

Ben F. Pierce Gore (SBN 128515)
PRATT & ASSOCIATES
1871 The Alameda
Suite 425
San Jose, CA 95126
(408) 369-0800
pgore@prattattorneys.com

J. Price Coleman (*pro hac vice*)
Coleman Law Firm
1100 Tyler Avenue, Suite 102
Oxford, MS 38655
(662) 236-0047
colemanlawfirm@bellsouth.net

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ADAM VICTOR individually and on
behalf of all others similarly situated,

Plaintiff,

v.

R.C. BIGELOW, INC.,

Defendant.

Case No.3:13-cv-02976-WHO

**FIRST AMENDED CLASS ACTION
AND REPRESENTATIVE ACTION**

**COMPLAINT FOR DAMAGES,
EQUITABLE AND INJUNCTIVE
RELIEF**

JURY TRIAL DEMANDED

Plaintiff, through his undersigned attorneys, brings this lawsuit against Defendant R.C. Bigelow, Inc. (hereinafter “Bigelow” or “Defendant”) as to his own acts upon personal knowledge and as to all other matters upon information and belief.

1. Plaintiff brings this action on behalf of a class of all persons in California who since June 25, 2009 to the present (the “Class Period”), purchased for household use one or more of the following black tea products manufactured and sold by Defendant:

Caramel Chai Black Tea
Chocolate Chai Tea
Constant Comment® Tea
Constant Comment® Decaffeinated Tea
Darjeeling Tea
English Breakfast Tea

FIRST AMENDED CLASS ACTION COMPLAINT
CIVIL ACTION NO. 3:13-CV-02976-WHO

1 English Teatime Tea
2 English Teatime Decaffeinated Tea
3 Cinnamon Stick® Tea
4 Earl Grey Tea
5 Earl Grey Decaffeinated Tea
6 French Vanilla Tea
7 French Vanilla Decaffeinated Tea
8 Spiced Chai Tea
9 Spiced Chai Decaffeinated Tea
10 Vanilla Caramel Tea
11 Vanilla Chai Tea
12 Chinese Oolong Tea
13 Plantation Mint® Tea
14 Lemon Lift Tea
15 Lemon Lift Decaffeinated Tea
16 Raspberry Royale Tea
17 Pomegranate Black Tea
18 White Chocolate Obsession
19 Pumpkin Spice Tea
20 Eggnogg'n Tea
21 Six Assorted Teas Variety Pack
22 Six Assorted Teas Decaffeinated Variety Pack

23 The products listed in paragraph 1 are referred to herein as the “Black Tea Products.”

24 2. “Purchased Products” are those products among those listed in Paragraph 1 that
25 Plaintiff purchased during the class period. Plaintiff purchased the following Bigelow black tea
26 products throughout the Class Period: (1) Earl Grey Tea, (2) English Teatime Tea, (3) Constant
27 Comment® Tea; and (4) Six Assorted Teas Variety Pack which contained (1)-(3) plus Lemon
28 Lift black tea.

29 3. “Substantially Similar Products” are the Defendant’s products that: (i) make the
30 same label representations, as described herein, as the Black Tea Products (via label and website)
31 and (ii) violate the same regulations of the Sherman Food Drug & Cosmetic Law, California
32 Health & Safety Code § 109875, *et seq.* (the “Sherman Law”) as the Black Tea Products, as
33 described herein.

34 4. The list of Black Tea Products will be amended if evidence is adduced during
35 discovery to show that other Bigelow black tea products had labels which violate the same
36 provisions of the Sherman Law and have the same label representations as the Black Tea
37 Products.

38

PARTIES

1
2 5. Plaintiff Adam Victor is a resident of Campbell, California who purchased four of
3 Defendant's Black Tea Products in California at various times during the Class Period.

4 6. Defendant, R. C. Bigelow, Inc. is a Connecticut corporation with its principal
5 place of business in Fairfield, Connecticut. Bigelow is one of the largest tea producers in the
6 country with sale in the hundreds of millions of dollars over the Class Period.

7 7. Bigelow is a leading producer of retail specialty tea products as well as black and
8 green tea products. Bigelow sells its Black Tea Products to consumers through grocery stores,
9 other retail stores and on its website throughout California.

10 **JURISDICTION AND VENUE**

11 8. This Court has original jurisdiction over this action under 28 U.S.C. § 1332(d)
12 because this is a class action in which: (1) there are over 100 members in the proposed class;
13 (2) members of the proposed class have a different citizenship from Defendant; and (3) the claims
14 of the proposed class members exceed \$5,000,000 in the aggregate whether the class is limited to
15 products purchased by Plaintiff or is extended to other Bigelow tea products with substantially
16 similar unlawful claims on the packages and on Bigelow's website.

17 9. Alternatively, the Court has jurisdiction over all claims alleged herein pursuant to
18 28 U.S.C. § 1332, because the matter in controversy exceeds the sum or value of \$75,000, and is
19 between citizens of different states.

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

26 11. Because Plaintiff made numerous purchases of Defendant's Black Tea Products in
27 this District a substantial part of the events or omissions giving rise to these claims occurred in

1 this District and because the Court has personal jurisdiction over Defendant, venue is proper in
2 this Court pursuant to 28 U.S.C. § 1391(a) and (b).

3 **FACTUAL STATEMENT**

4 **A. THE LABELS ON THE BLACK TEA PRODUCTS**

5 12. All of Defendant's Black Tea Products have labels stating, *inter alia*, that the
6 product "*delivers healthful antioxidants*." This phrase is (1) an unlawful antioxidant related
7 nutrient content claim and (2) an unlawful "health claim" in the following respects:

- 8 • Bigelow's antioxidant representations are in violation of the general nutrient content
9 labeling rules provided in 21 C.F.R. § 101.13 adopted by California in the Sherman Law.
10 The general nutrient content labeling rules require a manufacturer to use only approved
11 nutrient content claims on the label of a food product. The use of an unapproved nutrient
12 content claim is prohibited. 58 Fed. Reg. 2302. In addition, 21 U.S.C. § 343(r)(2), which
13 has been adopted by California in the Sherman Law, prohibits using unauthorized (as the
14 antioxidant claims on Bigelow tea products are) or undefined terms and declares foods
15 that do so misbranded. None of Bigelow's tea products, including those purchased by
16 Plaintiff, contain an antioxidant nutrient recognized by regulation; therefore the use of the
17 term "antioxidant" on the product labels violates the general nutrient content labeling
18 rules.
- 19 • Bigelow's antioxidant representations are also in violation of specific California and
20 federal regulations dealing specifically with antioxidants including 21 C.F.R. § 101.54(g).
21 Bigelow violated this regulation by making antioxidant-related nutrient content claims on
22 its labels when in fact (a) its tea products do not name the antioxidant as required by the
23 regulation; (b) its tea products do not contain any nutrient which has an established
24 recommended daily intake value (RDI) as required by the regulation and (c) there is no
25 nutrient in its tea products with recognized antioxidant activity, i.e. there is no scientific
26 evidence that after the tea product and all of its ingredients are ingested and absorbed from
27 the gastrointestinal tract the substance participates in the physiological, biochemical or

1 cellular processes that inactivate free radicals or prevent free radical initiated chemical
2 reactions as required by the regulation.

