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6	UNITED STATES	DISTRICT COURT
7	NORTHERN DISTRI	CT OF CALIFORNIA
8	SAN JOSE	DIVISION
9 10	NANCY LANOVAZ, individually and on behalf of all others similarly situated,	Case No. 5:12-cv-02646-RMW
11	Plaintiff,	AMENDED CLASS ACTION AND REPRESENTATIVE ACTION
12 13	v. TWININGS OF NORTH AMERICA, INC.,	THIRD AMENDED COMPLAINT FOR DAMAGES, EQUITABLE AND INJUNCTIVE RELIEF
14 15	Defendant.	JURY TRIAL DEMANDED
 16 17 18 19 20 21 22 23 24 25 26 27 28 	her own acts upon personal knowledge and as to order to remedy the harm arising from Defendant profits, Plaintiff brings this action on behalf of a 2, 2008 to the present (the "Class Period"), purch products for personal or household use ("Misbrar <u>INTROD</u>	's illegal conduct, which has resulted in unjust class of all persons in California who, since May ased Defendant's green, black, and white tea nded Food Products"). <u>UCTION</u> purchase and consume packaged foods. In order California laws require truthful, accurate s case is about a company that flouts those laws n similar claims on their labels received warning
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1	Defendant was and is fully aware of these laws as well as FDA guidance documents on the
2	subjects, and the aforementioned warning letters. The law is clear: misbranded food cannot
3	legally be manufactured, held, advertised, distributed or sold. Misbranded food has no economic
4	value and is worthless as a matter of law, and purchasers of misbranded food are entitled to a
5	refund of their purchase price or other relief and compensation as determined by this Court.
6	2. Defendant Twinings of North America, Inc. (hereinafter "Twinings" or
7	"Defendant") is a tea company based in Clifton, New Jersey. Twinings is a wholly owned
8	subsidiary of Associated British Foods which is based in London, England. It markets over 50
9	varieties of tea, including green, black, red, and white teas.
10	3. Twinings recognizes that health claims drive sales. It actively promotes the
11	presence of antioxidants and other nutrients in its tea products and the alleged health benefits
12	from using these products. It does this on its product labels, its product labeling which includes
13	the website referenced on its product packaging, and its press releases and other marketing and
14	advertising materials. For example, on its website Twinings states (emphasis added):
15 16	You might not have heard of them, but flavonoid antioxidants are naturally present in lots of food, including fruit, vegetables and tea.
17	Along with other antioxidants like vitamin C, vitamin A and chlorophyll, flavonoid antioxidants can help to keep cells and tissues healthy .
18 19 20	They do this by mopping up free radicals—atoms or molecules with unpaired electrons. Free radicals are made by all living organisms, but they're also in things like pollution. While we all need free radicals, a build-up in our bodies can damage cells and DNA.
21 22	Green tea is naturally rich in antioxidants that may help protect the body from damage caused by free radicals.
23	
24	Did you know: Tea is a healthy beverage. Rich in antioxidants , refreshing and less than 1 calorie per serving if you don't add sugar or milk.
25 26	http://www.twiningsusa.com/template.php?id=22.
26 27	4. Twinings makes unlawful (i) health claims, (ii) nutrient content claims and (iii)
27 28	antioxidant related nutrient content claims directly on packages of the Misbranded Food Products.
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1	5. All Misbranded Food Products are substantially similar. The products are of a
2	single kind (tea). According to the Defendant all products come from the same plant—Camellia
3	sinensis. The process used (fermentation, oxidation, etc.) determines classification of the tea
4	(green, black, white or red). The only difference is flavor. All of Twinings' green, black and
5	white tea products share the same size and shape packaging.
6	6. Substantially similar unlawful antioxidant related nutrient content claims appear
7	on the labels of each of these Misbranded Food Products and in claims on its website which
8	Plaintiff reviewed at various times during the Class Period.
9	<u>GREEN TEA</u>
10	7. Defendant has sold at least the following green tea products in the Class Period:
11	Green Tea
12	Camomile Green Tea Mint Green Tea
13	Gunpowder Green Tea Green Tea with Jasmine 100% Organic & Fair Trade Certified
14	Green Tea with Mint Organic & Fair Trade Certified Jasmine Green Tea
15	Lemon Green Tea Lemon Green Tea
16	Cranberry Green Tea Pure Green 100% Organic & Fair Trade Certified
17	Green Tea with a hint of Citrus Organic & Fair Trade Certified Green Tea Decaffeinated
18	Green Tea with Mint Cold Brewed Iced Tea
19	The label of each green tea product listed in this paragraph, including Twinings' Green Tea,
20	Green Tea Decaffeinated, and Jasmine Green Tea (all purchased by Plaintiff), bear the statement
21	"Natural Source of Antioxidants." Attached hereto as Exhibit 1 is a compilation of pictures of
22	Twinings green tea products as depicted on its website showing that each product has the same
	unlawful "Natural Source of Antioxidants" claim in a banner across the top left of the front of the
23	package. Such claims have been repeatedly targeted by the FDA as unlawful for tea and other
24	food products. Additionally, upon information and belief, the label of all green tea products,
25	including Twinings' Jasmine Green Tea purchased by Plaintiff unlawfully boasts "A natural
26	source of protective antioxidants and blended using only 100% natural ingredients, Twinings
27	Green Tea provides a great tasting and healthy tea experience." This same unlawful claim
28	
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1 appears on all the other Twinings green tea products as well. Such claims have been repeatedly

2 targeted by the FDA as unlawful for tea and other food products. Plaintiff saw and relied on these



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1	LABEL #2
2	GREEN TEA
3	JASMINE
4	Pure Green Tea expertly blended with the fresh scent of jasmine flowers to deliver a "Natural Source of Antioxidants"
5	fragrant tea with a unique floral aroma and taste.
6	NATURAL SOURCE
7	OF ANTIOXIDANTS
8	GREEN TEAS SMOOTH, FRESH & AROMATIC For over 300 years Twinings has been sources "A natural source of
9	and blending the finest, the has been as the protective antioxidants and blended using only 100%
10	wholesome tea with a fresh taste, smooth flavour and enticing aroma. A natural source of protective
11	tasting and healthy tea experience. THE TWININGS STORY experience "
12	In 1706 Thomas Twining began selling fine tea In 1706 Thomas Twining began selling fine tea from an English storefront in The Strand, London, from an English storefront in the world's best
13	
14	BLACK AND WHITE TEA
15	8. Statements similar to those appearing on the packages of all of the Twinings green
16	tea products also appear on each of the other Misbranded Food Products manufactured and sold
17	by the Defendant, including all of its black and white tea products including the following:
18	Twinings Black Tea
19	Lady Grey English Breakfast
20	Prince of Wales Variety Pack black Teas
21	Darjeeling Ceylon Orange Pekoe
22	Blackcurrant Breeze Orange Bliss Pomegranate Delight
23	Breakfast Blend 100% Organic & Fair Trade Certified Christmas Tea
24	Earl Grey English Afternoon
25	Irish Breakfast Lapsong Souchong
26	China Oolong Mixed Berry
27	Lemon Twist Pure Mint Earl Grey Organic & Fair Trade Certified
28	Black Tea with Lemon 100% Organic & Fair Trade Certified
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1 2 3 4 5 6 7 8 9	Chai Almond Chai Hazelnut Chai Ultra Spice Chai Spiced Apple Chai French Vanilla Chai Pumpkin Spice Chai Decaf Chai Lady Grey Decaf Tea Earl Grey Decaf Tea Irish Breakfast Decaf Tea English Breakfast Decaf Tea English Classic Cold Brewed Iced Tea Citrus Twist Cold Brewed Iced Tea English Classic Cold Brewed Iced Tea Lady Grey Cold Brewed Iced Tea Mixed Berries Cold Brewed Iced Tea
10	Twinings White Tea
11	Pure White Tea
12	9. These claims violate the same statutory provisions as the claims on the green tea
13	and are factually indistinguishable from those claims. Each of Defendant's black and white tea
14	products, including Twinings' (i) Earl Grey Black Tea, (ii) Black Tea with Lemon Organic and
15	Fair Trade Certified, and (iii) Lemon Twist (black tea) purchased by the Plaintiff has the same
16	unlawful "Tea is a Natural Source of Antioxidants" seal on the label. Such claims have been
17	repeatedly targeted by the FDA as unlawful for tea and other food products. As will be fully
18	shown in this Third Amended Complaint claims that Twinings' teas "contain" or "provide" or are
19	a "natural source" of antioxidants are false and unlawful. Defendant's teas do not meet the
20	minimum nutrient level threshold to make such a claim which is 10% or more of the RDI or the
21	DRV of a nutrient with a recognized RDI per reference amount customarily consumed. Said seal
22	which appears an all Twinings Black and White tea is shown below.
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1 10. For example, as shown below the Earl Grey Tea (black tea) product purchased by 2 Plaintiff has the ubiquitous seal "tea is a natural source of antioxidants" as do all other black and 3 white tea products. 4 5 EARL GREY TEA 6 7 "Tea is a Natural Source 8 Of Antioxidants" Twinings has been blending my family tea for years. 9 Today, I am proud to continue this tradition with the tea celebrated throughout the world 10 known as Twinings Earl Grey. Legend 11 has it that my ancestor, the second Earl Grey, was presented with this 12 exquisite recipe by an envoy on his 13 return from China. a shith Earl Grey 14

11. During various times during the Class Period, Plaintiff read the antioxidant related 16 nutrient content claims regarding the presence of beneficial antioxidants and the health claims 17 appearing on Defendant's labels as specified above and on Twinings website and relied on this 18 information in making her decisions to purchase Defendant's tea products. Plaintiff paid a 19 premium for Defendant's products with the purported nutritional and health benefits. Had 20 Plaintiff known the truth-- that the products did not in fact contain recognized and accepted 21 nutritional and healthful value, Plaintiff would not have paid such a premium or would not have 22 bought the products. 23

2412. If a manufacturer is going to make a claim on a food label, the label must meet25certain legal requirements that help consumers make informed choices and ensure that they are26not misled. As described more fully below, Defendant has made, and continues to make, false27and deceptive claims in violation of federal and California laws that govern the types of28representations that can be made on food labels. These laws recognize that reasonable consumers

