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APR - 6 2012

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CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE

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(Co-counsel listed on signature page)

Attorneys for Plaintiff

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8
9 IN THE UNITED STATES DISTRICT COURT
10 FOR THE NORTHERN DISTRICT OF CALIFORNIA
11 SAN JOSE DIVISION

12 *(Handwritten mark)*
13 AMY MAXWELL, individually and on
14 behalf of all others similarly situated,

Plaintiff,

v.

15
16 UNILEVER UNITED STATES, INC.,
17 UNILEVER SUPPLY CHAIN, INC.,
18 and PEPSICO, INC.,

Defendants.

Case No. **CV 12-01736**

CLASS ACTION AND REPRESENTATIVE ACTION

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

JURY TRIAL DEMANDED

HRL

19
20
21 Plaintiff, through her undersigned attorneys, brings this lawsuit against Defendants as to
22 her own acts upon personal knowledge, and as to all other matters upon information and belief.
23 In order to remedy the harm arising from Defendants' illegal conduct, which has resulted in
24 unjust profits, Plaintiff brings this action on behalf of a class of California consumers who
25 purchased Lipton Tea products within the last four years.

26 **INTRODUCTION**

27 1. Every day, millions of Americans purchase and consume packaged foods.
28 Identical federal and California laws require truthful, accurate information on the labels of

1 packaged foods. This case is about a company that flouts those laws, before and after receiving a
2 warning letter from the FDA. The law, however, is clear: misbranded food cannot legally be
3 manufactured, held, advertised, distributed or sold. Misbranded food is worthless as a matter of
4 law, and purchasers of misbranded food are entitled to a refund of their purchase price.

5 2. Unilever is a multinational corporation with 400 brands, including Lipton Tea.
6 Unilever's website claims that "[o]n any given day, two billion people use our products." Lipton
7 employs "more than 80,000 people." According to Unilever, "tea is the second most widely-
8 consumed beverage on earth, behind water." In the U.S., Unilever markets Lipton Tea under
9 more than twelve labels, including Lipton Regular Tea, Lipton Cold Brew Iced Tea Bags, Lipton
10 Green Tea Purple Acai and Blueberry, Lipton Regular Family Size Iced Tea Bags, Lipton Lemon
11 Iced Tea Mix, Lipton Diet Lemon Ice Tea Mix, Lipton Green Tea, Lipton Mandarin Mango
12 Green Tea To Go, Lipton Herbal Chamomile Tea, Lipton Harvest Strawberry & Passion Fruit,
13 Lipton Orange Spice Tea and Lipton Ready to Drink PureLeaf Tea.

14 <http://www.unileverusa.com/brands/foodbrands/lipton/index.aspx>

15 3. Unilever recognizes that health claims drive sales, and actively promotes the health
16 benefits of Lipton Tea, including flavonoids:

17 Made from real tea leaves, many Lipton teas contain tea flavonoids. The flavonoid
18 content per serving can be found on all Lipton tea packages with the Tea Goodness
19 seal which signals that the tea contains a specific level of tea flavonoids.
20 Flavonoids are dietary compounds found in tea, wine, cocoa, fruit and vegetables.
21 They contribute significantly to taste and color, and possibly help maintain certain
normal, healthy body functions. A diet rich in flavonoids is generally associated
with helping maintain normal healthy heart function.

22 <http://www.unileverusa.com/brands/foodbrands/lipton/index.aspx>

23 4. On the Lipton Tea website, Unilever goes even further in promoting the health
24 benefits of Lipton Tea, specifically focusing on tea flavonoids:

25 Studies suggest that drinking black or green tea may help maintain normal, healthy
26 heart function as part of a diet that is consistent with dietary guidelines. Research
27 suggests that drinking 2 to 3 cups per day of black or green tea may help support
normal, healthy vascular function. The mechanism behind this effect has yet to be
fully demonstrated, but research suggests that tea flavonoids may be responsible.