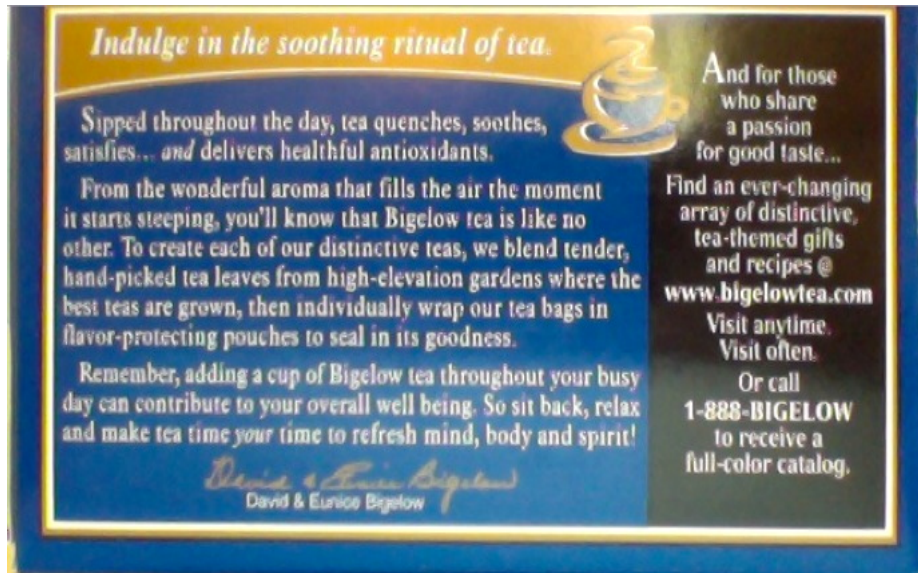
- 3 • Bigelow’s “healthful” representations are in violation of 21 CFR § 101.65(d)(2) which
4 expressly covers not only “healthy” but related terms including ‘healthful,’ ‘healthfully,’
5 ‘healthfulness,’ ‘healthier,’ ‘healthiest,’ ‘healthily,’ and ‘healthiness’.” Bigelow Black
6 Tea products do not contain any ingredient which provides at least 10% of the daily value
7 (DV) of vitamin A, vitamin C, calcium, iron, protein, or fiber per reference amount as
8 required by the regulation. Therefore the use of the term “healthful” is unlawful and
9 misleading.

10 13. The products listed in paragraph 1 above (both those purchased by Plaintiff and
11 those not-purchased) are of a single kind (black tea). All of the Black Tea Products come from the
12 same plant—Camellia sinensis. The process used (fermentation, oxidation, etc.) determines
13 classification of the tea. The only difference is flavor. The Black Tea Products share the same
14 size and shape packaging. The same unlawful health claims and antioxidant related nutrient
15 content claims as set out above appear on the label of each of the Black Tea Products.

16 14. The phrase “*delivers healthful antioxidants*” suggests that the food, because of its
17 nutrient content, may be useful in maintaining healthy dietary practices and is made in association
18 with an explicit claim that the claimed antioxidants in tea (which are flavonoids or polyphenols)
19 are “healthful” and have a beneficial effect on humans. This is not true and is fraudulent and
20 misleading. FDA has not set a recommended daily intake (RDI) for flavonoids, polyphenols or
21 any other substance in tea and has not recognized a substantial consensus of the scientific or
22 medical community of any beneficial effects on humans. Therefore, the claim on Bigelow’s
23 black tea products is in violation of §§ 21 C.F.R. 101.13, 101.54 and 101.65 and identical
24 California law, and the products at issue are unlawfully misbranded as a matter of law and are
25 legally worthless.

26 15. For example, one of the Black Tea Products purchased by Plaintiff was Bigelow
27 English Teatime Tea. The label of this purchased product states the product “*delivers healthful*
28 *antioxidants*.” All of the Black Tea Products contain this same representation. The label is as

1 follows:



23
24 16. This language “*delivers healthful antioxidants*” makes this product unlawfully
25 “misbranded” because it violates the regulations set forth above and hereinafter discussed.

26 17. This language “*delivers healthful antioxidants*” also makes this product
27 misleading because it would lead a reasonable consumer to believe the products provide a
28 beneficial effect on humans when they do not contain any nutrient recognized as having such an
29 effect.

30 18. During various times during the Class Period, Plaintiff read the “*delivers healthful*
31 *antioxidants*” claim appearing on the labels of the Black Tea Products and relied on this
32 information in making his decisions to purchase the Black Tea Products listed above. Plaintiff
33 paid a premium for Defendant’s Black Tea Products with the purported nutritional and health
34 benefits. There were other tea products available to Plaintiff at a lower price. Likewise, there
35 were other alternative beverages available to Plaintiff at a lower price. Moreover, Plaintiff could
36 have avoided purchasing anything. Had Plaintiff known the truth that the products did not in fact

1 contain recognized and accepted beneficial nutritional and healthful value, and in fact were
2 misbranded, Plaintiff would not have paid such a premium or would not have bought the products
3 at all.

4 19. Bigelow's practices on labeling its black Tea Products as discussed herein are
5 illegal and mislead consumers by depriving them of the information they require to make
6 informed purchasing decisions. These practices, in fact, deceived Plaintiff. Plaintiff relied on
7 Defendant's claims that its products contained antioxidant nutrients that would provide healthful
8 and beneficial nutrients when, in fact the tea products did not contain any such nutrients that
9 would do so.

10 20. Identical federal and California laws regulate the content of labels on packaged
11 food. The requirements of the federal Food Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*
12 ("FDCA") were adopted by the California legislature in the Sherman Law. Under both the
13 Sherman Law and FDCA section 403(a), food is "misbranded" if (1) "its labeling is false or
14 misleading in any particular," or (2) if it does not contain certain information on its label or in its
15 labeling. 21 U.S.C. § 343(a).

16 21. Under the FDCA, the term "false" has its usual meaning of "untruthful," while the
17 term "misleading" is a term of art. Misbranding reaches not only false claims, but also those
18 claims that might be technically true, but still misleading. If any single representation in the
19 labeling is misleading, then the entire food is misbranded, and no other statement in the labeling
20 can cure a misleading statement. "Misleading" is judged in reference to "the ignorant, the
21 unthinking and the credulous who, when making a purchase, do not stop to analyze." *United*
22 *States v. El-O-Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951). Under the FDCA, it is not
23 necessary to prove that anyone was actually misled.