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1	are likely to choose products claiming to have a health or nutritional benefit over otherwise
2	similar food products that do not claim such benefits.
3	13. On its website, Twinings also promotes the health benefits of its tea
4	products, specifically focusing on antioxidants. It also claims that its green, black and
5	white teas are "rich" or "high" or "contain" antioxidants. The website contains the
6	following statements (emphasis added):
7 8	DID YOU KNOW? Tea is a healthy beverage. Rich in antioxidants , refreshing and less than 1 calorie per serving if you don't add sugar or milk.
9	
10	ANTIOXIDANTS
11	You might not have heard of them, but flavonoid antioxidants are naturally present in lots of food, including fruit, vegetables and tea. Along with other
12	antioxidants like vitamin C, vitamin A and chlorophyll, flavonoid antioxidants can help to keep cells and tissues healthy.
13	They do this by mopping up free radicals—atoms or molecules with unpaired electrons. Free radicals are made by all living organisms, but they're also in things
14	like pollution. While we all need free radicals, a build-up in our bodies can damage cells and DNA.
15	Green teas aren't oxidised at all, which lets the tea leaves retain their green colour
16 17	and keep their very delicate flavour. To prevent the freshly picked leaves from oxidising, green tea leaves are either pan fried or steamed to kill active enzymes in the leaf before rolling. Green tea is naturally rich in antioxidants that may help protect the body from damage caused by free radicals.
18	What are antioxidants?
19	See Health Benefits. All tea has antioxidants (Black, Oolong, Green, and Rooibos Red
20	Tea). Levels of antioxidants will vary by tea type due to the product process. A growing body of research indicates that the tannins in tea are naturally-occurring flavonoids which
21	have strong antioxidant properties. Drinking tea is a natural and pleasant way to increase dietary intake of antioxidants.
22	Decaffeination Process: The Twinings Way Decaffeinating does not affect the beneficial antioxidant properties of tea.
23	http://www.twiningsusa.com.
24	<u>intp://www.twiningsusa.com</u> .
25	14. Plaintiff reviewed the website at various times during the Class Period and read the
26	health claims and antioxidant related nutrient content claims appearing on Defendant's website as
27	specified above prior to purchasing said products and relied on this information in making her
28	decisions to purchase Defendant's tea products.
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- 1 15. In doing so, Twinings uses its website to make unlawful (i) antioxidant related 2 nutrient content claims and (ii) health claims that have been expressly condemned by the Federal 3 Food and Drug Administration ("FDA") in numerous enforcement actions and warning letters.
- 4 16. These health claims and antioxidant related nutrient content claims on Twinings' 5 website become part of the product labels because all Misbranded Food Products have Twinings' 6 website on the label, www.twiningsusa.com, and refer consumers to the website for more 7 information.
- 8 17. Under federal and California law (21 U.S.C. § 321(m)) these 9 claims/representations are incorporated into the labels as if the physical product label itself 10 contained the language found on Defendant's website. The label reference to a website becoming 11 part of the label was pointed out by FDA in warning letters to other tea companies, including 12 Unilever for its Lipton Tea products as shown in Exhibit 2 attached hereto and made a part hereof 13 by reference, in which FDA stated: "A link to your website... appears on ... product label... We 14 have determined that your websites... are labeling within the meaning of 201(m) of the act...." 15 Therefore, all of Defendant's Misbranded Food Products are misbranded.
- 16 18. During various times during the Class Period, Plaintiff read the health claims and 17 nutrient content (antioxidant and other) claims appearing on Defendant's product labels as 18 specified above including the claims that Twinings Tea was "natural source of antioxidants" and 19 "*natural source of protective antioxidants*" prior to purchasing said products relied on this 20 information in making her decisions to purchase Defendant's tea products. During various times 21 during the Class Period and before purchasing Twinings' tea products, Plaintiff also read the 22 health claims and nutrient content (antioxidant and other) claims appearing on Defendant's 23 website as specified above including the claims that Defendants' tea was "rich in antioxidants", 24 "contains antioxidants", "natural source of antioxidants" as well as the claims that "Black and 25 green teas also contain Vitamins A, B1, B2 and B6, along with calcium, zinc and folic acid. Tea is 26 also a rich source of potassium—vital for maintaining a normal heartbeat and regulating fluid 27 levels in cells and manganese, an essential mineral for bone growth" and relied on this 28 information in making her decisions to purchase Defendant's tea products. Plaintiff paid a THIRD AMENDED CLASS ACTION COMPLAINT 9

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1	premium for Defendant's products with the purported health benefits. Had Plaintiff known the
2	truth that the products did not in fact contain recognized and accepted nutritional and healthful
3	value, Plaintiff would not have paid such a premium or would not have bought the products.
4	19. Under California law, which is identical to federal law, a number of the
5	Defendant's food labeling practices are unlawful because they are deceptive and misleading to
6	consumers. These include:
7 8	a. Making unlawful nutrient content claims on the labels of food products that fail to meet the minimum nutritional requirements legally required for the nutrient content claims being made;
9 10	b. Making unlawful antioxidant claims on the labels of food products that fail to meet the minimum nutritional requirements legally required for the antioxidant claims being made;
11 12	c. Making unlawful and unapproved health claims about their products that are prohibited by law; and
12 13 14	d. Making unlawful claims that suggest to consumers that their products can prevent the risk or treat the effects of certain diseases like cancer or heart disease.
15	20. These practices are not only illegal but they mislead consumers and deprive them
16	of the information they require to make informed purchasing decisions. Thus, for example, a
17	mother who reads labels because she wants to purchase healthy foods for her family would be
18	misled by Defendant's practices and labeling.
19	21. California and federal laws have placed numerous requirements on food
20	companies that are designed to ensure that the claims that companies make about their products to
21	consumers are truthful, accurate and backed by acceptable forms of scientific proof. When a
22	company such as Twinings makes unlawful antioxidant related nutrient content or health claims
23	that are prohibited by regulation, consumers such as Plaintiff are misled.
24	22. Identical federal and California laws regulate the content of labels on packaged
25	food. The requirements of the federal Food Drug & Cosmetic Act, 21 U.S.C. § 301 et seq.
26	("FDCA") were adopted by the California legislature in the Sherman Food Drug & Cosmetic
27	Law, California Health & Safety Code § 109875 et seq. (the "Sherman Law"). Under both the
28	Sherman Law and FDCA section 403(a), food is "misbranded" if "its labeling is false or
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1 misleading in any particular," or if it does not contain certain information on its label or in its 2 labeling. 21 U.S.C. § 343(a). Under the FDCA, the term "false" has its usual meaning of "untruthful," while the 3 23. 4 term "misleading" is a term of art. Misbranding reaches not only false claims, but also those 5 claims that might be technically true, but still misleading. If any one representation in the 6 labeling is misleading, then the entire food is misbranded, and no other statement in the labeling 7 can cure a misleading statement. "Misleading" is judged in reference to "the ignorant, the 8 unthinking and the credulous who, when making a purchase, do not stop to analyze." United 9 States v. El-O-Pathic Pharmacy, 192 F.2d 62, 75 (9th Cir. 1951). Under the FDCA, it is not 10 necessary to prove that anyone was actually misled. 11 24. On August 23, 2010, the FDA sent a warning letter to Unilever, the parent 12 company of Lipton Tea, one of Twinings' biggest competitors, informing Unilever of Lipton 13 Tea's failure to comply with the FDCA and its regulations (the "FDA Warning Letter," is 14 attached hereto as Exhibit 2) for remarkably similar nutrient content claims to those Twinings is 15 presently making on its product labels. The FDA Warning Letter to Unilever stated, in pertinent 16 part: 17 **Unauthorized Nutrient Content Claims** 18 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 19 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 20 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. 21 Nutrient content claims using the term "antioxidant" must also comply with the 22 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 23 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 24 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)). 25 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). 26 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 27 "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 28 the name or names of the nutrients with recognized antioxidant activity (21 CFR

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1	101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant"	
2	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.	
3	Your webpage entitled "Tea and Health" and subtitled "Tea Antioxidants" includes the statement, "LIPTON Tea is made from tea leaves rich in naturally	
4	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	
5	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	
6	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.	
7	This webpage also states: "[t]ea is a naturally rich source of antioxidants." The	
8	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	
9	Act and 21 CFR 101.13(b)). Even if we determined that the term "rich source"	
10	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	
11	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	
12	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	
13	403(r)(2)(A)(i) of the Act.	
14	The product label back panel includes the statement "packed with protective FLAVONOID ANTIOXIDANTS." The term "packed with" characterizes the level	
15	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	
16	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	
17	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)	
18	because no RDI has been established for flavonoids. Thus, this unauthorized nutrient content claim causes your product to be misbranded under section	
19	403(r)(2)(A)(i) of the Act.	
20	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	
21	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	
22	these violations may result in regulatory actions without further notice, such as seizure and/or injunction.	
23	http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm224509.htm.	
24		
25	As shown above, the label on Twinings green tea products contains the unlawful	
26	statement " <i>Natural Source of Antioxidants</i> ." The label also touts the " <i>Natural Source of</i>	
27	Protective Antioxidants". The label also touts claimed health benefits from drinking these tea	
28	products, "healthy tea experience". Similarly, the labels of Twinings black and white tea produc	rts
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contain the unlawful statement "*tea is a natural source of antioxidants*". As made clear by
governing regulations such as 21 C.F.R. §§ 101.13, 101.54 and 101.65 such claims are unlawful
and as determined by the FDA in the Unilever/Lipton warning letter, such nutrient content and
health claims are in violation of such regulations and 21 U.S.C. § 352(f)(1), and therefore the
products are misbranded.

6 25. Defendant has made, and continues to make, food label claims that are prohibited 7 by California and federal law. Under California and federal law, Defendant's Misbranded Food 8 Products cannot legally be manufactured, advertised, distributed, held or sold. Defendant's false 9 and misleading labeling practices stem from its global marketing strategy. Thus, the violations 10 and misrepresentations are similar across product labels and product lines. Defendant's violations 11 of law are numerous and include: (1) the illegal advertising, marketing, distribution, delivery and 12 sale of Defendant's Misbranded Food Products to consumers and (2) the utilization of unlawful 13 nutrient content claims (antioxidant and otherwise) and health claims on its product labels and 14 website.

15

PARTIES

16 26. Plaintiff Nancy Lanovaz is a resident of Los Gatos, California who purchased
17 Misbranded Food Products in California since May 2, 2008, four (4) years prior to the filing of
18 the original complaint.

19 27. Defendant, Twinings of North America, Inc. is a Delaware corporation with its
20 principle place of business in Clifton, New Jersey. Twinings is one of the largest tea producers in
21 the country with sale in the hundreds of millions of dollars over the Class Period.

22 28. Twinings is a leading producer of retail specialty tea products including green,
23 black and white and products. Twinings sells its Misbranded Food Products to consumers through

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JURISDICTION AND VENUE

grocery stores, other retail stores and on its website throughout the United States and California.

26 29. This Court has original jurisdiction over this action under 28 U.S.C. § 1332(d)

27 because this is a class action in which: (1) there are over 100 members in the proposed class;

28 (2) members of the proposed class have a different citizenship from Defendant; and (3) the claims

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1	of the proposed class members exceed \$5,000,000 in the aggregate whether the class is limited to
2	products purchased by Plaintiff or is extended to other Twinings tea products with similar, if not
3	identical, unlawful claims on the packages and on Twinings' website.
4	30. Alternatively, the Court has jurisdiction over all claims alleged herein pursuant to
5	28 U.S.C. § 1332, because the matter in controversy exceeds the sum or value of \$75,000, and is
6	between citizens of different states.
7	31. The Court has personal jurisdiction over Defendant because a substantial portion
8	of the wrongdoing alleged in this Third Amended Complaint occurred in California, Defendant is
9	authorized to do business in California, has sufficient minimum contacts with California, and
10	otherwise intentionally avails itself of the markets in California through the promotion, marketing
11	and sale of merchandise, sufficient to render the exercise of jurisdiction by this Court permissible
12	under traditional notions of fair play and substantial justice.
13	32. Because a substantial part of the events or omissions giving rise to these claims
14	occurred in this District and because the Court has personal jurisdiction over Defendant, venue is
15	proper in this Court pursuant to 28 U.S.C. § 1391(a) and (b).
16	FACTUAL ALLEGATIONS
17	A. <u>Identical California and Federal Laws Regulate Food Labeling</u>
18	33. Food manufacturers are required to comply with federal and state laws and
19	regulations that govern the labeling of food products. First and foremost among these is the
	regulations that govern the labeling of food products. First and foremost among these is the FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101.
19	
19 20	FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101.
19 20 21	FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101.34. Pursuant to the Sherman Law, California has expressly adopted the federal
19 20 21 22	 FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101. 34. Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements as its own and indicated that "[a]ll food labeling regulations and any
 19 20 21 22 23 	 FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101. 34. Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements as its own and indicated that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993,
 19 20 21 22 23 24 	 FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101. 34. Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements as its own and indicated that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food regulations of this state." California Health &
 19 20 21 22 23 24 25 	 FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101. 34. Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements as its own and indicated that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food regulations of this state." California Health & Safety Code § 110100.
 19 20 21 22 23 24 25 26 	 FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101. 34. Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements as its own and indicated that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food regulations of this state." California Health & Safety Code § 110100. 35. Pursuant to the Sherman Law, California has expressly adopted the federal

1 or adopted on or after that date shall be the food regulations of this state." California Health & 2 Safety Code § 110100.