28 http://www.lipton.com/tea_health/healthy_diet/index.aspx

1 5. Unilever makes health nutrient claims directly on packages of Lipton Tea. For
2 example, the package front panel of certain Lipton Tea products bears the “AOX Naturally
3 Protective Antioxidants” label. The back panel further touts the “protective flavonoid
4 antioxidants” and “flavonoid content” of Lipton Tea, by comparing Lipton Tea to “selected
5 beverages and fruits,” including orange juice, broccoli, cranberry juice and coffee. Lipton
6 Decaffeinated Tea Bags, 72 count.

7 6. In promoting the health benefits of its products, including Lipton Tea, Unilever
8 adopted “Global Principles for Responsible Food and Beverage Marketing.” These Global
9 Principles apply to “all of Unilever’s food and beverage marketing activities and
10 communications,” and include the following provisions:

11 These marketing activities and communications include but are not limited to packaging
12 and labeling . . .

13 Marketing communications must comply with all relevant laws/regulations in the local
14 country . . .

15 All food and beverage marketing communications must be truthful and not misleading.

16 [www.unileverusa.com/Images/30370 Global Principles A5 PDF-2 tcm23-48998.pdf](http://www.unileverusa.com/Images/30370_Global_Principles_A5_PDF-2_tcm23-48998.pdf)

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

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

1 9. Under the FDCA, the term “false” has its usual meaning of “untruthful,” while the
2 term “misleading” is a term of art. Misbranding reaches not only false claims, but also those
3 claims that might be technically true, but still misleading. If any one representation in the
4 labeling is misleading, then the entire food is misbranded, nor can any other statement in the
5 labeling cure a misleading statement. “Misleading” is judged in reference to “the ignorant, the
6 unthinking and the credulous who, when making a purchase, do not stop to analyze.” *United*
7 *States v. El-O-Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951). Under the FDCA, it is not
8 necessary to prove that anyone was actually misled.

9 10. On August 23, 2010, the FDA sent a warning letter to Unilever, informing
10 Unilever of its failure to comply with the requirements of the FDCA and its regulations (the
11 “FDA Warning Letter,” attached hereto as Exhibit 1). The FDA Warning Letter stated, in
12 pertinent part:

13 **Unauthorized Nutrient Content Claims**

14 Under section 403(r)(1)(A) of the Act [21 U.S.C. 343(r)(1)(A)], a claim that
15 characterizes the level of a nutrient which is of the type required to be in the
16 labeling of the food must be made in accordance with a regulation promulgated by
17 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.

18 Nutrient content claims using the term “antioxidant” must also comply with the
19 requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for
20 a product to bear such a claim, an RDI must have been established for each of the
21 nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these
22 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
23 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
24 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
25 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”
26 but does not comply with the requirements of 21 CFR 101.54(g) misbrands a
27 product under section 403(r)(2)(A)(i) of the Act.

28 Your webpage entitled “Tea and Health” and subtitled “Tea Antioxidants” includes
the statement, “LIPTON Tea is made from tea leaves rich in naturally protective

1 antioxidants." The term "rich in" is defined in 21 CFR 101.54(b) and may be used
2 to characterize the level of antioxidant nutrients (21 CFR 101.54(g)(3)). However,
3 this claim does not comply with 21 CFR 101.54(g)(4) because it does not include
4 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.

5 This webpage also states that "tea is a naturally rich source of antioxidants." The
6 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
7 Act and 21 CFR 101.13(b)). Even if we determined that the term "rich source"
8 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
9 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
10 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
11 403(r)(2)(A)(i) of the Act.