24 22. On August 23, 2010, the FDA sent a warning letter to Unilever, the parent
25 company of Lipton Tea, one of Bigelow's biggest competitors, informing Unilever of Lipton
26 Tea's failure to comply with the FDCA and its regulations (the "FDA Warning Letter," is
27 attached hereto as Exhibit 1 and made a part hereof by reference) for nutrient content claims

1 similar to those Bigelow is presently making on its product labels. Bigelow knew or should have
2 known about this warning letter. The FDA Warning Letter to Unilever stated, in pertinent part:

3 4 **Unauthorized Nutrient Content Claims**

5
6 Under section 403(r)(1)(A) of the Act [21 U.S.C. 343(r)(1)(A)], a claim that
7 characterizes the level of a nutrient which is of the type required to be in the
8 labeling of the food must be made in accordance with a regulation promulgated by
9 the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The
10 use of a term, not defined by regulation, in food labeling to characterize the level
11 of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

12
13 Nutrient content claims using the term “antioxidant” must also comply with the
14 requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for
15 a product to bear such a claim, an RDI must have been established for each of the
16 nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these
17 nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2). The
18 level of each nutrient that is the subject of the claim must also be sufficient to
19 qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)).
20 For example, to bear the claim “high in antioxidant vitamin C,” the product must
21 contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b).
22 Such a claim must also include the names of the nutrients that are the subject of
23 the claim as part of the claim or, alternatively, the term “antioxidant” or
24 “antioxidants” may be linked by a symbol (e.g., an asterisk) that refers to the same
25 symbol that appears elsewhere on the same panel of the product label, followed by
26 the name or names of the nutrients with recognized antioxidant activity (21 CFR
27 101.54(g)(4)). The use of a nutrient content claim that uses the term “antioxidant”
28 but does not comply with the requirements of 21 CFR 101.54(g) misbrands a
29 product under section 403(r)(2)(A)(i) of the Act.

30
31 ...

32
33 The product label back panel includes the statement “packed with protective
34 FLAVONOID ANTIOXIDANTS.” The term “packed with” characterizes the level
35 of flavonoid antioxidants in the product; therefore, this claim is a nutrient content
36 claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we
37 determined that the term “packed with” could be considered a synonym for a term
38 defined by regulation, nutrient content claims that use the term “antioxidant” must
39 meet the requirements of 21 CFR 101.54(g). The claim “packed with
40 FLAVONOID ANTIOXIDANTS” does not comply with 21 CFR 101.54(g)(1)
41 because no RDI has been established for flavonoids. Thus, this unauthorized
42 nutrient content claim causes your product to be misbranded under section
43 403(r)(2)(A)(i) of the Act.

44
45
46 <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm224509.htm>.

47 23. As shown above, the labels of Bigelow Black Tea Products contain the unlawful
48 statement “*delivers healthful antioxidants.*” Pursuant to 21 C.F.R. §§ 101.13, 101.54 and 101.65

1 such claims are unlawful because they make an implied nutrient content claim when no
2 recommended daily intake value has been established by the FDA.

3
4 **B. Identical California and Federal Laws Regulate Food**
5 **Labeling**

6 24. Food manufacturers are required to comply with the FDCA and its labeling
7 regulations, including those set forth in 21 C.F.R. § 101.

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

22 26. Defendant's label statement "*delivers healthful antioxidants*" violates all of the
23 above-referenced California statutes.

24 **C. FDA Position**

25 27. In October 2009, the FDA issued a *Guidance for Industry: Letter Regarding Point*
26 *of Purchase Food Labeling* to address its concerns about front of package labels ("2009 FOP
27 Guidance").

28 28. The 2009 FOP Guidance advised the food industry, in relevant part:

1
2 ...FOP and shelf labeling, while currently voluntary, is subject to the provisions of
3 the Federal Food, Drug, and Cosmetic Act that prohibit false or misleading claims
4 and restrict nutrient content claims to those defined in FDA regulations. Therefore,
5 FOP and shelf labeling that is used in a manner that is false or misleading
6 misbrands the products it accompanies. Similarly, a food that bears FOP or shelf
7 labeling with a nutrient content claim that does not comply with the regulatory
8 criteria for the claim as defined in Title 21 Code of Federal Regulations (CFR)
9 101.13 and Subpart D of Part 101 is misbranded. We will consider enforcement
10 actions against clear violations of these established labeling requirements. . .
11

12 29. Defendant ignored the FDA's 2009 Guidance for Industry. Defendant continues to
13 utilize unlawful antioxidant claims on the labels of its Black Tea Products. As such, Defendant's
14 Black Tea Products continue to violate FDA guidance as well as California and federal law.

15 30. Plaintiff did not know, and had no reason to know, that the Defendant's Black Tea
16 Products were misbranded and bore food labeling claims despite failing to meet the requirements
17 to make those food labeling claims. Similarly, Plaintiff did not know, and had no reason to know,
18 that Bigelow's Black Tea Products he purchased were misbranded because their labeling was
19 false and misleading. As will be more fully set forth herein, Plaintiff was deceived and misled by
20 Defendant's misbranded products because he was only presented with the "*delivers healthful*
21 *antioxidants*" label representation of Defendant when in fact Bigelow's tea products did not
22 contain any nutrient that would have any healthful or beneficial effect on humans.

23 **D. Defendant's Food Products Are Misbranded**

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

28 32. Nutrient content claims are claims about specific nutrients contained in a product.
29 They are typically made on the front of packaging in a font large enough to be read by the
30 average consumer. Because consumers rely upon these claims when making purchasing
31 decisions, the regulations govern what claims can be made in order to prevent misleading claims.

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

4 34. 21 C.F.R. § 101.13 provides the general requirements for nutrient content claims,
5 which California has expressly adopted. *See* California Health & Safety Code § 110100.

6 35. The intent of this statute is to avoid misleading consumers and provide them with
7 full disclosure of both healthy and unhealthy ingredients.

8 36. The statement “*delivers healthful antioxidants*” is an implied nutrient content
9 claim as defined under FDA regulations. An “implied nutrient content claim” is defined as any
10 claim that: (i) describes the food or an ingredient therein in a manner that suggests that a nutrient
11 is absent or present in a certain amount (*e.g.*, “high in oat bran”); or (ii) suggests that the food,
12 because of its nutrient content, may be useful in maintaining healthy dietary practices and is made
13 in association with an explicit claim or statement about a nutrient (*e.g.*, “healthy, contains 3 grams
14 (g) of fat”). 21 C.F.R. § 101.13(b)(2)(i-ii). The phrase “*delivers healthful antioxidants*”
15 suggests that the food, because of its nutrient content, may be useful in maintaining healthy
16 dietary practices and is made in association with an explicit claim that the claimed antioxidants in
17 tea (which are flavonoids or polyphenols) are “healthful” and have a beneficial effect on humans.
18 FDA has not set a recommended daily intake (RDI) for flavonoids, polyphenols or any other
19 substance in tea and has not recognized a substantial consensus of the scientific or medical
20 community of any beneficial effects on humans from consuming tea.

21 **E. Defendant Has Made Unlawful and Misleading Antioxidant Related**
22 **Nutrient Content Claims**

23 37. Defendant’s nutrient contents claim that its black tea “*delivers healthful*
24 *antioxidants*” is both (1) unlawful under the Sherman Law and (2) misleading.