3 36. In addition to its blanket adoption of federal labeling requirements, California has 4 also enacted a number of laws and regulations that adopt and incorporate specific enumerated 5 federal food laws and regulations. For example, food products are misbranded under California 6 Health & Safety Code § 110660 if their labeling is false and misleading in one or more 7 particulars; are misbranded under California Health & Safety Code § 110665 if their labeling fails 8 to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q) and 9 regulations adopted thereto; are misbranded under California Health & Safety Code § 110670 if 10 their labeling fails to conform with the requirements for nutrient content and health claims set 11 forth in 21 U.S.C. § 343(r) and regulations adopted thereto; are misbranded under California 12 Health & Safety Code § 110705 if words, statements and other information required by the 13 Sherman Law to appear on their labeling are either missing or not sufficiently conspicuous; are 14 misbranded under California Health & Safety Code § 110735 if they are represented as having 15 special dietary uses but fail to bear labeling that adequately informs consumers of their value for 16 that use; and are misbranded under California Health & Safety Code § 110740 if they contain 17 artificial flavoring, artificial coloring and chemical preservatives but fail to adequately disclose 18 that fact on their labeling.

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B. **FDA Enforcement History**

20 37. In recent years the FDA has become increasingly concerned that food 21 manufacturers were disregarding food labeling regulations. To address this concern, the FDA 22 elected to take steps to inform the food industry of its concerns and to place the industry on notice 23 that food labeling compliance was an area of enforcement priority.

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38. In October 2009, the FDA issued a *Guidance For Industry: Letter Regarding* 25 *Point Of Purchase Food Labeling* to address its concerns about front of package labels ("2009 26 FOP Guidance"). The 2009 FOP Guidance advised the food industry:

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FDA's research has found that with FOP labeling, people are less likely to check the Nutrition Facts label on the information panel of foods (usually, the back or side of the package). It is thus essential that both the criteria and symbols used in

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1 2 3	front-of-package and shelf-labeling systems be nutritionally sound, well-designed to help consumers make informed and healthy food choices, and not be false or misleading. The agency is currently analyzing FOP labels that appear to be misleading. The agency is also looking for symbols that either expressly or by implication are nutrient content claims. We are assessing the criteria established by
4	food manufacturers for such symbols and comparing them to our regulatory criteria.
5	It is important to note that nutrition-related FOP and shelf labeling, while currently voluntary, is subject to the provisions of the Federal Food, Drug, and Cosmetic
6	Act that prohibit false or misleading claims and restrict nutrient content claims to those defined in FDA regulations. Therefore, FOP and shelf labeling that is used in
7	a manner that is false or misleading misbrands the products it accompanies. Similarly, a food that bears FOP or shelf labeling with a nutrient content claim that
8 9	does not comply with the regulatory criteria for the claim as defined in Title 21 Code of Federal Regulations (CFR) 101.13 and Subpart D of Part 101 is misbranded. We will consider enforcement actions against clear violations of these
10	established labeling requirements Accurate food labeling information can assist consumers in making healthy
11	nutritional choices. FDA intends to monitor and evaluate the various FOP labeling systems and their effect on consumers' food choices and perceptions. FDA
12	recommends that manufacturers and distributors of food products that include FOP labeling ensure that the label statements are consistent with FDA laws and
13	regulations. FDA will proceed with enforcement action against products that bear FOP labeling that are explicit or implied nutrient content claims and that are not
14 15	consistent with current nutrient content claim requirements. FDA will also proceed with enforcement action where such FOP labeling or labeling systems are used in a manner that is false or misleading.
16	mainer that is faise of misleading.
17	39. The 2009 FOP Guidance recommended that "manufacturers and distributors of
18	food products that include FOP labeling ensure that the label statements are consistent with
19	FDA law and regulations" and specifically advised the food industry that it would "proceed
20	with enforcement action where such FOP labeling or labeling systems are used in a manner that
21	is false or misleading."
22	40. Despite the issuance of the 2009 FOP Guidance, Defendant did not remove the
23	unlawful and misleading food labeling claims from its Misbranded Food Products.
24	41. On March 3, 2010, the FDA issued an "Open Letter to Industry from [FDA
25	Commissioner] Dr. Hamburg" (hereinafter, "Open Letter"). The Open Letter reiterated the
26	FDA's concern regarding false and misleading labeling by food manufacturers. In pertinent part
27	the letter stated:
28	In the early 1990s, the Food and Drug Administration (FDA) and the food industry worked together to create a uniform national system of nutrition labeling, which
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includes the now-iconic Nutrition Facts panel on most food packages. Our citizens appreciate that effort, and many use this nutrition information to make food choices. Today, ready access to reliable information about the calorie and nutrient content of food is even more important, given the prevalence of obesity and dietrelated diseases in the United States. This need is highlighted by the announcement recently by the First Lady of a coordinated national campaign to reduce the incidence of obesity among our citizens, particularly our children.

With that in mind, I have made improving the scientific accuracy and usefulness of food labeling one of my priorities as Commissioner of Food and Drugs. The latest focus in this area, of course, is on information provided on the principal display panel of food packages and commonly referred to as "front-of-pack" labeling. The use of front-of-pack nutrition symbols and other claims has grown tremendously in recent years, and it is clear to me as a working mother that such information can be helpful to busy shoppers who are often pressed for time in making their food selections. ...

As we move forward in those areas, I must note, however, that there is one area in which more progress is needed. As you will recall, we recently expressed concern, in a "Dear Industry" letter, about the number and variety of label claims that may not help consumers distinguish healthy food choices from less healthy ones and, indeed, may be false or misleading.

At that time, we urged food manufacturers to examine their product labels in the context of the provisions of the Federal Food, Drug, and Cosmetic Act that prohibit false or misleading claims and restrict nutrient content claims to those defined in FDA regulations. As a result, some manufacturers have revised their labels to bring them into line with the goals of the Nutrition Labeling and Education Act of 1990. Unfortunately, however, we continue to see products marketed with labeling that violates established labeling standards.

To address these concerns, FDA is notifying a number of manufacturers that their labels are in violation of the law and subject to legal proceedings to remove misbranded products from the marketplace. While the warning letters that convey our regulatory intentions do not attempt to cover all products with violative labels, they do cover a range of concerns about how false or misleading labels can undermine the intention of Congress to provide consumers with labeling information that enables consumers to make informed and healthy food choices

These examples and others that are cited in our warning letters are not indicative
of the labeling practices of the food industry as a whole. In my conversations with
industry leaders, I sense a strong desire within the industry for a level playing field
and a commitment to producing safe, healthy products. That reinforces my belief
that FDA should provide as clear and consistent guidance as possible about food
labeling claims and nutrition information in general, and specifically about how
the growing use of front-of-pack calorie and nutrient information can best help
consumers construct healthy diets.

I will close with the hope that these warning letters will give food manufacturers further clarification about what is expected of them as they review their current labeling. I am confident that our past cooperative efforts on nutrition information and claims in food labeling will continue as we jointly develop a practical, science-based front-of-pack regime that we can all use to help consumers choose healthier foods and healthier diets.

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

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

44. In these letters dealing with unlawful nutrient content claims, the FDA indicated 6 7 that, as a result of the same type of claims utilized by the Defendant, products were in "violation" 8 of the Federal Food, Drug, and Cosmetic Act ... and the applicable regulations in Title 21, Code 9 of Federal Regulations, Part 101 (21 CFR § 101)" and "misbranded within the meaning of section 10 403(r)(1)(A) because the product label bears a nutrient content claim but does not meet the 11 requirements to make the claim." These warning letters were not isolated as the FDA has issued 12 numerous warning letters to other companies for the same type of food labeling claims at issue in 13 this case; the same being released as public records discoverable and downloadable from the 14 internet.

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

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

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

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1	48. Plaintiff did not know, and had no reason to know, that the Defendant's	
2	Misbranded Food Products were misbranded and bore food labeling claims despite failin	g to meet
3	the requirements to make those food labeling claims. Similarly, Plaintiff did not, and had	d no
4	reason to know, that Twinings' Misbranded Food Products she purchased were misbrand	led
5	because their labeling was false and misleading.	
6	C. <u>Defendant's Food Products Are Misbranded</u>	
7	49. Pursuant to Section 403 of the FDCA, a claim that characterizes the level	of a
8	nutrient in a food is a "nutrient content claim" that must be made in accordance with the	
9	regulations that authorize the use of such claims. 21 U.S.C. § 343(r)(1)(A). California e	xpressly
10	adopted the requirements of 21 U.S.C. § 343(r) in § 110670 of the Sherman Law.	
11	50. Nutrient content claims are claims about specific nutrients contained in a	product.
12	They are typically made on the front or top of packaging in a font large enough to be read	d by the
13	average consumer. Because these claims are relied upon by consumers when making put	rchasing
14	decisions, the regulations govern what claims can be made in order to prevent misleading	g claims.
15	51. Section $403(r)(1)(A)$ of the FDCA governs the use of expressed and impli	ed
16	nutrient content claims on labels of food products that are intended for sale for human	
17	consumption. See 21 C.F.R. § 101.13.	
18	52. 21 C.F.R. § 101.13 provides the general requirements for nutrient content	claims,
19	which California has expressly adopted. See California Health & Safety Code § 110100.	21
20	C.F.R. § 101.13 requires that manufacturers include certain disclosures when a nutrient c	laim is
21	made and, at the same time, the product contains certain levels of unhealthy ingredients,	such as
22	fat and sodium. It also sets forth the manner in which that disclosure must be made, as for	ollows:
23	(4)(i) The disclosure statement "See nutrition information for content" shall be	be
24	in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, and in a size no less than that required by \$101.105(i) for the net	
25	quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the	
26	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	
27	101.2(c)(2), in which case the disclosure statement may be in type of not less than one thirty-second of an inch.	
28	(ii) The disclosure statement shall be immediately adjacent to the nutrient content	t
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claim and may have no intervening material other than, if applicable, other information in the statement of identity or any other information that is required to be presented with the claim under this section (e.g., see paragraph (j)(2) of this section) or under a regulation in subpart D of this part (e.g., see \$\$101.54 and 101.62). If the nutrient content claim appears on more than one panel of the label, the disclosure statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information where it may be omitted.

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

8 54. An "implied nutrient content claim" is defined as any claim that: (i) describes the 9 food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a 10 certain amount (*e.g.*, "high in oat bran"); or (ii) suggests that the food, because of its nutrient 11 content, may be useful in maintaining healthy dietary practices and is made in association with an 12 explicit claim or statement about a nutrient (*e.g.*, "healthy, contains 3 grams (g) of fat"). 21 13 C.F.R. § 101.13(b)(2)(i-ii).

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

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

57. Similarly, the regulations specify absolute and comparative levels at which foods
qualify to make these claims for particular nutrients (e.g., low fat . . . more vitamin C) and list
synonyms that may be used in lieu of the defined terms. Certain implied nutrient content claims

(e.g., "healthy") also are defined. The daily values (DVs) for nutrients that the FDA has
 established for nutrition labeling purposes have application for nutrient content claims, as well.
 Claims are defined under current regulations for use with nutrients having established DVs;
 moreover, relative claims are defined in terms of a difference in the percent DV of a nutrient
 provided by one food as compared to another. *See e.g.*, 21 C.F.R. §§ 101.13 and 101.54.

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1. <u>Defendant Has Made Unlawful and Misleading Nutrient Content</u> <u>Claims (Antioxidant, Vitamin and Other) That Violate The General</u> <u>Nutrient Content Labeling Rules</u>

8 58. Defendant's nutrient contents claims on its product labels and its website (and 9 therefore its label) that its green, black and white teas are "natural source of antioxidants" or 10 "natural source of protective antioxidants" or "rich in antioxidants", or "ideal source of 11 antioxidants" or "contain antioxidants" are unlawful and misleading. Moreover, Defendant's 12 claims that "Black and green teas also contain Vitamins A, B1, B2 and B6, along with calcium, 13 zinc and folic acid. Tea is also a rich source of potassium—vital for maintaining a normal 14 heartbeat and regulating fluid levels in cells and manganese, an essential mineral for bone 15 growth" is unlawful, false and misleading because none of these vitamins or minerals are present 16 in a sufficient quantity to support such a claim.