12 The product label back panel includes the statement "packed with protective
13 FLAVONOID ANTIOXIDANTS." The term "packed with" characterizes the level
of flavonoid antioxidants in the product; therefore, this claim is a nutrient content
14 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
15 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
16 FLAVONOID ANTIOXIDANTS" does not comply with 21 CFR 101.54(g)(1)
because no RDI has been established for flavonoids. Thus, this unauthorized
17 nutrient content claim causes your product to be misbranded under section
403(r)(2)(A)(i) of the Act.
18

19 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
20 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
21 these violations may result in regulatory actions without further notice, such as
seizure and/or injunction.
22

23 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
24 your product with the amount of antioxidants in orange juice, broccoli, cranberry
juice and coffee. However, the information provided may be misinterpreted by the
25 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
26 stating the total amount of antioxidants rather than specifically measuring the
amount of flavonoids in the product.
27

28 <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm224509.htm>

1 11. In response to the FDA Warning letter, Unilever modified its Lipton web site and
2 its packaging by removing some of the most outlandish claims of health and therapeutic benefits
3 that FDA had found in violation of law. However, there are several unlawful statements on
4 Lipton’s web site that remain, including but not limited to: “Flavonoids are dietary compounds
5 found in tea, wine, cocoa, fruit and vegetables. They contribute significantly to taste and color,
6 and possibly help maintain certain normal, healthy body functions. A diet rich in flavonoids is
7 generally associated with helping maintain normal, healthy heart function.” “Flavonoids” are a
8 substance or nutrient without an established referenced daily intake value (“RDI”).

9 12. In addition, the package front panel of many Lipton Tea products contains the
10 following statement: “Regular tea drinking, as part of a healthy diet, may help maintain healthy
11 vascular function.” Such health claims are in violation of 21 U.S.C. § 352(f)(1), and therefore the
12 products are misbranded.

13 13. Defendants have made, and continue to make, food label claims that are prohibited
14 by federal and California law. Under federal and California law, Defendants’ misbranded food
15 products, including Lipton Tea, cannot legally be manufactured, advertised, distributed, held or
16 sold. Defendants’ false and misleading labeling practices stem from their global marketing
17 strategy. Thus, the violations and misrepresentations are similar across product labels and
18 product lines.

19 **PARTIES**

20 14. Plaintiff Amy Maxwell is a resident of San Jose, California who purchased Lipton
21 Tea products in California during the four (4) years prior to the filing of this Complaint (the
22 “Class Period”).

23 15. Defendant Unilever United States, Inc. is a Delaware corporation with its principle
24 place of business at 700 Sylvan Avenue, Englewood Cliffs, New Jersey.

25 16. Defendant Unilever Supply Chain, Inc. is a Delaware corporation with its principle
26 place of business at 800 Sylvan Avenue, Englewood Cliffs, New Jersey.

27 17. Defendant PepsiCo, Inc. (“PepsiCo”) is a North Carolina corporation with its
28 principle place of business at 700 Anderson Hill Road, Purchase, New York.

1 18. In 1991, Unilever created a joint venture with PepsiCo, the Pepsi Lipton
2 Partnership (the "Partnership"), for the marketing of ready to drink teas in North America. The
3 Partnership operates as a subsidiary of PepsiCo, with its principle place of business at 700
4 Anderson Hill Road, Purchase, New York. PepsiCo and Lipton each control 50% of the shares in
5 the Partnership. The Partnership manufactures, distributes and sells certain Lipton Tea products.

6 19. Collectively, Defendants are leading producers of retail food products, including
7 Lipton Tea products. They sell their misbranded food products to consumers through grocery and
8 other retail stores throughout California.

9 **JURISDICTION AND VENUE**

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

14 21. The Court has jurisdiction over the federal claim alleged herein pursuant to 28
15 U.S.C. § 1331, because it arises under the laws of the United States.

16 22. The Court has jurisdiction over the California claims alleged herein pursuant to 28
17 U.S.C. § 1367, because they form part of the same case or controversy under Article III of the
18 United States Constitution.

19 23. Alternatively, the Court has jurisdiction over all claims alleged herein pursuant to
20 28 U.S.C. § 1332, because the matter in controversy exceeds the sum or value of \$75,000, and is
21 between citizens of different states.