25 38. The claim is unlawful because it fails to comply with the nutrient content claim
26 provisions in violation of 21 C.F.R. §§ 101.13, 101.54 and 101.65, which have been incorporated
27 in California’s Sherman Law.

1 39. Defendant's "*delivers healthful antioxidants*" claim concerning unnamed
2 antioxidant nutrients is false and misleading to the reasonable consumer because Defendant's
3 label representation is a claim that the products will provide a beneficial effect on humans and
4 that the unnamed ingredients have met the minimum nutritional requirements for the use of the
5 defined term (antioxidants) when they have not.

6 40. By using an undefined term such as "delivers," Defendant is, in effect, falsely
7 asserting that its products meet at least the lowest minimum threshold for any nutrient content
8 claim, which would be 10% of the daily value of the nutrient at issue. Such a threshold represents
9 the lowest level that a nutrient can be present in a food and provide a recognized beneficial effect.
10 A claim about the presence of a nutrient not recognized as having a beneficial effect on humans
11 becomes deceptive and misleading when it highlights the presence of a nutrient without any such
12 benefit. Thus, it is deceptive and misleading for Defendant to claim that each of its Black Tea
13 Products "delivers" healthful antioxidants. None of the nutrients in tea have a recognized
14 beneficial effect on humans, nor do they have an FDA prescribed daily value and thus it is
15 misleading as well as unlawful to make such an implied nutrient content claim about them.

16 41. FDA enforcement actions targeting identical or similar claims to those made by
17 Defendant have made clear the unlawfulness of such claims. Defendant knew or should have
18 known about these enforcement actions. For example, on March 24, 2011, the FDA sent Jonathan
19 Sprouts, Inc. a warning letter (attached as Exhibit 2) where the FDA specifically targeted a
20 "source" type claim like the one used by Defendant. In that letter the FDA stated:

21 Your Organic Clover Sprouts product label bears the claim "Phytoestrogen
22 Source[.]" Your webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins,
23 Minerals and Phytochemicals" bears the claim "Alfalfa sprouts are one of our
24 finest food sources of . . . saponin." These claims are nutrient content claims
25 subject to section 403(r)(1)(A) of the Act because they characterize the level of
26 nutrients of a type required to be in nutrition labeling (phytoestrogen and saponin)
27 in your products by use of the term "source." Under section 403(r)(2)(A) of the
28 Act, nutrient content claims may be made only if the characterization of the level
29 made in the claim uses terms which are defined by regulation. However, FDA has
30 not defined the characterization "source" by regulation. Therefore, this
31 characterization may not be used in nutrient content claims.
32

33 42. It is thus clear that a "source" claim similar to the one utilized by Defendant is
34 unlawful because the "FDA has not defined the characterization 'source' by regulation" and thus

1 such a “characterization may not be used in nutrient content claims.” The same is true with
2 “delivers” which obviously means and would be interpreted by a reasonable consumer to mean
3 that the Black Tea Products “contain” a beneficial ingredient that would be “delivered” by
4 consuming the product.

5 43. Defendant’s “*delivers healthful antioxidants*” claim would be considered by a
6 reasonable consumer like the Plaintiff when deciding to purchase the products. Plaintiff placed,
7 and a reasonable consumer would place, great importance on the claimed statement that black tea
8 “*delivers*” healthful or healthy antioxidants in choosing Defendant’s products over other tea
9 products and alternative beverage products.

10 44. Defendant has violated the above referenced regulations by placing the
11 representation “*delivers healthful antioxidants*” on its product labels. Plaintiff relied on
12 Bigelow’s antioxidant related nutrient content claim when making his purchase decisions and was
13 misled because he erroneously believed the misrepresentation that the Bigelow products he was
14 purchasing were beneficial, healthy and met the minimum nutritional threshold to make such
15 claims. Antioxidant related nutrient content was important to the Plaintiff in trying to buy
16 “healthy” food products. Plaintiff would not have purchased these products had he known that the
17 Bigelow products did not have the beneficial effects claimed and in fact did not satisfy such
18 minimum nutritional requirements with regard to the claimed antioxidant nutrients and in fact
19 were misbranded.

20 45. For these reasons, Defendant’s antioxidant related nutrient content claims at issue
21 in this Complaint are false and misleading and in violation of 21 C.F.R. §§ 101.13, 101.54 and
22 101.65 and identical California law, and the products at issue are unlawfully misbranded as a
23 matter of law and are legally worthless.

24 46. Plaintiff was misled by the Defendant’s unlawful labeling practices and actions
25 into purchasing products he would not have otherwise purchased had he known the truth about
26 those products. Plaintiff would not have purchased the products without the “*delivers healthful*
27 *antioxidants*” label representation. Plaintiff had cheaper alternatives. Defendant’s claim is false
28 and misleading and the products are misbranded under identical California and federal laws.

1 F. **Defendant Has Made Unlawful and Misleading Antioxidant**
 2 **Related Nutrient Content Claims That Violate The Specific**
 3 **Antioxidant Labeling Rules**

4 47. In addition to Defendant’s violation of the Sherman Law as to making a nutrient
 5 content claim generally, Defendant also has violated identical California and federal labeling
 6 regulations specific to antioxidants.

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

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

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

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

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

21 (5) the antioxidant nutrient must meet the requirements for nutrient content
 22 claims in 21 C.F.R. § 101.54(b), (c), or (e) for “High” claims, “Good Source” claims, and “More”
 23 claims, respectively. For example, to use a “High” claim, the food would have to contain 20% or
 24 more of the Daily Reference Value (“DRV”) or RDI per serving. For a “Good Source” claim, the

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.

1 food would have to contain between 10-19% of the DRV or RDI per serving, *see* 21 C.F.R. §
2 101.54(g)(3); and

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

7 49. The antioxidant labeling for Bigelow's Black Tea Products violates California law
8 as it relates to the regulations specific to antioxidants in the following respects: (1) because the
9 names of the antioxidants are not disclosed on the product labels in violation of 21 C.F.R. §
10 101.54(g)(4); (2) because there are no RDIs for the claimed antioxidant substances in tea,
11 including flavonoids and polyphenols; and (3) because Defendant lacks adequate scientific
12 evidence that the claimed antioxidant nutrients participate in physiological, biochemical, or
13 cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions
14 after they are eaten and absorbed from the gastrointestinal tract.

15 50. The package label for all Bigelow's black tea products states it "***delivers healthful***
16 ***antioxidants.***" Plaintiff was deceived by this label representation, and members of the class were
17 deceived, because affirmative representations were made to them that recognized and beneficial
18 antioxidants were present in Defendant's Black Tea Products and consuming these antioxidants
19 would prove "healthful" to them. This representation was made even though Bigelow's tea
20 products did not contain any substance which fulfills the requirements of making such a claim
21 and the manner in which the statement is made does not comply with the requirements of 21
22 C.F.R. § 101.54(g)(4).

23 51. These same types of violations were condemned in the FDA Warning Letter to
24 Unilever/Lipton discussed above and attached as Exhibit 1.