17 59. In order to appeal to consumer preferences, Defendant has repeatedly made 18 unlawful nutrient content claims about antioxidants and other nutrients that fail to utilize one of 19 the limited defined terms. These nutrient content claims are unlawful because they failed to 20 comply with the nutrient content claim provisions in violation of 21 C.F.R. §§ 101.13, 101.54 and 21 101.65, which have been incorporated in California's Sherman Law. To the extent that the terms 22 used to describe antioxidants without a recognized daily value or RDI (such as "natural source") 23 are deemed to be a synonym for a defined term like "contain" the claim would still be unlawful 24 because, as these nutrients do not have established daily values, they cannot serve as the basis for 25 a term that has a minimum daily value threshold as the defined terms at issue here do. To the 26 extent that the claims refer to Vitamins A, B1, B2, and B6; or to calcium, zinc, folic acid and 27 potassium, none of these are present in sufficient quantities (if at all) to comply with the nutrient 28 content provisions.

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1 60. Defendant's claims concerning unnamed antioxidant nutrients or the other 2 vitamins or nutrients are false because Defendant's use of a defined term is in effect a claim that 3 the products have met the minimum nutritional requirements for the use of the defined term when 4 they have not. For example, antioxidant related nutrient content claims that Defendant make on 5 the labels of its green, black and white and on its website about its teas are false and unlawful 6 because they use defined terms such as "rich in," "protective", "ideal" and "contains." Defendant 7 uses these terms to describe antioxidants and flavonoids in its teas that fail to satisfy the minimum 8 nutritional thresholds for these defined terms.

9 61. An "excellent source" claim requires a nutrient to be present at a level at least 20% 10 of the Daily Value for that nutrient while "contains" and "provides" claims require a nutrient to 11 be present at a level at least 10% of the Daily Value for that nutrient. Defendants' "rich in 12 antioxidants" or "ideal source of antioxidants" claims require 20% DV. Defendant's "contains", 13 "natural source" and "provides" claims about its teas are nutrient content claims require a 14 minimum 10% DV.

15 62. Therefore, the claims that Twinings' teas are "rich in antioxidants" or "ideal 16 source of antioxidants are false and unlawful. Defendant's teas do not meet the minimum nutrient 17 level threshold to make such a claim, which is 20% or more of the RDI or the DRV of a nutrient 18 with an established RDI per reference amount customarily consumed. Similarly, claims that 19 Twinings' teas "contain" or "provide" or are a "natural source" of antioxidants are false and 20 unlawful. Defendant's teas do not meet the minimum nutrient level threshold to make such a 21 claim which is 10% or more of the RDI or the DRV of a nutrient with a recognized RDI per 22 reference amount customarily consumed.

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63. Defendant's misuse of defined terms is not limited the antioxidant related nutrient 24 content claims on one or two products. Defendant's tea related claims are part of a widespread 25 practice of misusing defined nutrient content claims to overstate the nutrient content of all of its 26 tea products. The statements regarding antioxidants and the health benefits to be derived from 27 consuming defendant's products appear on each variety of Defendant's green, black and white tea 28 products. These other products are substantially similar to the tea products purchased by Plaintiff THIRD AMENDED CLASS ACTION COMPLAINT 22

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- in that they are all the same product (tea), derived from the same plant, packaged the same and
 bear the same or similar nutrient content claims on the product packages.
- 3 64. By using a defined term like "good source" or an undefined term such as "natural 4 source of," Defendant is, in effect, falsely asserting that its products meet at least the lowest 5 minimum threshold for any nutrient content claim which would be 10% of the daily value of the 6 nutrient at issue. Such a threshold represents the lowest level that a nutrient can be present in a 7 food before it becomes deceptive and misleading to highlight its presence in a nutrient content 8 claim. Thus, for example, it is deceptive and misleading for Defendant to claim that its teas are a 9 "good source" or "natural source" of antioxidants. Tea does not contain an antioxidant with a 10 recognized RDI, much less at a level as required by the regulations. None of the nutrients in tea 11 has a DV and thus it is unlawful to make nutrient content claims about them.
- 65. With regard to the claims that Twinings' green and black teas "contain Vitamins *A*, *B1*, *B2* and *B6*, along with calcium, zinc and folic acid" and "a rich source of potassium ... *and manganese*" it is deceptive and misleading to make such claims because Twinings' tea
 products do not contain any of these nutrients in a significant amount (10% or 20% DV). The
 FDA has repeatedly condemned any reference to such nutrients on product labels where the
 product did not contain at least the lowest minimum threshold for any nutrient content claim
 which would be 10% of the daily value of the nutrient at issue.
- 19 66. FDA enforcement actions targeting identical or similar claims to those made by
 20 Defendant have made clear the unlawfulness of such claims. Defendant knew or should have
 21 known about these enforcement actions. For example, on March 24, 2011, the FDA sent
 22 Jonathan Sprouts, Inc. a warning letter where it specifically targeted a "source" type claim like
 23 the one used by Defendant. In that letter the FDA stated:
- Your Organic Clover Sprouts product label bears the claim "Phytoestrogen Source[.]" Your webpage entitled "Sprouts, The Miracle Food! - Rich in Vitamins, Minerals and Phytochemicals" bears the claim "Alfalfa sprouts are one of our finest food sources of . . . saponin." These claims are nutrient content claims subject to section 403(r)(1)(A) of the Act because they characterize the level of nutrients of a type required to be in nutrition labeling (phytoestrogen and saponin) in your products by use of the term "source." Under section 403(r)(2)(A) of the Act, nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined by regulation. However, FDA has

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1	not defined the characterization "source" by regulation. Therefore, this characterization may not be used in nutrient content claims.
2	67. It is thus clear that a "source" claim like the one utilized by Defendant is unlawful
3	because the "FDA has not defined the characterization 'source' by regulation" and thus such a
4	"characterization may not be used in nutrient content claims." Similarly, claims that Twinings
5	teas are a "natural source" of antioxidants violate the express provisions of 21 C.F.R. § 101.54
6	because the teas fail to satisfy the minimum 10% DV threshold.
7	68. Another example of FDA enforcement action for unlawful claims on product
8	labels of the presence of antioxidant and other nutrients is the October 23, 2012 FDA warning
9	letter to Hail Merry, LLC regarding claims on product labels and its website that its chocolate,
10	almond and coconut products contained various nutrients, including antioxidants, vitamins,
11	manganese, potassium and magnesium when, in fact the products did not contain these nutrients
12	in a sufficient threshold amount to make the claim (10% or 20% DV). In finding the products
13	misbranded FDA stated:
14	Your Grawnola Orange Cranberry, Merry's Miracle Tart Chocolate,
15	Almonds Vanilla Maple, and Sunflower Seeds Salt n Black Pepper products are misbranded within the meaning of section $403(r)(1)(A)$ of the Act, 21
16	U.S.C. $343(r)(1)(A)$, because the labels bear nutrient content claims, but the products do not meet the requirements to bear the claims. Under section
17	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
18	in accordance with a regulation authorizing the use of such a claim. Characterizing the level of a nutrient in food labeling without complying
19	with the specific requirements pertaining to nutrient content claims for that nutrient misbrands the product under section $403(r)(1)(A)$ of the Act. For
20	example:
21	Your Grawnola Orange Cranberry product label bears the nutrient content claim "Cranberries are loaded with antioxidants." Nutrient content claims
22	using the term "antioxidant" must comply with, among other requirements,
23	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)
24	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
25	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
26	21 CFR 101.54(b), (c), or (e) [21 CFR 101.54(g)(3)]. For example, to bear
27	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
28	claim must also include the names of the nutrients that are the subject of the

1 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 2 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 3 activity [21 CFR 101.54(g)(4)]. The antioxidant claim found on your product labels is a nutrient content claim because it characterizes the level of 4 antioxidants in your products, but it does not comply with 21 CFR 5 101.54(g)(4) because the claim does not include the names of the nutrients that are the subject of the claim or link the nutrients with the claim by use of 6 a symbol. 7 Your Sunflower Seeds Salt n Black pepper product label contains the nutrient content claim "[R]ich source [of] ... iron ." A product that claims to 8 be "rich" in a nutrient must contain at least 20 percent of the RDI per RACC for the nutrient as required by 21 CFR 101 .54(b). Based upon your nutrition 9 information, a 28 g serving contains 10 percent of the RDI for iron. This equates to approximately 11% of RDI per RACC. Therefore, your product 10 does not meet the requirements to bear a "rich" claim for iron. In addition, 11 your Sunflower Seeds Salt n Black pepper product label contains the nutrient content claim "[R]ich source [of] ... B vitamins, vitamin E as well 12 as minerals copper, manganese, potassium, and magnesium, however the nutrient levels are not declared for these vitamins and minerals as required 13 under 21 CFR 101.9(c)(8)(ii) and 101.13(n). Therefore the product is misbranded under section 403(q) and 403(r)(1)(A) of the Act. Further, 14 because these nutrient levels are not declared, it is not clear whether the 15 product has the required minimum 20 percent of the RDI per RACC of these nutrients as required under 21 CFR 101.54(b). 16 http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm326550.htm 17 The types of misrepresentations made above would be considered by a reasonable 69. 18 consumer like the Plaintiff when deciding to purchase the products. Plaintiff placed, and a 19 reasonable consumer would place, great importance on the claimed presence of "rich in 20 antioxidants" or that the green, black or white tea was a "natural source of antioxidants" in 21 choosing Defendant's products over other tea products and alternative beverage products. 22 70. The nutrient content claims regulations discussed above are intended to ensure that 23 consumers are not misled as to the actual or relative levels of nutrients in food products. 24 71. Defendant has violated these referenced regulations. Plaintiff relied on Twinings' 25 nutrient content claims (antioxidant, vitamin, and mineral) when making her purchase decisions 26 and was misled because she erroneously believed the implicit misrepresentation that the Twinings 27 products she was purchasing were beneficial, healthy and met the minimum nutritional threshold 28 to make such claims. Antioxidant and other claimed nutrient content was important to the THIRD AMENDED CLASS ACTION COMPLAINT 25 CASE NO. 12-CV-02646 (RMW)

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Plaintiff in trying to buy "healthy" food products. Plaintiff would not have purchased these
 products had she known that the Twinings products did not have the beneficial effects claimed
 and in fact did not satisfy such minimum nutritional requirements with regard to the claimed
 nutrients.

5 72. For these reasons, Defendant's nutrient content claims at issue in this Amended 6 Complaint are false and misleading and in violation of 21 C.F.R. §§ 101.13, 101.54 and 101.65 7 and identical California law, and the products at issue are misbranded as a matter of law. 8 Defendant has violated these referenced regulations. Therefore, Defendant's Misbranded Food 9 Products are misbranded as a matter of California and federal law and cannot be sold or held and 10 thus have no economic value and are legally worthless. Plaintiff and members of the Class who 11 purchased the Defendant's Misbranded Food Products paid an unwarranted premium for the 12 products. 13 73. Plaintiff was thus misled by the Defendant's unlawful labeling practices and

Plaintiff was thus misled by the Defendant's unlawful labeling practices and
 actions into purchasing products she would not have otherwise purchased had she known the truth
 about those products. Plaintiff had cheaper alternatives. Defendant's claims in this respect are
 false and misleading and the products are in this respect misbranded under identical California
 and federal laws.