22 24. The Court has personal jurisdiction over Defendants because a substantial portion
23 of the wrongdoing alleged in this Complaint occurred in California, Defendants are authorized to
24 do business in California, have sufficient minimum contacts with California, and otherwise
25 intentionally avail themselves of the markets in California through the promotion, marketing and
26 sale of merchandise, sufficient to render the exercise of jurisdiction by this Court permissible
27 under traditional notions of fair play and substantial justice.
28

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

4 **FACTUAL ALLEGATIONS**

5 **A. Identical California And Federal Laws Regulate Food Labeling**

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

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

14 28. In addition to its blanket adoption of federal labeling requirements, California has
15 also enacted a number of laws and regulations that adopt and incorporate specific enumerated
16 federal food laws and regulations. For example, food products are misbranded under California
17 Health & Safety Code § 110660 if their labeling is false and misleading in one or more
18 particulars; are misbranded under California Health & Safety Code § 110665 if their labeling fails
19 to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q) and
20 regulations adopted thereto; are misbranded under California Health & Safety Code § 110670 if
21 their labeling fails to conform with the requirements for nutrient content and health claims set
22 forth in 21 U.S.C. § 343(r) and regulations adopted thereto; are misbranded under California
23 Health & Safety Code § 110705 if words, statements and other information required by the
24 Sherman Law to appear on their labeling are either missing or not sufficiently conspicuous; are
25 misbranded under California Health & Safety Code § 110735 if they are represented as having
26 special dietary uses but fail to bear labeling that adequately informs consumers of their value for
27 that use; and are misbranded under California Health & Safety Code § 110740 if they contain
28

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

3 **B. Defendants' Food Products Are Misbranded**

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

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

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

15 32. 21 C.F.R. § 101.13 provides the general requirements for nutrient content claims,
16 which California has expressly adopted. *See* California Health & Safety Code § 110100. 21
17 C.F.R. § 101.13 requires that manufacturers include certain disclosures when a nutrient claim is
18 made and, at the same time, the product contains certain levels of unhealthy ingredients, such as
19 fat and sodium. It also sets forth the manner in which that disclosure must be made, as follows:

20 (4)(i) The disclosure statement "See nutrition information for ___ content" shall
21 be in easily legible boldface print or type, in distinct contrast to other printed or
22 graphic matter, and in a size no less than that required by §101.105(i) for the net
23 quantity of contents statement, except where the size of the claim is less than two
24 times the required size of the net quantity of contents statement, in which case the
disclosure statement shall be no less than one-half the size of the claim but no
smaller than one-sixteenth of an inch, unless the package complies with
§101.2(c)(2), in which case the disclosure statement may be in type of not less
than one thirty-second of an inch.

25 (ii) The disclosure statement shall be immediately adjacent to the nutrient content
26 claim and may have no intervening material other than, if applicable, other
27 information in the statement of identity or any other information that is required
28 to be presented with the claim under this section (e.g., see paragraph (j)(2) of this
section) or under a regulation in subpart D of this part (e.g., see §§101.54 and
101.62). If the nutrient content claim appears on more than one panel of the label,
the disclosure statement shall be adjacent to the claim on each panel except for the

1 panel that bears the nutrition information where it may be omitted.

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

5 34. An “implied nutrient content claim” is defined as any claim that: (i) describes the
6 food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a
7 certain amount (e.g., “high in oat bran”); or (ii) suggests that the food, because of its nutrient
8 content, may be useful in maintaining healthy dietary practices and is made in association with an
9 explicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams (g) of fat”). 21
10 C.F.R. § 101.13(b)(2)(i-ii).

11 **1. Defendants Make Unlawful Antioxidant Claims**

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

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

16 (2) there must be an established RDI for that antioxidant, and if not, no
17 “antioxidant” claim can be made about it;

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

21 (4) the nutrient that is the subject of the antioxidant claim must also have
22 recognized antioxidant activity, *i.e.*, there must be scientific evidence that after it is eaten and
23 absorbed from the gastrointestinal tract, the substance participates in physiological, biochemical
24

25
26 ¹ Alternatively, when used as part of a nutrient content claim, the term “antioxidant” or
27 “antioxidants” (such as “high in antioxidants”) may be linked by a symbol (such as an asterisk)
28 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 or cellular processes that inactivate free radicals or prevent free radical-initiated chemical
2 reactions, *see* 21 C.F.R. § 101.54(g)(2);