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

1
2 Additionally, your website bears nutrient content claims using the term
3 “antioxidant.” ... Such a claim must also include the names of the nutrients that
4 are the subject of the claim as part of the claim The use of a nutrient content
5 claim that uses the term “antioxidant” but does not comply with the requirements
6 of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the
7 Act. The following are examples of nutrient content claims on your website that
8 use the term “antioxidant” but do not include the names of the nutrients that are the
9 subject of the claim as required under 21 CFR 101.54(g)(4): “Yerba Maté is...rich
10 in... antioxidants.”; ... “Caffeine-free Green Rooibos...contain[s] high
11 concentrations of antioxidants....
12

13 Additionally, the following are examples of nutrient content claims on your
14 website that use the term “antioxidant,” but where the nutrients that are the subject
15 of the claim do not have an established RDI as required under 21 CFR
16 101.54(g)(1): ... “White Tea... contain[s] high concentrations of... antioxidant
17 polyphenols (tea catechins)....” ; ... “Antioxidant rich...222mg polyphenols per
18 serving!”; ... “Antioxidant rich...109mg polyphenols per serving!”
19

20 53. The types of label misrepresentations described above were considered by Plaintiff
21 when purchasing the subject products and would be considered by a reasonable consumer when
22 deciding to purchase the products.

23 54. Defendant’s antioxidant claims do not satisfy the legal and regulatory requirement
24 that the nutrient that is the subject of the antioxidant claim must also have recognized antioxidant
25 activity, *i.e.*, there must be substantial scientific evidence that after it is eaten and absorbed from
26 the gastrointestinal tract, the substance participates in physiological, biochemical or cellular
27 processes that inactivate free radicals or prevent free radical-initiated chemical reactions, *see* 21
28 C.F.R. § 101.54(g)(2).

29 55. Plaintiff relied on Defendant’s antioxidant claim on the labels of Defendant’s
30 Black Tea Products when making his purchase decisions over the Class Period and was misled
31 because he erroneously believed the misrepresentation that the Defendant’s products he was
32 purchasing met the minimum nutritional threshold to make such a claim. Plaintiff would not have
33 purchased these products had he known that the Defendant’s products did not in fact satisfy such
34 minimum nutritional requirements with regard to antioxidants and the consumption of
35 defendant’s tea did not, in fact, result in the purported health benefits touted by Defendant and in
36 fact the products were misbranded and illegal to purchase, own or possess.

1 56. For these reasons, Defendant's antioxidant claims at issue in this Complaint are
 2 false and misleading and in violation of 21 C.F.R. §§ 101.13, 101.54 and 101.65 and identical
 3 California law, and the products at issue are misbranded as a matter of law. Defendant's Black
 4 Tea Products are misbranded as a matter of California and federal law and cannot be sold or held
 5 and thus have no economic value and are legally worthless. Additionally, Plaintiff was misled and
 6 deceived by the actions of the Defendant in violation of California Law.

7 **G. Defendant Has Made Unlawful and Misleading Health Claims**

8 57. Defendant violated identical California and federal law by making health claims
 9 about its products. A health claim is a statement expressly or implicitly linking the consumption
 10 of a food substance (*e.g.*, ingredient, nutrient, or complete food) to risk of a disease (*e.g.*,
 11 cardiovascular disease) or a health-related condition (*e.g.*, hypertension). *See* 21 C.F.R. §
 12 101.14(a)(1), (a)(2), and (a)(5). Only health claims made in accordance with FDCA requirements,
 13 or authorized by FDA as qualified health claims, may be included in food labeling. Other express
 14 or implied statements that constitute health claims, but that do not meet statutory requirements,
 15 are prohibited in labeling foods.

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

18 59. 21 C.F.R. § 101.65, which has been adopted by California, sets certain minimum
 19 nutritional requirements for making an implied nutrient content claim that a product is healthy.
 20 For example, the food must supply at least 10 percent of the RDI of one or more specified
 21 nutrients. Tea does not contain any of the specified nutrients. Defendants have misrepresented
 22 the healthiness of their products while failing to meet the regulatory requirements for making
 23 such claims. In general, the term "healthy" may be used in labeling an individual food product
 24 that:

25 Qualifies as both low fat and low saturated fat;

26 Contains 480 mg or less of sodium per reference amount and per labeled serving,
 27 and per 50 g (as prepared for typically rehydrated foods) if the food has a reference
 28 amount of 30 g or 2 tbsps or less;

29 Does not exceed the disclosure level for cholesterol (*e.g.*, for most individual food
 30
 31
 32

1 products, 60 mg or less per reference amount and per labeled serving size); *and*

2
3 Except for raw fruits and vegetables, certain frozen or canned fruits and
4 vegetables, and enriched cereal-grain products that conform to a standard of
5 identity, **provides at least 10% of the daily value (DV) of vitamin A, vitamin C,**
6 **calcium, iron, protein, or fiber per reference amount.**
7

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

10
11 21 C.F.R. § 101.65(d)(2) (emphasis added)

12 60. FDA's regulation on the use of the term healthy also encompasses other, derivative
13 uses of the term health (*e.g.*, healthful, healthier) in food labeling. 21 C.F.R. § 101.65(d).
14 Therefore, Bigelow's use of the term "healthful" falls squarely under the provisions of the
15 regulation specified above.

16 61. Bigelow has violated the provisions of 21 C.F.R. § 101.13, 21 C.F.R. § 101.14,
17 C.F.R. § 21 C.F.R. § 101.54, 21 C.F.R. § 101.65, 21 U.S.C. § 321(g)(1)(D), 21 U.S.C. § 321(m)
18 and 21 U.S.C. § 352(f)(1) on a number of its products. The claim on each of the Bigelow Black
19 Tea Products package back panel "***delivers healthful antioxidants***" is in violation of the aforesaid
20 laws.

21 62. The package back panel of Bigelow's black tea products claim "***delivers healthful***
22 ***antioxidants***" but the products do not contain any substance or nutrient specified in §
23 101.65(d)(2) as set out above, nor any other nutrient with recognized beneficial effects on
24 humans. Therefore, the Bigelow products are misbranded.

25 63. Plaintiff saw the health related antioxidant claim on the labels prior to purchasing
26 Defendant's products at various times during the Class Period and relied on the Defendant's
27 health claims on the labels which influenced his decision to purchase the Defendant's products.
28 These claims continue to be made on Defendant's packaging to this day. Plaintiff would not have
29 bought the products had he known Defendant's claims were unlawful, false, misleading,
30 unapproved and that the products were misbranded.

31 64. Plaintiff and members of the Class were misled into the belief that such claims
32 were legal and had passed regulatory muster and were supported by substantial and recognized

1 scientific and medical evidence capable of securing regulatory acceptance. Because this was not
2 the case, the Plaintiff and members of the Class have been deceived.