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2. <u>Defendant Has Made Unlawful and Misleading Antioxidant</u> <u>Related Nutrient Content Claims That</u> <u>Violate The Specific</u> <u>Antioxidant Labeling Rules</u>

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

- 75. Federal and California regulations regulate antioxidant claims as a particular type
 of nutrient content claim. Specifically, 21 C.F.R. § 101.54(g) contains special requirements for
 nutrient claims that use the term "antioxidant":
- 26

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

27 28 (2) there must be an established Recommended Daily Intake ("RDI") for that antioxidant, and if not, no "antioxidant" claim can be made about it;

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1	(3)	the label claim must include the specific name of the nutrient that is an	
2		antioxidant and cannot simply say "antioxidants" (e.g., "high in antioxidant	
3		vitamins C and E"), ¹ see 21 C.F.R. § 101.54(g)(4);	
4	(4)	the nutrient that is the subject of the antioxidant claim must also have	
5		recognized antioxidant activity, <i>i.e.</i> , there must be scientific evidence that	
6		after it is eaten and absorbed from the gastrointestinal tract, the substance	
7		participates in physiological, biochemical or cellular processes that	
8		inactivate free radicals or prevent free radical-initiated chemical reactions,	
9		see 21 C.F.R. § 101.54(g)(2);	
10	(5)	the antioxidant nutrient must meet the requirements for nutrient content	
11		claims in 21 C.F.R. § 101.54(b), (c), or (e) for "High" claims, "Good	
12		Source" claims, and "More" claims, respectively. For example, to use a	
13		"High" claim, the food would have to contain 20% or more of the Daily	
14		Reference Value ("DRV") or RDI per serving. For a "Good Source"	
15		claim, the food would have to contain between 10-19% of the DRV or RDI	
16		per serving, see 21 C.F.R. § 101.54(g)(3); and	
17	(6)	the antioxidant nutrient claim must also comply with general nutrient	
18		content claim requirements such as those contained in 21 C.F.R. §	
19		101.13(h) that prescribe the circumstances in which a nutrient content	
20		claim can be made on the label of products high in fat, saturated fat,	
21		cholesterol or sodium.	
22	76. The ar	ntioxidant labeling for Twinings' Misbranded Food Products and the claims	
23	on Twinings' website	promoting these products violate California law: (1) because the names of	
24	the antioxidants are n	ot disclosed on the product labels; (2) because there are no RDIs for the	
25			
26	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)		
27	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		
28	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.THIRD AMENDED CLASS ACTION COMPLAINT27CASE NO. 12-CV-02646 (RMW)		

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antioxidants being touted, including flavonoids and polyphenols; (3) because the claimed
antioxidant related nutrients fail to meet the requirements for nutrient content claims in 21 C.F.R.
§ 101.54(b), (c), or (e) for "High" claims, "Good Source" claims, and "More" claims,
respectively; and (4) because Defendant lacks adequate scientific evidence that the claimed
antioxidant nutrients participate in physiological, biochemical, or cellular processes that
inactivate free radicals or prevent free radical-initiated chemical reactions after they are eaten and
absorbed from the gastrointestinal tract.

8 77. For example, as discussed above, the package label of Twinings Green Tea 9 Jasmine bears the statement "Natural source of Antioxidants." The label further boasts, "Natural 10 Source of Protective Antioxidants", and "Healthy Tea Experience". Identical antioxidant related 11 nutrient content claims appear on each and every Twinings green tea product as shown on Exhibit 12 1. Likewise the package label for all Twinings' black and white tea products bears a seal that 13 states: "tea is a natural source of antioxidants." Additional antioxidant nutrient content claims 14 appear on Twinings' website sometimes referring to green tea, or black tea, or white tea and 15 sometimes to all teas. These same types of violations were condemned in the FDA Warning 16 Letter to Unilever/Lipton discussed above and attached as Exhibit 2. 17 78. These same violations were condemned in numerous other warning letters to other 18 tea companies of which Defendant knew or should have known including the April 11, 2011 19 warning letter to Diaspora Tea & Herb Co., LLC (attached as Exhibit 3) which states in pertinent 20 part: 21 Additionally, your website bears nutrient content claims using the term "antioxidant." ... Such a claim must also include the names of the nutrients that 22 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 23 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 24 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 25 101.54(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 26 term "antioxidant" but do not include the names of the nutrients that are the subject of the claim as required under 21 CFR 101.54(g)(4): "Yerba Maté is...rich 27 in... antioxidants."; ... "Caffeine-free Green Rooibos...contain[s] high concentrations of antioxidants.... 28

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1 2	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		
2 3	101.54(g)(1): "White Tea contain[s] high concentrations of antioxidant polyphenols (tea catechins)"; "Antioxidant rich222mg polyphenols per		
4	serving!"; "Antioxidant rich109mg polyphenols per serving!"		
5	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 recyclations. We		
6	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		
7 8	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.		
9	79. For these reasons, Defendant's antioxidant claims at issue in this Complaint are		
10	misleading and in violation of 21 C.F.R. § 101.54 and California law, and the products at issue		
11	are misbranded as a matter of law. Misbranded products cannot be legally manufactured,		
12	advertised, distributed, held or sold and have no economic value and are legally worthless.		
13	Plaintiff and members of the Class who purchased these products paid an unwarranted premium		
14	for these products.		
15	80. In addition to the FDA Warning Letters to Unilever and Diaspora Tea & Herb Co.,		
16	LLC discussed above (Exhibits 2 and 3), the FDA has issued numerous warning letters addressing		
17	similar unlawful antioxidant nutrient content claims. See, e.g., FDA warning letter dated		
18	February 22, 2010 to Redco Foods, Inc. regarding its misbranded Salada Naturally Decaffeinated		
19	Green Tea product because "there are no RDIs for (the antioxidants) grapeskins, rooibos red tea)		
20	and anthocyanins"; FDA warning letter dated February 22, 2010 to Fleminger Inc. regarding its		
21	misbranded TeaForHealth products because the admonition "[d]rink high antioxidant green tea".		
22	"does not include the nutrients that are the subject of the claim or use a symbol to link the term		
23	antioxidant to those nutrients". These warning letters were hardly isolated. Defendant is aware of		
24	these FDA warning letters		
25	81. Additional evidence of Twinings' knowledge that its antioxidant and health claims		
26	are improper and misleading is provided by two findings of the British Advertising Standards		
27	Authority ("ASA"). The first is the September 26, 2007 Adjudication against an advertisement by		
28	the British Tea Counsel (a British Trade Association of tea producers of which Twinings is a		
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1	founding member) touting the presence of antioxidants in tea. ASA found the advertisement to be					
2						
	misleading stating in part (emphasis added):					
3 4	We considered, however, that readers were likely to infer from the ad that it had been proven that antioxidants, absorbed as a result of drinking four cups of tea per day, could help to protect the body against the damaging effects of free radical					
5	action. We considered that we had not seen substantive evidence to demonstrate that the antioxidant potential realised from the consumption of four cups of tea					
6	per day could have any effect on free radical activity; we concluded, therefore, that the claim " We recommend 4 cups a day to contribute to a diet rich in antioxidants which could help to protect your body against the damaging effects of free radicals" was likely to mislead.					
7						
8	Adjudication of the ASA, United Kingdom Tea Counsil, September 26, 2007,					
9 http://www.asa.org.uk/Rulings/Adjudications/2007/9/United-H Council/TF_ADJ_43234.aspx						
10	82. The Second is the November 25, 2009 ASA against one of Twinings' biggest					
11	competitors, Tetley Tea. On information and belief Twinings was aware of this Adjudication					
12 13	against its competitor. There, the ASA found that Tetley's print and TV advertisements stating					
13	that Tetley's products were: "rich in antioxidants that can keep your heart healthy" were					
15	misleading. In so holding, ASA stated:					
16 17	Because the evidence we had seen was not directly relevant to the implied claim that green tea, or the antioxidants in it, had general health benefits, we considered it was not sufficient substantiation for that claim. We concluded that the ad was					
18	misleading.					
19	On this point, the ad breached CAP (Broadcast) TV Advertising Standards Code rules 5.1.1 (Misleading advertising), 5.2.1 (Evidence), 5.2.2 (Implications), 8.3.1(a) (Accuracy in food advertising)					
20	The ad must not be broadcast again in its current form. We told Tetley not to					
21	imply that a product had greater health benefits than it did if they did not hold substantiation for the implied claims					
22	Adjudication of the ASA, Tetley GB Ltd., November 25, 2009,					
23	http://www.asa.org.uk/ASA-action/Adjudications/2009/11/Tetley-GB- Ltd/TF_ADJ_47670.aspx					
24	83. The types of misrepresentations made above would be considered by a reasonable					
25	consumer when deciding to purchase the products. Not only do Twinings' antioxidant, nutrient					
26	content and health claims regarding the benefits of "flavonoids" violate FDA rules and					
27	regulations, they directly contradict current scientific research, which has concluded: "[T]he					
28	evidence today does not support a direct relationship between tea consumption and a					
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1	physiological AOX [antioxidant] benefit." This conclusion was reported by Dr. Jane Rycroft,
2	Director of Lipton Tea Institute of Tea, in an article published in January, 2011, in which Dr.
3	Rycroft states:
4	Only a few scientific publications report an effect of tea on free radical damage in
5	humans using validated biomarkers in well designed human studies. Unfortunately, the results of these studies are at variance and the majority of the
6	studies do not report significant effects
7	Therefore, despite more than 50 studies convincingly showing that flavonoids possess potent antioxidant activity <i>in vitro</i> , the ability of flavonoids to act as an antioxidant in vitro line humanal, has not been demonstrated.
8	antioxidant <i>in vivo</i> [in humans], has not been demonstrated.
9	Based on the current scientific consensus that the evidence today does not support a direct relationship between tea consumption and a physiological AOX benefit
10	No evidence has been provided to establish that having antioxidant activity/content and/or antioxidant properties is a beneficial physiological effect.
11	
12	Rycroft, Jane, "The Antioxidant Hypothesis Needs to be Updated," Vol. 1, <i>Tea Quarterly Tea Science Overview</i> , Lipton Tea Institute of Tea Research (Jan. 2011),
13	pp. 2-3.
14	84. This scientific evidence and consensus conclusively establishes the improper
15	nature of the Defendant's antioxidant claims as they cannot possibly satisfy the legal and
16	regulatory requirement that the nutrient that is the subject of the antioxidant claim must also have
17	recognized antioxidant activity, <i>i.e.</i> , there must be substantial scientific evidence that after it is
18	eaten and absorbed from the gastrointestinal tract, the substance participates in physiological,
19	biochemical or cellular processes that inactivate free radicals or prevent free radical-initiated
20	chemical reactions, see 21 C.F.R. § 101.54(g)(2). In fact, the United States Department of
21	Agriculture (USDA) recently removed its ORAC data base related to foods with antioxidant
22	properties "because the values indicating antioxidant capacity have no relevance to the effects of
23	specific bioactive compounds on the human health" and that "ORAC values [the former
24	USDA data base] are routinely misused by food and dietary supplement manufacturing
25	companies to promote their products" and "[t]here is no evidence that the beneficial effects of
26	polyphenol-rich foods can be attributed to the antioxidant properties of these foods. "USDA
27	Agricultural Research Service Oxygen Radical Absorbance Capacity (ORAC) of Selected Foods,
28	Release 2 (2010). http://www.ars.usda.gov/Services/docs.htm?docid=15866
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- 1 85. The antioxidant regulations discussed above are intended to ensure that consumers 2 are not misled as to the actual or relative levels of antioxidants in food products and purported 3 beneficial health benefits from consuming the food product.
- 4 86. Plaintiff relied on Defendant's nutrient content, antioxidant and health claims 5 when making her purchase decisions over the last four years and was misled because she 6 erroneously believed the implicit misrepresentation that the Defendant's products she was 7 purchasing met the minimum nutritional threshold to make such claims. Antioxidant and 8 flavonoid content was important to Plaintiff in trying to buy "healthy" food products. Plaintiff 9 would not have purchased these products had she known that the Defendant's products did not in 10 fact satisfy such minimum nutritional requirements with regard to antioxidants and the 11 consumption of defendant's tea did not, in fact, result in the purported health benefits touted by 12 Defendant.
- 13 87. For these reasons, Defendant's antioxidant claims at issue in this Third Amended 14 Complaint are false and misleading and in violation of 21 C.F.R. §§ 101.13, 101.54 and 101.65 15 and identical California law, and the products at issue are misbranded as a matter of law. 16 Defendant has violated these referenced regulations. Therefore, Defendant's Misbranded Food 17 Products are misbranded as a matter of California and federal law and cannot be sold or held and 18 thus have no economic value and are legally worthless. Additionally, Plaintiff was misled and 19 deceived by the actions of the Defendant in violation of California Law.
- 20 88. Defendants' claims in this respect are false and misleading and the products are in 21 this respect misbranded under identical California and federal laws, Misbranded products cannot 22 be legally sold and have no economic value and are legally worthless. Plaintiff and members of 23 the Class who purchased these products paid an unwarranted premium for these products.
- 24