3 (5) the antioxidant nutrient must meet the requirements for nutrient content claims
4 in 21 C.F.R. § 101.54(b), (c), or (e) for “High” claims, “Good Source” claims, and “More”
5 claims, respectively. For example, to use a “High” claim, the food would have to contain 20% or
6 more of the Daily Reference Value (“DRV”) or RDI per serving. For a “Good Source” claim, the
7 food would have to contain between 10-19% of the DRV or RDI per serving, *see* 21 C.F.R. §
8 101.54(g)(3); and

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

13 36. The antioxidant labeling for Lipton Tea products violates California law. The
14 antioxidant claims on the packages of these products violate California law: (1) because the
15 names of the antioxidants are not disclosed on the product labels; (2) because there are no RDIs
16 for the antioxidants being touted, including flavonoids; (3) because the claimed antioxidant
17 nutrients fail to meet the requirements for nutrient content claims in 21 C.F.R. § 101.54(b), (c), or
18 (e) for “High” claims, “Good Source” claims, and “More” claims, respectively; and (4) because
19 Defendants lack adequate scientific evidence that the claimed antioxidant nutrients participate in
20 physiological, biochemical, or cellular processes that inactivate free radicals or prevent free
21 radical-initiated chemical reactions after they are eaten and absorbed from the gastrointestinal
22 tract.

23 37. For example, the package label of Lipton Decaffeinated Tea Bags bears the
24 “Naturally Protective Antioxidants AOX” seal, and the package back panel compares the
25 “Flavonoid Content” of “Lipton Decaf Tea” to orange juice, broccoli, cranberry juice and coffee.
26 Additional specific violations are detailed in the FDA Warning Letter, attached hereto as Exhibit
27 1.

28

1 38. For these reasons, Defendants' antioxidant claims at issue in this Complaint are
2 misleading and in violation of 21 C.F.R. § 101.54 and California law, and the products at issue
3 are misbranded as a matter of law. Misbranded products cannot be legally manufactured,
4 advertised, distributed, held or sold and are legally worthless.

5 39. In addition to the FDA Warning Letter to Unilever discussed above (Exhibit 1),
6 the FDA has issued warning letters addressing similar unlawful antioxidant nutrient content
7 claims. *See, e.g.*, Exhibit 2 (FDA warning letter dated August 30, 2010 to Dr. Pepper Snapple
8 Group regarding its misbranded Canada Dry Sparkling Green Tea Ginger Ale product because
9 green tea and green tea flavonoids "are not nutrients with recognized antioxidant activity");
10 Exhibit 3 (FDA warning letter dated February 22, 2010 to Redco Foods, Inc. regarding its
11 misbranded Salada Naturally Decaffeinated Green Tea product because "there are no RDIs for
12 (the antioxidants) grapeskins, rooibos (red tea) and anthocyanins"); Exhibit 4 (FDA warning letter
13 dated February 22, 2010 to Fleminger Inc. regarding its misbranded TeaForHealth products
14 because the admonition "[d]rink high antioxidant green tea" . . . "does not include the nutrients
15 that are the subject of the claim or use a symbol to link the term antioxidant to those nutrients").
16 Defendants are aware of these FDA warning letters.

17 **2. Defendants Make Unlawful Nutritional Value Claims**

18 40. Defendants have also violated 21 C.F.R. § 101.54(g)(1), which prohibits food
19 manufacturers from making claims regarding the nutritional value of their products when the
20 products fail to disclose that no RDI has been established for the touted nutrients.

21 41. For example, certain Lipton Tea products claim to be "packed with flavonoids" but
22 they fail to disclose that no RDI has been established for flavonoids. Thus, these products violate
23 21 C.F.R. § 101.54(g)(1).

24 42. The types of misrepresentations made above would be considered by a reasonable
25 consumer when deciding to purchase Defendants' misbranded food products. The failure to
26 comply with the labeling requirements of 21 C.F.R. § 101.54 renders Defendants' products
27 misbranded as a matter of federal and California law.