3 **H. Defendant Has Violated California Law**

4 65. The package front panel of Bigelow's Black Tea Products claims a level of
5 "antioxidants" but their products do not contain any antioxidant substance or nutrient with an
6 established RDI nor any nutrient with recognized antioxidant activity, *i.e.*, substantial scientific
7 evidence that after it is eaten and absorbed from the gastrointestinal tract, the substance
8 participates in physiological, biochemical or cellular processes that inactivate free radicals or
9 prevent free radical-initiated chemical reactions as required by 21 C.F.R. § 101.54(g)(2).

10 66. Bigelow claims health related benefits to be derived from using its products but, as
11 with the Lipton and Diaspora Tea & Herb Co. products, Bigelow's Black Tea Products do not
12 have approval from FDA to make the health related claims. Moreover, the health related claims
13 are in violation of 21 U.S.C. § 352(f)(1) and therefore the products are misbranded.

14 67. By its conduct set forth in the foregoing paragraphs, Defendant has violated
15 California Health & Safety Code §§ 109885 and 110390 which make it unlawful to disseminate
16 false or misleading food advertisements that include statements on products and product
17 packaging or labeling or any other medium used to directly or indirectly induce the purchase of a
18 food product.

19 68. By its conduct set forth in the foregoing paragraphs, Defendant has violated
20 California Health & Safety Code § 110395 which makes it unlawful to manufacture, sell, deliver,
21 hold or offer to sell any misbranded food.

22 69. By its conduct set forth in the foregoing paragraphs, Defendant has violated
23 California Health & Safety Code § 110398 which makes it unlawful to deliver or proffer for
24 delivery any food that has been falsely advertised.

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

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

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

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

10 71. By its conduct set forth in the foregoing paragraphs, Defendant has violated
11 California Health & Safety Code § 110760 which makes it unlawful for any person to
12 manufacture, sell, deliver, hold, or offer for sale any food that is misbranded.

13 72. By its conduct set forth in the foregoing paragraphs, Defendant has violated
14 California Health & Safety Code § 110765 which makes it unlawful for any person to misbrand
15 any food.

16 73. By its conduct set forth in the foregoing paragraphs, Defendant has violated
17 California Health & Safety Code § 110770 which makes it unlawful for any person to receive in
18 commerce any food that is misbranded or to deliver or proffer for deliver any such food.

19 74. By its conduct set forth in the foregoing paragraphs, Defendant has violated the
20 standard set by 21 C.F.R. § 101.2, which has been incorporated by reference in the Sherman Law,
21 by failing to include on their product labels the nutritional information required by law.

22 75. By its conduct set forth in the foregoing paragraphs, Defendant has violated the
23 standards set by 21 CFR §§ 101.13, and 101.54, which have been adopted by reference in the
24 Sherman Law, by including unauthorized antioxidant claims on their products. Defendant has
25 violated the standards set by 21 CFR §§ 101.14, and 101.65, which have been adopted by
26 reference in the Sherman Law, by including unauthorized health and healthy claims on their
27 products.

1 **I. Plaintiff Purchased Four of Defendant's Black Tea Products**

2 76. Plaintiff purchased the following Bigelow black tea products throughout the Class
3 Period: (1) Earl Grey Tea, (2) English Teatime Tea, (3) Constant Comment® Tea; and (4) Six
4 Assorted Teas Variety Pack which contained (1)-(3) plus Lemon Lift black tea.

5 77. Prior to making his decisions to purchase Defendant's products Plaintiff read the
6 product labels including the aforesaid information regarding the health benefits to be gained from
7 consuming Defendant's products. Specifically, Plaintiff read and relied upon the label
8 representation that the products "*delivers healthful antioxidants.*"

9 78. Plaintiff read the labels on Defendant's Black Tea Products before purchasing
10 them. But for the misrepresentations on Defendant's labeling, Plaintiff would have foregone
11 purchasing Defendant's products and bought other products readily available at a lower price or
12 would not have purchased any product at all.

13 79. Plaintiff reasonably relied on Defendant's package labeling, packaging and
14 product placement concerning Defendant's Black Tea Products including the antioxidant related
15 nutrient content claims including the "healthful antioxidants," and based and justified his
16 decision to purchase Defendant's products in substantial part on Defendant's package labeling
17 and representations related to Defendant's food products before purchasing them.

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

21 81. After Plaintiff learned that Defendant's Black Tea Products are falsely labeled, he
22 stopped purchasing them.

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

25 83. As a result of Defendant's misrepresentations, Plaintiff and thousands of others in
26 California purchased the Black Tea Products at issue.

27 84. A reasonable person would also attach importance to whether Defendant's
28 products were legally salable, and capable of legal possession, and to Defendant's representations

1 about these issues in determining whether to purchase the products at issue. Plaintiff would not
 2 have purchased Defendant's Black Tea Products had he known they were not capable of being
 3 legally sold or held.

4 85. These Black Tea Products 1) whose essential characteristics had been
 5 misrepresented by the Defendant; 2) which had their nutritional and health benefits
 6 misrepresented and overstated by the Defendant, and 3) which were misbranded products which
 7 could not be resold and whose very possession was illegal; had no economic value; and were
 8 worthless to the Plaintiff and as a matter of law.

9 **J. All of the Black Tea Products Are Substantially Similar**

10 86. All of Defendant's black teas are substantially similar. All products come from the
 11 same plant—Camellia sinensis. The process used (fermentation, oxidation, etc.) determines
 12 classification of the tea (black or green).

13 87. All of Defendant's black teas have the same labels, labeling, packaging, and sizes.
 14 The Defendant makes the same antioxidant related nutrient content claims on the labels of all of
 15 its black teas and on its website it makes the same unlawful antioxidant and health claims about
 16 its black teas.

17 88. The same antioxidant related nutrient content claim is made on all Bigelow black
 18 tea products, those that Plaintiff purchased and those that Plaintiff did not purchase. The
 19 antioxidant nutrient content claims appearing on Bigelow's website are not product-specific but
 20 relate in some instances to all black tea products and in some instances to all tea products (black
 21 and green). Because of the similarity of the products (tea) and the claims (antioxidant related
 22 nutrient content claims) and for judicial economy the Black Tea Products should all be included
 23 in the class.

24 **CLASS ACTION ALLEGATIONS**

25 89. Plaintiff brings this action as a class action pursuant to Federal Rule of Procedure
 26 23(b)(2) and 23(b)(3) on behalf of the following class:

27 All persons in California who purchased Defendant's Black Tea Products for
 28 personal or household use from June 25, 2009 to the present (the "Class").