3. **Defendant Has Made Unlawful and Misleading Health Claims**

89. 25 Defendant violated identical California and federal law by making numerous 26 unapproved health claims about its products. It has also violated identical California and federal 27 law by making numerous unapproved claims about the ability of its products to cure, mitigate, 28 treat and prevent various diseases that render its products unapproved drugs under California and THIRD AMENDED CLASS ACTION COMPLAINT 32 CASE NO. 12-CV-02646 (RMW)

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1 federal law. Moreover, in promoting the ability of its products to have an effect on certain 2 diseases such as cancer and heart disease among others, Defendant has violated the advertising 3 provisions of the Sherman law. 4 90. A health claim is a statement expressly or implicitly linking the consumption of a 5 food substance (e.g., ingredient, nutrient, or complete food) to risk of a disease (e.g., 6 cardiovascular disease) or a health-related condition (e.g., hypertension). See 21 C.F.R. § 7 101.14(a)(1), (a)(2), and (a)(5). Only health claims made in accordance with FDCA requirements, 8 or authorized by FDA as qualified health claims, may be included in food labeling. Other express 9 or implied statements that constitute health claims, but that do not meet statutory requirements, 10 are prohibited in labeling foods. 91. 11 21 C.F.R. § 101.14, which has been expressly adopted by California, provides 12 when and how a manufacturer may make a health claim about its product. A "Health Claim" 13 means any claim made on the label or in labeling of a food, including a dietary supplement, that 14 expressly or by implication, including "third party" references, written statements (e.g., a brand 15 name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes 16 the relationship of any substance to a disease or health-related condition. Implied health claims 17 include those statements, symbols, vignettes, or other forms of communication that suggest, 18 within the context in which they are presented, that a relationship exists between the presence or 19 level of a substance in the food and a disease or health-related condition (see 21 CFR § 20 101.14(a)(1)). 21 92. Further, health claims are limited to claims about disease risk reduction, and 22 cannot be claims about the diagnosis, cure, mitigation, or treatment of disease. An example of an 23 authorized health claim is: "Three grams of soluble fiber from oatmeal daily in a diet low in

saturated fat and cholesterol may reduce the risk of heart disease. This cereal has 2 grams perserving."

26 93. A claim that a substance may be used in the diagnosis, cure, mitigation, treatment,
27 or prevention of a disease is a drug claim and may not be made for a food. 21 U.S.C. §
28 321(g)(1)(D).

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1	94. The use of the term "healthy" is not a health claim but rather an implied nutrient				
2	content claim about general nutrition that is defined by FDA regulation.				
;	95. 21 C.F.R. § 101.65, which has been adopted by California, sets certain minimum				
	nutritional requirements for making an implied nutrient content claim that a product is healthy.				
	For example, for unspecified foods the food must supply at least 10 percent of the RDI of one or				
	more specified nutrients. Defendants have misrepresented the healthiness of their products while				
	failing to meet the regulatory requirements for making such claims. In general, the term may be				
	used in labeling an individual food product that:				
	Qualifies as both low fat and low saturated fat;				
	Contains 480 mg or less of sodium per reference amount and per labeled serving,				
	and per 50 g (as prepared for typically rehydrated foods) if the food has a reference amount of 30 g or 2 tbsps or less;				
	Does not exceed the disclosure level for cholesterol ($e.g.$, for most individual food				
	products, 60 mg or less per reference amount and per labeled serving size); <i>and</i>				
	Except for raw fruits and vegetables, certain frozen or canned fruits and vegetables, and enriched cereal-grain products that conform to a standard of identity, provides at least 10% of the daily value (DV) of vitamin A, vitamin C, calcium, iron, protein, <i>or</i> fiber per reference amount.				
	Where eligibility is based on a nutrient that has been added to the food, such fortification must comply with FDA's fortification policy.				
	21 C.F.R. § 101.65(d)(2).				
	96. FDA's regulation on the use of the term healthy also encompasses other, derivative				
	uses of the term health (e.g., healthful, healthier) in food labeling. 21 C.F.R. § 101.65(d).				
	97. Twinings has violated the provisions of 21 C.F.R. §101.13, 21 C.F.R. §101.14,				
	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) and				
	21 U.S.C. §352(f)(1) on a number of its products and on its websites. For example, the claim on				
	each of the green tea package front labels: "Healthy tea experience" and the claim on the package				
	top panel: "A natural Source of Protective Antioxidants" is in violation of the aforesaid law."				
	98. Likewise the numerous claimed health benefits appearing on Twinings' website				
	which Plaintiff had reviewed on several occasions during the Class Period are in violation of the				
	aforesaid laws.				

1 99. As FDA found in regard to the therapeutic claims made by Unilever/Lipton and 2 Diaspora Tea & Herb Co. discussed above, the therapeutic claims on Twinings' website and on 3 its labels establish that their products are drugs because they are intended for use in the cure, 4 mitigation, treatment, or prevention of disease. Twinings' Misbranded Food Products are not 5 generally recognized as safe and effective for the above referenced uses and, therefore, the 6 products are "new drugs" under section 201(p) of 21 U.S.C. § 321(p). New drugs may not be 7 legally marketed in the U.S. without *prior* approval from FDA as described in section 505(a) of 8 21 U.S.C. § 355(a). FDA approves a new drug on the basis of scientific data submitted by a drug 9 sponsor to demonstrate that the drug is safe and effective. Twinings' health claims on its website 10 are deceptive, misleading and unlawful.

11 100. As discussed above and as shown in Exhibits 2 and 3, the FDA has conducted 12 reviews of similar products to Twinings' tea products and concluded that those companies were 13 "in violation of the Federal Food, Drug, and Cosmetic Act ... and the applicable regulations in 14 Title 21, Code of Federal Regulations, Part 101 (21 CFR 101)." FDA found the products to be 15 misbranded stating, "Your product is offered for conditions that are not amenable to self-16 diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate 17 directions for use cannot be written so that a layperson can use this drug safely for its intended 18 purposes. Thus, your ... product is misbranded under section 502(f)(1) of the Act in that the 19 labeling for this drug fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)]."See 20 Exhibits 2 and 3.

21 101. The package front panel of Twinings' Misbranded Food Products claims a level of 22 "protective antioxidants" and "healthy tea experience" but their products do not contain any 23 antioxidant substance or nutrient with an established RDI. As set out above it also makes various 24 health related claims on its website of health benefits to be derived from using its products but, as 25 with the Lipton and Diaspora Tea & Herb Co. products, Twinings' tea products do not have 26 approval from FDA to make the health related claims. In fact some of the health claims made by 27 Twinings on its websites were specifically condemned by the FDA in finding the products of 28 Unilever and Diaspora Tea misbranded. For example Diaspora Tea's products were found to be THIRD AMENDED CLASS ACTION COMPLAINT 35 CASE NO. 12-CV-02646 (RMW)

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1 misbranded because it claimed: "The powerful antioxidants found in tea are believed to help 2 prevent cancer [and] lower cholesterol...." Likewise, Unilever's products were found to be 3 misbranded because it claimed on its website "[F]our recent studies in people at risk for coronary 4 disease have shown a significant cholesterol lowering effect from tea or tea flavonoids". Yet as 5 indicated in the quotations from its website appearing above and which was reviewed by Plaintiff 6 Twinings continues to claim its tea products "... have many health benefits" and "boosts your 7 immune system" and "increase metabolism and help maintain healthy skin and complexion", 8 "promote restful sleep and help with digestion", "maintain regular heartbeat and regulate fluid 9 levels ... bone growth". "stop plaque, which can prevent gum disease and reduce bad breath", 10 and "help reduce the effects of damaging free radicals". As with Unilever and Diaspora Tea, 11 these health related claims are in violation of 21 U.S.C. § 352(f)(1) and therefore the Twinings 12 products are misbranded. 102. Plaintiff saw the health related claims on the packages and on Defendant's website

13 102. Plaintiff saw the health related claims on the packages and on Defendant's website 14 prior to purchasing Defendant's products at various times during the Class Period and relied on 15 the Defendant's health claims which influenced her decision to purchase the Defendant's 16 products. These unlawful claims continue to be made on Defendant's packaging and websites to 17 this day. Plaintiff would not have bought the products had she known Defendant's claims were 18 unlawful, false, misleading, unapproved and that the products were misbranded.

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

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

27 105. Defendant's health claims were also improper because of their inadequate
28 nutritional profiles.

