic by QAI," and "Product of USA" on the information panel between the name and place of business and ingredients statement. However, 21 CFR 101.2(e) requires that all required information appearing on the information panel shall appear in one place without intervening material.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your respons should outline the specific things you are doing to correct these violations. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to the Food and Drug Administration, Attention: Attention: Lori A. Holmquist, Compliance Officer, 330 Civic Center Drive, Suite 1, Box 4, Augusta, Maine 04330. If you have questions regarding any issues in this letter, please contact Ms. Holmquist at 207.622.8268 x13.

Sincerely,

/S/

Mutahar S. Shamsi

District Director

New England District

Close Out Letter

- Jonathan's Sprouts Inc - Close Out Letter 6/22/11[4]

Page Last Updated: 06/23/2011
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
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