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

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

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

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

- 15 a. Whether Defendant engaged in unlawful, unfair or deceptive
16 business practices by failing to properly package and label its Black
17 Tea Products sold to consumers;
18
19 b. Whether the food products at issue were misbranded or unlawfully
20 packaged and labeled as a matter of law;
21
22 c. Whether Defendant made unlawful and misleading antioxidant,
23 nutrient content claims with respect to the food products it sold to
24 consumers;
25
26 d. Whether Defendant violated California Bus. & Prof. Code § 17200
27 *et seq.*, California Bus. & Prof. Code § 17500 *et seq.*, the Consumer
28 Legal Remedies Act, Cal. Civ. Code § 1750 *et seq.*, and the
29 Sherman Law;
30
31 e. Whether Plaintiff and the Class are entitled to equitable and/or
32 injunctive relief; and
33
34 f. Whether Defendant's unlawful, unfair and/or deceptive practices
35 harmed Plaintiff and the Class.
36
37

38 94. Typicality: Plaintiff's claims are typical of the claims of the Class because
39 Plaintiff bought Defendant's Black Tea Products during the Class Period. Defendant's

1 unlawful, unfair and/or fraudulent actions concern the same business practices described
2 herein irrespective of where they occurred or were experienced. Plaintiff and the Class
3 sustained similar injuries arising out of Defendant's conduct in violation of California law.
4 The injuries of each member of the Class were caused directly by Defendant's wrongful
5 conduct. In addition, the factual underpinning of Defendant's misconduct is common to
6 all Class members and represents a common thread of misconduct resulting in injury to all
7 members of the Class. Plaintiff's claims arise from the same practices and course of
8 conduct that give rise to the claims of the Class members and are based on the same legal
9 theories.

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

18 96. Superiority: There is no plain, speedy or adequate remedy other than by
19 maintenance of this class action. The prosecution of individual remedies by members of the
20 Class will tend to establish inconsistent standards of conduct for Defendant and result in the
21 impairment of Class members' rights and the disposition of their interests through actions to
22 which they were not parties. Class action treatment will permit a large number of similarly
23 situated persons to prosecute their common claims in a single forum simultaneously, efficiently
24 and without the unnecessary duplication of effort and expense that numerous individual actions
25 would engender. Further, as the damages suffered by individual members of the Class may be
26 relatively small, the expense and burden of individual litigation would make it difficult or
27 impossible for individual members of the Class to redress the wrongs done to them, while an
28 important public interest will be served by addressing the matter as a class action. Class

1 treatment of common questions of law and fact would also be superior to multiple individual
2 actions or piecemeal litigation in that class treatment will conserve the resources of the Court and
3 the litigants, and will promote consistency and efficiency of adjudication.

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

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

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

15 **CAUSES OF ACTION**

16 **FIRST CAUSE OF ACTION**

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

19 100. Plaintiff incorporates by reference each allegation set forth above.

20 101. Defendant's conduct constitutes unlawful business acts and practices.
21 Defendant sold misbranded Black Tea Products nationwide and in California during the Class
22 Period.
23

24 102. Defendant is a corporation and, therefore, is a "person" within the meaning of the
25 Sherman Law.
26

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

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

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

3 106. Defendant sold Plaintiff and the Class misbranded Black Tea Products that were
4 not capable of being sold or held legally and which had no economic value and were legally
5 worthless. Plaintiff and the Class paid a premium for the misbranded Black Tea Products.

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

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

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

18 **SECOND CAUSE OF ACTION**

19 **Business and Professions Code § 17200 *et seq.***
20 **Unfair Business Acts and Practices**
21

22 110. Plaintiff incorporates by reference each allegation set forth above.

23 111. Defendant's conduct as set forth herein constitutes unfair business acts and
24 practices.

25 112. Defendant sold misbranded Black Tea Products nationwide and in California
26 during the Class Period.

27 113. Plaintiff and members of the Class suffered a substantial injury by virtue of buying
28 Defendant's misbranded Black Tea Products that they would not have purchased absent
29 Defendant's illegal conduct as set forth herein.

1 114. Defendant's deceptive marketing, advertising, packaging and labeling of its
2 misbranded Black Tea Products and its sale of unsalable misbranded Black Tea Products that
3 were illegal to possess were of no benefit to consumers, and the harm to consumers and
4 competition is substantial.

5 115. Defendant sold Plaintiff and the Class misbranded Black Tea Products that were
6 not capable of being legally sold or held and that had no economic value and were legally
7 worthless. Plaintiff and the Class paid a premium for the misbranded Black Tea Products.

8 116. Plaintiff and the Class who purchased Defendant's misbranded Black Tea Products
9 had no way of reasonably knowing that the products were misbranded and were not properly
10 marketed, advertised, packaged and labeled, and thus could not have reasonably avoided the
11 injury suffered.

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

16 118. As a result of Defendant's conduct, Plaintiff and the Class, pursuant to Business
17 and Professions Code § 17203, are entitled to an order enjoining such future conduct by
18 Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's
19 ill-gotten gains and restore any money paid for Defendant's misbranded Black Tea Products by
20 Plaintiff and the Class.

21 **THIRD CAUSE OF ACTION**

22 **Business and Professions Code § 17200 *et seq.*** 23 **Fraudulent Business Acts and Practices** 24

25 119. Plaintiff incorporates by reference each allegation set forth above.

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

28 121. Defendant sold Misbranded Food products nationwide and in California during the
29 Class Period.

1 122. Defendant's misleading marketing, advertising, packaging and labeling of the
2 misbranded Black Tea Products were likely to deceive reasonable consumers, and in fact,
3 Plaintiff and members of the Class were deceived. Defendant has engaged in fraudulent business
4 acts and practices.

5 123. Defendant's fraud and deception caused Plaintiff and the Class to purchase
6 Defendant's misbranded Black Tea Products that they would otherwise not have purchased had
7 they known the true nature of those products.

8 124. Defendant sold Plaintiff and the Class misbranded Black Tea Products that were
9 not capable of being sold or held legally and that had no economic value and were legally
10 worthless. Plaintiff and the Class paid a premium price for the misbranded Black Tea Products.

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

16 **FOURTH CAUSE OF ACTION**

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

19 126. Plaintiff incorporates by reference each allegation set forth above.

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

22 128. Defendant sold misbranded Black Tea Products nationwide and in California
23 during the Class Period.

24 129. Defendant engaged in a scheme of offering Defendant's misbranded Black Tea
25 Products for sale to Plaintiff and members of the Class by way of, *inter alia*, product packaging
26 and labeling, and other promotional materials. These materials misrepresented and/or omitted the
27 true contents and nature of Defendant's misbranded Black Tea Products. Defendant's
28 advertisements and inducements were made within California and come within the definition of
29
30

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

7 130. In furtherance of its plan and scheme, Defendant prepared and distributed within
8 California and nationwide via product packaging and labeling, and other promotional materials,
9 statements that misleadingly and deceptively represented the composition and nature of
10 Defendant's misbranded Black Tea Products. Plaintiff and the Class necessarily and reasonably
11 relied on Defendant's materials, and were the intended targets of such representations.

12 131. Defendant's conduct in disseminating misleading and deceptive statements in
13 California and nationwide to Plaintiff and the Class was and is likely to deceive reasonable
14 consumers by obfuscating the true composition and nature of Defendant's misbranded Black Tea
15 Products in violation of the "misleading prong" of California Business and Professions Code §
16 17500 *et seq.*

17 132. As a result of Defendant's violations of the "misleading prong" of California
18 Business and Professions Code § 17500 *et seq.*, Defendant has been unjustly enriched at the
19 expense of Plaintiff and the Class. Misbranded products cannot be legally sold or held and had
20 no economic value and are legally worthless. Plaintiff and the Class paid a premium price for the
21 misbranded Black Tea Products.