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1	106. 21 C.F.R. § 101.14, which has been expressly adopted by California, prohibits						
2	manufacturers from making any health claim about products that have inadequate nutrient levels.						
3	107. In addition, 21 C.F.R. § 101.65, which has been adopted by California, sets certain						
4	minimum nutritional requirements for making an implied nutrient content claim that a product is						
5	healthy. For example, for unspecified foods the food must be low in fat, saturated fat, sodium and						
6	cholesterol and supply at least 10 percent of the RDI of one or more specified nutrients.						
7	108. Defendant has misrepresented the healthiness of its products while failing to meet						
8	the regulatory thresholds for making such claims either because the products lack minimum						
9	nutritional requirements to make such a claim.						
10	109. Defendant Misbranded Food Products violate 21 C.F.R. § 101.14 or 21 C.F.R. §						
11	101.65 as well as 21 C.F.R. § §101.13 and 101.54						
12	110. Plaintiff saw such health related claims and relied on the Defendant's health						
13	claims, which influenced her decision to purchase the Defendant's products. Plaintiff would not						
14	have bought the products had she known Defendant's products failed to meet the minimum						
15	nutritional threshold for such health claims.						
16	111. Plaintiff and members of the Class were misled into the belief that Defendant's						
17	products would provide the claimed health benefits and met the minimum nutritional thresholds						
18	for the health claims that were made about them. Because this was not the case, the Plaintiff and						
19	members of the Class have been deceived.						
20	112. Plaintiff and members of the Class have been misled by Defendant's unlawful						
21	labeling practices and actions into purchasing products they would not have otherwise purchased						
22	had they known the truth about these products. Plaintiff and members of the Class who purchased						
23	these products paid an unwarranted premium for these products.						
24	113. Defendant's health related claims are false and misleading and the products are in						
25	this respect misbranded under identical California and federal laws, Misbranded products cannot						
26	be legally sold and thus have no economic value and are legally worthless.						
27	D. <u>Defendant Has Violated California Law</u>						
28							
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1	114 The peokese front peopl of Twinings' Mishrey ded Deed Deedwate shiws a basel of					
1	114. The package front panel of Twinings' Misbranded Food Products claims a level of					
2	"antioxidants" but their products do not contain any antioxidant substance or nutrient with an					
3	established RDI. Twinings makes various health related claims of benefits to be derived from					
4	using its products but, as with the Lipton and Diaspora Tea & Herb Co. products, Twinings' tea					
5	products do not have approval from FDA to make the health related claims. Moreover, the health					
6	related claims are in violation of 21 U.S.C. § 352(f)(1) and therefore the products are misbranded.					
7	115. Defendant has manufactured, advertised, distributed and sold products that are					
8	misbranded under California law. Misbranded products cannot be legally manufactured,					
9	advertised, distributed, sold or held and have no economic value and are legally worthless as a					
10	matter of law.					
11	116. Defendant has violated California Health & Safety Code §§ 109885 and 110390					
12	which make it unlawful to disseminate false or misleading food advertisements that include					
13	statements on products and product packaging or labeling or any other medium used to directly or					
14	indirectly induce the purchase of a food product.					
15	117. Defendant has violated California Health & Safety Code § 110395 which makes it					
16	unlawful to manufacture, sell, deliver, hold or offer to sell any misbranded food.					
17	118. Defendant has violated California Health & Safety Code § 110398 which makes it					
18	unlawful to deliver or proffer for delivery any food that has been falsely advertised.					
19	119. Defendant has violated California Health & Safety Code § 110660 because its					
20	labeling is false and misleading in one or more ways, as follows:					
21	120. They are misbranded under California Health & Safety Code § 110665 because					
22	their labeling fails to conform to the requirements for nutrient labeling set forth in 21 U.S.C. §					
23	343(q) and the regulations adopted thereto;					
24	121. They are misbranded under California Health & Safety Code § 110670 because					
25	their labeling fails to conform with the requirements for nutrient content and health claims set					
26	forth in 21 U.S.C. § 343(r) and the regulations adopted thereto; and					
27						
28						
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1	122. They are misbranded under California Health & Safety Code § 110705 because						
2	words, statem	nents and other information required by the Sherman Law to appear on their labels	ing				
3	either are missing or not sufficiently conspicuous.						
4	123. Defendant has violated California Health & Safety Code § 110760 which makes it						
5	unlawful for a	any person to manufacture, sell, deliver, hold, or offer for sale any food that is					
6	misbranded.						
7	124.	Defendant has violated California Health & Safety Code § 110765 that makes it	t				
8	unlawful for a	any person to misbrand any food.					
9	125.	Defendant has violated California Health & Safety Code § 110770 which makes	s it				
10	unlawful for a	any person to receive in commerce any food that is misbranded or to deliver or					
11	proffer for de	liver any such food.					
12	126.	Defendant has violated the standard set by 21 C.F.R. § 101.2, which has been					
13	incorporated	by reference in the Sherman Law, by failing to include on their product labels the					
14	nutritional inf	formation required by law.					
15	127.	Defendant has violated the standards set by 21 CFR §§ 101.13, and 101.54, whi	ch				
16	have been ado	opted by reference in the Sherman Law, by including unauthorized antioxidant an	d				
17	other nutrient	claims on their products. Defendant has violated the standards set by 21 CFR §§					
18	101.14, and 1	01.65, which have been adopted by reference in the Sherman Law, by including					
19	unauthorized	health and healthy claims on their products.					
20	Е.	Plaintiff Purchased Defendant's Misbranded Food Products					
21	128.	Plaintiff cares about the nutritional content of food and seeks to maintain a heal	thy				
22	diet.						
23	129. Plaintiff purchased Defendant's Misbranded Food Products at issue in this Third						
24	Amended Complaint and throughout the Class Period.						
25	130.	Prior to making her decisions to purchase Defendant's products Plaintiff read th	e				
26	labels and had	d reviewed the aforesaid information on the website regarding the health benefits	to				
27	be gained from	m consuming Defendant's products.					
28							
	THIRD AMENDI	ED CLASS ACTION COMPLAINT	39				

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1 131. Plaintiff purchased a wide variety of Defendant's Misbranded Food Products at
 issue in this Third Amended Complaint on numerous occasions throughout the Class Period
 including, but not limited to, the following products: Green Tea, Jasmine Green Tea, Green Tea
 Decaffeinated, Earl Grey Black Tea, Black Tea with Lemon Organic and Fair Trade Certified,
 and Lemon Twist (black tea).

Bantion 132. Plaintiff read the labels on Defendant's Misbranded Food Products, including the
antioxidant, nutrient content, and health claims, where applicable, before purchasing them.
Plaintiff would have foregone purchasing Defendant's products and bought other products readily
available at a lower price.

10 Plaintiff reasonably relied on Defendant's package labeling and packaging and 133. 11 product placement. Plaintiff read Defendant's website and web claims concerning Defendant's 12 Misbranded Food Products including the antioxidant related nutrient content and health labeling 13 claims including, "natural source of antioxidants", "rich in antioxidants"; "Black and green teas 14 also contain Vitamins A, B1, B2 and B6, along with calcium, zinc and folic acid; and Tea is also 15 a rich source of potassium" and based and justified the decision to purchase Defendant's 16 products in substantial part on Defendant's package labeling including the nutrient (antioxidant 17 and other) content claims and health labeling claims, and representations related to Defendant's 18 food products before purchasing them.

19 134. At the point of sale, Plaintiff did not know, and had no reason to know, that
20 Defendant's products were misbranded as set forth herein and did not contain the healthful
21 benefits claimed by the Defendant and would not have bought the products, or paid a premium for
22 them, had she known the truth about them.

23 135. At point of sale, Plaintiff did not know, and had no reason to know, that 24 Defendant's nutrient content (antioxidant and otherwise) and health claims including "rich in antioxidants"; or "natural source of antioxidants"; or "Black and green teas also contain 25 26 Vitamins A, B1, B2 and B6, along with calcium, zinc and folic acid;, Tea is also a rich source of 27 potassium—vital for maintaining a normal heartbeat and regulating fluid levels in cells and 28 manganese, an essential mineral for bone growth" claims on the products' labels or Defendant's THIRD AMENDED CLASS ACTION COMPLAINT 40 CASE NO. 12-CV-02646 (RMW)

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website and were false, unlawful and unauthorized as set forth herein, and would not have bought
 the products had she known the truth about them.

- 3 136. After Plaintiff learned that Defendant's Misbranded Food Products are falsely
 4 labeled, she stopped purchasing them.
- 5 137. Plaintiff justified the decision to purchase Defendant's products in substantial part
 6 on Defendant's false and unlawful representations.
- 7 138. As a result of Defendant's misrepresentations, Plaintiff and thousands of others in
 8 California purchased the Misbranded Food Products at issue.
- 9 139. Defendant's labeling, advertising and marketing as alleged herein are false and
 10 misleading and were designed to increase sales of the products at issue. Defendant's
 11 misrepresentations are part of an extensive labeling, advertising and marketing campaign, and a
 12 reasonable person would attach importance to Defendant's representations in determining
 13 whether to purchase the products at issue.
- 14 140. A reasonable person would also attach importance to whether Defendant's
 products were legally salable, and capable of legal possession, and to Defendant's representations
 about these issues in determining whether to purchase the products at issue. Plaintiff would not
 have purchased Defendant's Misbranded Food Products had she known they were not capable of
 being legally sold or held.
- 19 141. These Misbranded Food Products 1) whose essential characteristics had been
 20 misrepresented by the Defendant; 2) which had their nutritional and health benefits
 21 misrepresented and overstated by the Defendant, and 3) which were misbranded products which
 22 could not be resold and whose very possession was illegal; had no economic value; and were
 23 worthless to the Plaintiff and as a matter of law.
- 24

F. <u>All Misbranded Food Products Are Substantially Similar</u>

142. Defendant's Misbranded Food Products, i.e., all green, black and white teas, are
substantially similar. All green, black and white tea products come from the same plant—
Camellia sinensis. The process used (fermentation, oxidation, etc.) determines classification of
the tea.

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1	143. The Misbranded Food Products have the same labels, labeling, packaging, and
2	sizes as shown by way of example in Exhibit 1. The Defendant makes the same antioxidant
3	related nutrient content claims on the labels of all of its green tea products and likewise the same
4	antioxidant related nutrient content claims on the labels of all of its black and white teas
5	Moreover, on its website the Defendant makes the same unlawful nutrient content (antioxidant
6	and otherwise) claims and health about all of its green, black and white teas.
7	144. The Misbranded Food Products are the same product, tea from the Camellia
8	sinensis plant or the rooibos plant. The only difference in the Misbranded Food Products is the
9	flavor of the tea. The same or substantially similar antioxidant related nutrient content claims are
10	made on all Twinings tea products, those that Plaintiff purchased and those that she did not
11	purchase. The nutrient content (antioxidant and otherwise) claims appearing on Twinings'
12	website (and which Plaintiff reviewed at various times during the class period) are not product
13	specific but relate in some instances to all tea products; in some instances to all green tea
14	products; in some instances to all black tea products; in some instances to all green and black tea
15	products, in some instances to all white tea products.
16	145. Because of the similarity of the products (tea) and the claims (nutrient content—
17	antioxidant and other) claims and for judicial economy the Misbranded Food Products should all
18	be included in the class.
19	CLASS ACTION ALLEGATIONS
20	146. Plaintiff brings this action as a class action pursuant to Federal Rule of Procedure
21	23(b)(2) and 23(b)(3) on behalf of the following class:
22	All persons in California who purchased Defendant's green, black and white tea products for personal or household use since May 2, 2008 (the "Class").
23	147. The following persons are expressly excluded from the Class: (1) Defendant and
24 25	its subsidiaries and affiliates; (2) all persons who make a timely election to be excluded from the
25 26	proposed Class; (3) governmental entities; and (4) the Court to which this case is assigned and its
26 27	staff.
27 28	
28	
	THIRD AMENDED CLASS ACTION COMPLAINT42CASE NO. 12-CV-02646 (RMW)

1	148. This action can be maintained as a class action because there is a well-defined					
2	community of interest in the litigation and the proposed Class is easily ascertainable.					
3	149. <u>Numerosity</u> : Based upon Defendant's publicly available sales data with respect to					
4	the misbranded products at issue, it is estimated that the Class numbers in the thousands, and that					
5	joinder of all Class members is impracticable.					
6	150. <u>Common Questions Predominate</u> : This action involves common questions of law					
7	and fact applicable to each Class member that predominate over questions that affect only					
8	individual Class members. Thus, proof of a common set of facts will establish the right of each					
9	Class member to recover. Questions of law and fact common to each Class member include, for					
10	example:					
11	a. Whether Defendant engaged in unlawful, unfair or deceptive					
12	business practices by failing to properly package and label its Misbranded Food Products sold to consumers;					
13	b. Whether the food products at issue were misbranded or unlawfully packaged and labeled as a matter of law;					
14						
15 16	c. Whether Defendant made unlawful and misleading antioxidant, nutrient content and health related claims with respect to the food products it sold to consumers;					
10	d. Whether Defendant violated California Bus. & Prof. Code § 17200 et seq., California Bus. & Prof. Code § 17500 et seq., the Consumer					
18	Legal Remedies Act, Cal. Civ. Code § 1750 <i>et seq.</i> , and the Sherman Law;					
19	e. Whether Plaintiff and the Class are entitled to equitable and/or injunctive relief;					
20	f. Whether Defendant's unlawful, unfair and/or deceptive practices					
21	harmed Plaintiff and the Class; and					
22 23	g. Whether Defendant was unjustly enriched by its deceptive practices.					
23 24	151. <u>Typicality</u> : Plaintiff's claims are typical of the claims of the Class because					
	Plaintiff bought Defendant's Misbranded Food Products during the Class Period. Defendant's					
25 26	unlawful, unfair and/or fraudulent actions concern the same business practices described herein					
20 27	irrespective of where they occurred or were experienced. Plaintiff and the Class sustained similar					
27	injuries arising out of Defendant's conduct in violation of California law. The injuries of each					
20	THIRD AMENDED CLASS ACTION COMPLAINT43CASE NO. 12-CV-02646 (RMW)					

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

6 152. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class. 7 Neither Plaintiff nor Plaintiff's counsel have any interests that conflict with or are antagonistic to 8 the interests of the Class members. Plaintiff has retained highly competent and experienced class 9 action attorneys to represent her interests and those of the members of the Class. Plaintiff and 10 Plaintiff's counsel have the necessary financial resources to adequately and vigorously litigate 11 this class action, and Plaintiff and her counsel are aware of their fiduciary responsibilities to the 12 Class members and will diligently discharge those duties by vigorously seeking the maximum 13 possible recovery for the Class.