28

1 43. In addition, 21 C.F.R. § 101.65, which has been adopted by California, sets certain
2 minimum nutritional requirements for making an implied nutrient content claim that a product is
3 healthy. For example, for unspecified foods the food must supply at least 10 percent of the RDI
4 of one or more specified nutrients. Defendants have misrepresented the healthiness of their
5 products while failing to meet the regulatory requirements for making such claims.

6 **3. Defendants Make Unlawful “Natural” Claims**

7 44. In its rule-making and warning letters to manufacturers, the FDA has repeatedly
8 stated its policy to restrict the use of the term “natural” in connection with added color, synthetic
9 substances and flavors as provided in 21 C.F.R. § 101.22.

10 45. The FDA has also repeatedly affirmed its policy regarding the use of the term
11 “natural” as meaning that nothing artificial or synthetic (including all color additives regardless of
12 source) has been included in, or has been added to, a food that would not normally be expected to
13 be in the food.

14 46. For example, 21 C.F.R. § 70.3(f) makes clear that “where a food substance such as
15 beet juice is deliberately used as a color, as in pink lemonade, it is a color additive.” Similarly,
16 any coloring or preservative can preclude the use of the term “natural” even if the coloring or
17 preservative is derived from natural sources. Further, the FDA distinguishes between natural and
18 artificial flavors in 21 C.F.R. § 101.22.

19 47. Defendants’ “all natural” labeling practices violate FDA Compliance Guide CPG
20 Sec. 587.100, which states: [t]he use of the words “food color added,” “natural color,” or similar
21 words containing the term “food” or “natural” may be erroneously interpreted to mean the color is
22 a naturally occurring constituent in the food. Since all added colors result in an artificially
23 colored food, we would object to the declaration of any added color as “food” or “natural.”

24 48. Likewise, California Health & Safety Code § 110740 prohibits the use of artificial
25 flavoring, artificial coloring and chemical preservatives unless those ingredients are adequately
26 disclosed on the labeling.

27 49. The FDA has sent out numerous warning letters concerning this issue. *See, e.g.,*
28 Exhibit 5 (August 16, 2001 FDA warning letter to Oak Tree Farm Dairy because there was citric

1 acid in its all natural iced tea); Exhibit 6 (August 29, 2001 FDA warning letter to Hirzel Canning
2 Company because there was citric acid or calcium chloride in its all natural tomato products);
3 Exhibit 7 (August 2, 2001 FDA warning letter to GMP Manufacturing, Inc. stating: “[t]he
4 products, Cytomax Exercise and Recovery Drink (Peachy Keen flavor) and Cytomax Lite
5 (Lemon Iced Tea Flavor) are misbranded because they contain colors but are labeled using the
6 term “no artificial colors.”). Defendants are aware of these FDA warning letters.

7 50. Defendants have unlawfully labeled a number of their food products as being “all
8 natural” or “made with natural ingredients” when they actually contain artificial ingredients and
9 flavorings, artificial coloring and chemical preservatives. These products include Lipton Pure
10 Leaf Tea products and Lipton Iced Tea products.

11 51. For example, the label of Lipton 100% Iced Green Tea with Citrus states that it is
12 “100% natural” despite the fact that it contains a number of chemicals, preservatives and artificial
13 flavorings including sugar, citric acid, acerola, fruit extract, REB A (purified stevia extract).

14 52. Consumers are thus misled into purchasing Defendants’ products with synthetic
15 unnatural ingredients that are not “all natural” as falsely represented on their labeling.
16 Defendants’ products in this respect are misbranded under federal and California law.