22 133. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are
23 entitled to an order enjoining such future conduct by Defendant, and such other orders and
24 judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any
25 money paid for Defendant's misbranded Black Tea Products by Plaintiff and the Class.

26
27 **FIFTH CAUSE OF ACTION**

28 **Business and Professions Code § 17500 *et seq.***
29 **Untrue Advertising**
30

1 134. Plaintiff incorporates by reference each allegation set forth above.

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

4 136. Defendant sold mislabeled misbranded Black Tea Products nationwide and in
5 California during the Class Period.

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

16 138. In furtherance of its plan and scheme, Defendant prepared and distributed in
17 California and nationwide via product packaging and labeling, and other promotional materials,
18 statements that falsely advertise the composition of Defendant's misbranded Black Tea Products,
19 and falsely misrepresented the nature of those products. Plaintiff and the Class were the intended
20 targets of such representations and would reasonably be deceived by Defendant's materials.

21 139. Defendant's conduct in disseminating untrue advertising throughout California and
22 nationwide deceived Plaintiff and members of the Class by obfuscating the contents, nature and
23 quality of Defendant's misbranded Black Tea Products in violation of the "untrue prong" of
24 California Business and Professions Code § 17500.

25 140. As a result of Defendant's violations of the "untrue prong" of California Business
26 and Professions Code § 17500 *et seq.*, Defendant has been unjustly enriched at the expense of
27 Plaintiff and the Class. Misbranded products cannot be legally sold or held and had no economic

1 value and are legally worthless. Plaintiff and the Class paid a premium price for the misbranded
2 Black Tea Products.

3 141. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are
4 entitled to an order enjoining such future conduct by Defendant, and such other orders and
5 judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any
6 money paid for Defendant's misbranded Black Tea Products by Plaintiff and the Class.

7 SIXTH CAUSE OF ACTION

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

9 142. Plaintiff incorporates by reference each allegation set forth above.

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

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

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

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

21 147. Defendant sold misbranded Black Tea Products nationwide and in California
22 during the Class Period.

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

25 149. Defendant's misbranded Black Tea Products were and are "goods" within the
26 meaning of Cal. Civ. Code §1761(a).

27 150. By engaging in the conduct set forth herein, Defendant violated and continues to
28 violate Section 1770(a)(5) of the CLRA, because Defendant's conduct constitutes unfair methods

1 of competition and unfair or fraudulent acts or practices in that it misrepresents the particular
2 ingredients, characteristics, uses, benefits and quantities of the goods.

3 151. By engaging in the conduct set forth herein, Defendant violated and continues to
4 violate Section 1770(a)(7) of the CLRA, because Defendant's conduct constitutes unfair methods
5 of competition and unfair or fraudulent acts or practices in that it misrepresents the particular
6 standard, quality or grade of the goods.

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

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

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

20 **JURY DEMAND**

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

22 **PRAYER FOR RELIEF**

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

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

28 B. For an order awarding, as appropriate, damages, restitution or

1
2
3
4
5
6
7
8
9
10

disgorgement to Plaintiff and the Class in a sum in excess of \$5,000,000;

C. For an order requiring Defendant to immediately cease and desist from selling its Black Tea 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: April 12, 2014

Respectfully submitted,

/s/ J. Price Coleman

J. Price Coleman (*pro hac vice*)
Coleman Law Firm
1100 Tyler Avenue, Suite 102
Oxford, MS 38655
(662) 236-0047
colemanlawfirm@bellsouth.net

Ben F. Pierce Gore (SBN 128515)
PRATT & ASSOCIATES
1871 The Alameda
Suite 425
San Jose, CA 95126
(408) 369-0800
pgore@prattattorneys.com

Attorneys for Plaintiff

11
12

[Home](#) [Inspections, Compliance, Enforcement, and Criminal Investigations](#) [Enforcement Actions](#) [Warning Letters](#)

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.com¹ and www.liptont.com² 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.gov³.

A link to .your website, www.lipton.com⁴, appears on your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product label. This website directs U.S. visitors to another website, www.liptont.com⁵. We have determined that your websites, www.lipton.com⁶ and www.liptont.com⁷, 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.com⁸, 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](#).

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA No Fear Act](#) [Site Map](#) [Transparency Website](#)
[Policies](#)

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](#)



[For Government](#) [For Press](#)

[Combination Products](#) [Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety](#)
[Emergency Preparedness](#) [International Programs](#) [News & Events](#) [Training and Continuing Education](#)
[Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry](#) [Health Professionals](#) [FDA Archive](#)



U.S. Department of **Health & Human Services**

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>

[Home](#) [Inspections, Compliance, Enforcement, and Criminal Investigations](#) [Enforcement Actions](#) [Warning Letters](#)

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.com³ appears on your Organic Mung Bean Sprouts, Organic Alfalfa Sprouts, Organic Clover Sprouts and Organic Broccoli Sprouts product labels. We have reviewed your 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 leukemia 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; therefore 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 to 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 Organic 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 10 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 20 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 gram 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 claim 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 response 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](#).

[Accessibility](#) [Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA](#) [No Fear Act](#) [Site Map](#) [Transparency](#) [Website Policies](#)

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](#)



For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety
Emergency Preparedness International Programs News & Events Training and Continuing Education
Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive



Links on this page:

1. <http://www.jonathansorganic.com>
2. <http://www.fda.gov>
3. <http://www.jonathansorganic.com>
4. </ICECI/EnforcementActions/WarningLetters/2011/ucm260559.htm>

[Home](#) [Inspections, Compliance, Enforcement, and Criminal Investigations](#) [Enforcement Actions](#) [Warning Letters](#)

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/index.php>³ 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 to demonstrate that the drug is safe and effective.

II. Unauthorized Nutrient Content Claims

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

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

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

Pu-erh Tea

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

Super Green, Organic Japanese Green Tea

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

White Tea

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

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

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

Yerba Maté Shade Grown, Organic Yerba Maté

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

Blueberry Rooibos, Organic Fair Trade Rooibos Blend

- "Antioxidant-rich...."

Green Rooibos (Green Bush), Organic Fair Trade Botanical

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

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

White Tea

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

Matcha, 100% Premium Tea Powder

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

Genmai Green Tea, 100% Premium Tealeaf Powder

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

Green Oolong Tea, 100% Premium Tealeaf Powder

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

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

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

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

Sincerely,

/s/

Gerald J. Berg
Director
Minneapolis District

Close Out Letter

- [Diaspora Tea & Herb Co., LLC - Close Out Letter 2/3/12⁴](#)

Page Last Updated: 02/10/2012

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

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA](#) [No Fear Act](#) [Site Map](#) [Transparency Website](#)
[Policies](#)

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

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



For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety
Emergency Preparedness International Programs News & Events Training and Continuing Education
Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive



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>