17 **4. Defendants Make Unlawful Health Claims**

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

25 54. 21 C.F.R. § 101.14, which has been expressly adopted by California, provides
26 when and how a manufacturer may make a health claim about its product. A “Health Claim”
27 means any claim made on the label or in labeling of a food, including a dietary supplement, that
28 expressly or by implication, including “third party” references, written statements (*e.g.*, a brand

1 name including a term such as “heart”), symbols (e.g., a heart symbol), or vignettes, characterizes
2 the relationship of any substance to a disease or health-related condition. Implied health claims
3 include those statements, symbols, vignettes, or other forms of communication that suggest,
4 within the context in which they are presented, that a relationship exists between the presence or
5 level of a substance in the food and a disease or health-related condition (see 21 CFR
6 101.14(a)(1)).

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

12 56. A claim that a substance may be used in the diagnosis, cure, mitigation, treatment,
13 or prevention of a disease is a drug claim and may not be made for a food. 21 U.S.C. §
14 321(g)(1)(D).

15 57. The use of the term “healthy” is not a health claim but rather an implied nutrient
16 content claim about general nutrition that is defined by FDA regulation. In general, the term may
17 be used in labeling an individual food product that:

18 Qualifies as both low fat and low saturated fat;

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

22 Does not exceed the disclosure level for cholesterol (*e.g.*,
23 for most individual food products, 60 mg or less per
reference amount and per labeled serving size); *and*

24 Except for raw fruits and vegetables, certain frozen or
25 canned fruits and vegetables, and enriched cereal-grain
26 products that conform to a standard of identity, provides at
27 least 10% of the daily value (DV) of vitamin A, vitamin C,
calcium, iron, protein, *or* fiber per reference amount.
28 Where eligibility is based on a nutrient that has been added
to the food, such fortification must comply with FDA’s
fortification policy.

1 21 C.F.R. § 101.65(d)(2). The FDA's definition applies separate criteria to use of healthy on raw,
2 single ingredient seafood or game meat products. 21 C.F.R. § 101.65(d)(2)(ii). FDA's regulation
3 on healthy also encompasses other, derivative uses of health (*e.g.*, healthful, healthier) in food
4 labeling. 21 C.F.R. § 101.65(d).

5 58. Unilever has violated the provisions of § 21 C.F.R. §101.14, 21 C.F.R. §101.65,
6 21 U.S.C. § 321(g)(1)(D) and 21 U.S.C. § 352(f)(1) on a number of its products and on its
7 website. For example, until recently on the link to its webpage entitled "Tea and Health,"
8 subtitled "Heart Health Research" and further subtitled "Cholesterol Research" the following
9 claim is made: "[F]our recent studies in people at risk for coronary disease have shown a
10 significant cholesterol lowering effect from tea or tea flavonoids ... One of these studies, on post-
11 menopausal women, found that total cholesterol was lowered by 8% after drinking 8 cups of
12 green tea daily for 12 weeks" The therapeutic claims on its website establish that the product is
13 a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease.
14 Lipton's products are not generally recognized as safe and effective for the above referenced uses
15 and, therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)].
16 New drugs may not be legally marketed in the U.S. without prior approval from FDA as
17 described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the
18 basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and
19 effective.

20 59. As discussed in paragraph 8 and as shown in Exhibit 1, the FDA conducted a
21 review of one of Defendant's products (Lipton Green Tea 100% Natural Naturally Decaffeinated
22 Tea) and concluded that Lipton was "in violation of the Federal Food, Drug, and Cosmetic Act ...
23 and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101)."
24 FDA found the product to be misbranded stating, "Your Lipton Green Tea 100% Natural
25 Naturally Decaffeinated product is offered for conditions that are not amenable to self-diagnosis
26 and treatment by individuals who are not medical practitioners; therefore, adequate directions for
27 use cannot be written so that a layperson can use this drug safely for its intended purposes. Thus,
28 your Lipton Green Tea 100% Natural Naturally Decaffeinated product is misbranded under

1 section 502(f)(1) of the Act in that the labeling for this drug fails to bear adequate directions for
2 use [21 U.S.C. § 352(f)(1)].” See Exhibit 1.

3 60. In response to the FDA Warning Letter, Lipton modified its web site and its
4 packaging by removing some of the most outlandish claims of health and therapeutic benefits that
5 FDA had found in violation of law. However, there are several objectionable statements on
6 Lipton’s web site that remain. On the present day web site the following statement appears:
7 “Flavonoids are dietary compounds found in tea, wine, cocoa, fruit and vegetables. They
8 contribute significantly to taste and color, and possibly help maintain certain normal, healthy
9 body functions. A diet rich in flavonoids is generally associated with helping maintain normal,
10 healthy heart function.” And the package front panel of many Lipton Tea products claims a level
11 of “flavonoids,” a substance or nutrient without an established referenced daily intake value
12 (RDI), and contains the following statement, “Regular tea drinking, as part of a healthy diet, may
13 help maintain healthy vascular function.” Such health claims are in violation of 21 U.S.C. §
14 352(f)(1) and therefore the products are misbranded.

15 61. Not only do Unilever’s health claims regarding the benefits of “tea flavonoids”
16 violate FDA rules and regulations, they directly contradict Unilever’s own scientific research,
17 which has concluded: “[T]he evidence today does not support a direct relationship between tea
18 consumption and a physiological AOX [antioxidant] benefit.” This conclusion was reported by
19 Dr. Jane Rycroft, Director of Lipton Tea Institute of Tea, in an article published in January, 2011,
20 in which Dr. Rycroft states:

21 Only a few scientific publications report an effect of tea on free radical damage in humans
22 using validated biomarkers in well designed human studies. Unfortunately, the results of
23 these studies are at variance and the majority of the studies do not report significant
effects . . .

24 Therefore, despite more than 50 studies convincingly showing that flavonoids possess
25 potent antioxidant activity *in vitro*, the ability of flavonoids to act as an antioxidant *in vivo*
[in humans], has not been demonstrated.

26 Based on the current scientific consensus that the evidence today does not support a direct
27 relationship between tea consumption and a physiological AOX benefit . . .

28 No evidence has been provided to establish that having antioxidant activity/
content and/or antioxidant properties is a beneficial physiological effect.

1 Rycroft, Jane, "The Antioxidant Hypothesis Needs to be Updated", Vol. 1, *Tea Quarterly Tea*
2 *Science Overview*, Lipton Tea Institute of Tea Research (Jan. 2011), pp. 2-3. Nonetheless,
3 Unilever continues to tout the benefits of "tea flavonoids" on its product labels and on its website.

4 **C. Defendants Have Violated California Law**

5 62. Defendants have manufactured, advertised, distributed and sold products that are
6 misbranded under California law. Misbranded products cannot be legally manufactured,
7 advertised, distributed or sold and are legally worthless as a matter of law.

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

12 64. Defendants have violated California Health & Safety Code § 110395 which makes
13 it unlawful to manufacture, sell, deliver, hold or offer to sell any misbranded food.

14 65. Defendants have violated California Health & Safety Code § 110398 which makes
15 it unlawful to deliver or proffer for delivery any food that has been falsely advertised.

16 66. Defendants have violated California Health & Safety Code § 110660 because their
17 labeling is false and misleading in one or more ways, as follows:

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

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

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

27
28

1 67. Defendants have violated California Health & Safety Code § 110760 which makes
2 it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is
3 misbranded.

4 68. Defendants have violated California Health & Safety Code § 110765 which makes
5 it unlawful for any person to misbrand any food.

6 69. Defendants have violated California Health & Safety Code § 110770 which makes
7 it unlawful for any person to receive in commerce any food that is misbranded or to deliver or
8 proffer for deliver any such food.

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

12 71. Defendants have violated the standards set by 21 CFR §§ 101.13, and 101.54,
13 which have been adopted by reference in the Sherman Law, by including unauthorized
14 antioxidant claims on their products.

15 **D. Plaintiff Purchased Defendants' Misbranded Food Products**

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

18 73. Plaintiff purchased Defendants' misbranded food products at issue in this
19 Complaint, including certain Lipton Tea products, on occasions during the Class Period.

20 74. Plaintiff purchased the following Lipton Tea products:

21 Lipton Pureleaf Sweetened bottled iced tea, 16 oz. glass bottle