14 153. Superiority: There is no plain, speedy or adequate remedy other than by 15 maintenance of this class action. The prosecution of individual remedies by members of the 16 Class will tend to establish inconsistent standards of conduct for Defendant and result in the 17 impairment of Class members' rights and the disposition of their interests through actions to 18 which they were not parties. Class action treatment will permit a large number of similarly 19 situated persons to prosecute their common claims in a single forum simultaneously, efficiently 20 and without the unnecessary duplication of effort and expense that numerous individual actions 21 would engender. Further, as the damages suffered by individual members of the Class may be 22 relatively small, the expense and burden of individual litigation would make it difficult or 23 impossible for individual members of the Class to redress the wrongs done to them, while an 24 important public interest will be served by addressing the matter as a class action. Class 25 treatment of common questions of law and fact would also be superior to multiple individual 26 actions or piecemeal litigation in that class treatment will conserve the resources of the Court and 27 the litigants, and will promote consistency and efficiency of adjudication.

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1	154. The prerequisites to maintaining a class action for injunctive or equitable relief				
2	pursuant to Fed. R. Civ. P. 23(b)(2) are met as Defendant has acted or refused to act on grounds				
3	generally applicable to the Class, thereby making appropriate final injunctive or equitable relief				
4	with respect to the Class as a whole.				
5	155. The prerequisites to maintaining a class action pursuant to Fed. R. Civ. P. 23(b)(3)				
6	are met as questions of law or fact common to class members predominate over any questions				
7	affecting only individual members, and a class action is superior to other available methods for				
8	fairly and efficiently adjudicating the controversy.				
9	156. Plaintiff and Plaintiff's counsel are unaware of any difficulties that are likely to be	•			
10	encountered in the management of this action that would preclude its maintenance as a class				
11	action.				
12	CAUSES OF ACTION				
13	FIRST CAUSE OF ACTION				
14	Business and Professions Code § 17200 et seq. Unlawful Business Acts and Practices				
15	157. Plaintiff incorporates by reference each allegation set forth above.				
16	157. Plaintiff incorporates by reference each allegation set forth above.158. Defendant's conduct constitutes unlawful business acts and practices.				
17	159. Defendant sold Misbranded Food Products nationwide and in California during th	e			
18	Class Period.				
19	160. Defendant is a corporation and, therefore, is a "person" within the meaning of the				
20	Sherman Law.				
21	161. Defendant's business practices are unlawful under § 17200 <i>et seq</i> . by virtue of				
22	Defendant's violations of the advertising provisions of the Sherman Law (Article 3) and the				
23	misbranded food provisions of the Sherman Law (Article 6).				
24	162. Defendant's business practices are unlawful under § 17200 <i>et seq.</i> by virtue of				
25	Defendant's violations of § 17500 <i>et seq.</i> , which forbids untrue and misleading advertising.				
26	163. Defendant's business practices are unlawful under § 17200 et seq. by virtue of				
27	Defendant's violations of the Consumer Legal Remedies Act, Cal. Civil Code § 1750 et seq.				
28					
	THIRD AMENDED CLASS ACTION COMPLAINT45CASE NO. 12-CV-02646 (RMW)45	5			

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1	164. Defendant sold Plaintiff and the Class Misbranded Food Products that were not						
2	capable of being sold or held legally and which had no economic value and were legally						
3	worthless. Plaintiff and the Class paid a premium for the Misbranded Food Products.						
4	165. As a result of Defendant's illegal business practices, Plaintiff and the Class,						
5	pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future						
6	conduct and such other orders and judgments which may be necessary to disgorge Defendant's						
7	ill-gotten gains and to restore to any Class Member any money paid for the Misbranded Food						
8	Products.						
9	166. Defendant's unlawful business acts present a threat and reasonable continued						
10	likelihood of injury to Plaintiff and the Class.						
11	167. As a result of Defendant's conduct, Plaintiff and the Class, pursuant to Business						
12	and Professions Code § 17203, are entitled to an order enjoining such future conduct by						
13	Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's						
14	ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by						
15	Plaintiff and the Class.						
	SECOND CAUSE OF ACTION						
16 17	SECOND CAUSE OF ACTION Business and Professions Code § 17200 <i>et seq.</i> <u>Unfair Business Acts and Practices</u>						
16 17 18	Business and Professions Code § 17200 et seq.						
16 17 18 19	Business and Professions Code § 17200 <i>et seq.</i> <u>Unfair Business Acts and Practices</u>						
16 17 18 19 20	Business and Professions Code § 17200 et seq. Unfair Business Acts and Practices 168. Plaintiff incorporates by reference each allegation set forth above.						
16 17 18 19 20 21	Business and Professions Code § 17200 et seq. Unfair Business Acts and Practices 168. Plaintiff incorporates by reference each allegation set forth above. 169. Defendant's conduct as set forth herein constitutes unfair business acts and						
16 17 18 19 20 21 22 23	Business and Professions Code § 17200 et seq. Unfair Business Acts and Practices168.Plaintiff incorporates by reference each allegation set forth above.169.Defendant's conduct as set forth herein constitutes unfair business acts and practices.						
 16 17 18 19 20 21 22 23 	Business and Professions Code § 17200 et seq. Unfair Business Acts and Practices168.Plaintiff incorporates by reference each allegation set forth above.169.Defendant's conduct as set forth herein constitutes unfair business acts and practices.170.Defendant sold Misbranded Food Products nationwide and in California during the						
 16 17 18 19 20 21 22 23 24 	Business and Professions Code § 17200 et seq. Unfair Business Acts and Practices168.Plaintiff incorporates by reference each allegation set forth above.169.Defendant's conduct as set forth herein constitutes unfair business acts andpractices.170.170.Defendant sold Misbranded Food Products nationwide and in California during theClass Period.Vertices.						
 16 17 18 19 20 21 22 	Business and Professions Code § 17200 et seq. Unfair Business Acts and Practices168.Plaintiff incorporates by reference each allegation set forth above.169.Defendant's conduct as set forth herein constitutes unfair business acts andpractices.Infair Business Acts and Practices170.Defendant sold Misbranded Food Products nationwide and in California during theClass Period.Infair Business of the Class suffered a substantial injury by virtue of buying						
 16 17 18 19 20 21 22 23 24 25 	Business and Professions Code § 17200 et seq. Unfair Business Acts and Practices168.Plaintiff incorporates by reference each allegation set forth above.169.Defendant's conduct as set forth herein constitutes unfair business acts and practices.170.Defendant sold Misbranded Food Products nationwide and in California during the Class Period.171.Plaintiff and members of the Class suffered a substantial injury by virtue of buying Defendant's Urbanded Food Products that they would not have purchased absent Defendant's						
 16 17 18 19 20 21 22 23 24 25 26 	Business and Professions Code § 17200 et seq. Unfair Business Acts and Practices168.Plaintiff incorporates by reference each allegation set forth above.169.Defendant's conduct as set forth herein constitutes unfair business acts and practices.170.Defendant sold Misbranded Food Products nationwide and in California during the Class Period.171.Plaintiff and members of the Class suffered a substantial injury by virtue of buying Defendant's Undated Food Products that they would not have purchased absent Defendant's illegal conduct.						

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

3 173. Defendant sold Plaintiff and the Class Misbranded Food Products that were not
4 capable of being legally sold or held and that had no economic value and were legally worthless.
5 Plaintiff and the Class paid a premium for the Misbranded Food Products.

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

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

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

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

THIRD CAUSE OF ACTION

177. Plaintiff incorporates by reference each allegation set forth above.
 178. Defendant's conduct as set forth herein constitutes fraudulent business practices
 under California Business and Professions Code sections § 17200 *et seq.*

24 179. Defendant sold Misbranded Food products nationwide and in California during the
25 Class Period.

26 180. Defendant's misleading marketing, advertising, packaging and labeling of the
 27 Misbranded Food Products were likely to deceive reasonable consumers, and in fact, Plaintiff and

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1	members of the Class were deceived. Defendant has engaged in fraudulent business acts and					
2	practices.					
3	181. Defendant's fraud and deception caused Plaintiff and the Class to purchase					
4	Defendant's Misbranded Food Products that they would otherwise not have purchased had they					
5	known the true nature of those products.					
6	182. Defendant sold Plaintiff and the Class Misbranded Food Products that were not					
7	capable of being sold or held legally and that had no economic value and were legally worthless.					
8	Plaintiff and the Class paid a premium price for the Misbranded Food Products.					
9	183. As a result of Defendant's conduct as set forth herein, Plaintiff and the Class,					
10	pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future					
11	conduct by Defendant, and such other orders and judgments which may be necessary to disgorge					
12	Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food					
13	Products by Plaintiff and the Class.					
14	FOURTH CAUSE OF ACTION					
15	Business and Professions Code § 17500 <i>et seq.</i> <u>Misleading and Deceptive Advertising</u>					
16	184. Plaintiff incorporates by reference each allegation set forth above.					
17 18	185. Plaintiff asserts this cause of action for violations of California Business and					
10	Professions Code § 17500 et seq. for misleading and deceptive advertising against Defendant.					
20	186. Defendant sold Misbranded Food Products nationwide and in California during the					
20	Class Period.					
21	187. Defendant engaged in a scheme of offering Defendant's Misbranded Food					
22	Products for sale to Plaintiff and members of the Class by way of, inter alia, product packaging					
23	and labeling, and other promotional materials. These materials misrepresented and/or omitted the					
25	true contents and nature of Defendant's Misbranded Food Products. Defendant's advertisements					
26	and inducements were made within California and come within the definition of advertising as					
20	contained in Business and Professions Code §17500 et seq. in that such product packaging and					
28	labeling, and promotional materials were intended as inducements to purchase Defendant's					

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Misbranded Food Products and are statements disseminated by Defendant to Plaintiff and the
 Class that were intended to reach members of the Class. Defendant knew, or in the exercise of
 reasonable care should have known, that these statements were misleading and deceptive as set
 forth herein.

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

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

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

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

FIFTH CAUSE OF ACTION

Business and Professions Code § 17500 et seq. Untrue Advertising

Plaintiff incorporates by reference each allegation set forth above.

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- 26
- 27 28

THIRD AMENDED CLASS ACTION COMPLAINT CASE NO. 12-CV-02646 (RMW)

192.

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

3 194. Defendant sold mislabeled Misbranded Food Products nationwide and in 4 California during the Class Period.

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

14 In furtherance of its plan and scheme, Defendant prepared and distributed in 196. 15 California and nationwide via product packaging and labeling, and other promotional materials, 16 statements that falsely advertise the composition of Defendant's Misbranded Food Products, and 17 falsely misrepresented the nature of those products. Plaintiff and the Class were the intended 18 targets of such representations and would reasonably be deceived by Defendant's materials.

19 197. Defendant's conduct in disseminating untrue advertising throughout California and 20 nationwide deceived Plaintiff and members of the Class by obfuscating the contents, nature and 21 quality of Defendant's Misbranded Food Products in violation of the "untrue prong" of California 22 Business and Professions Code § 17500.

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198. As a result of Defendant's violations of the "untrue prong" of California Business 24 and Professions Code § 17500 et seq., Defendant has been unjustly enriched at the expense of 25 Plaintiff and the Class. Misbranded products cannot be legally sold or held and had no economic 26 value and are legally worthless. Plaintiff and the Class paid a premium price for the Misbranded 27 Food Products.

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1	199. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are					
2	entitled to an order enjoining such future conduct by Defendant, and such other orders and					
3	judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any					
4	money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.					
5	SIXTH CAUSE OF ACTION					
6	Consumers Legal Remedies Act, Cal. Civ. Code §1750 et seq.					
7	200. Plaintiff incorporates by reference each allegation set forth above.					
8	201. This sixth cause of action is brought pursuant to the CLRA.					
9	202. Defendant's acts were and are willful, oppressive and fraudulent, thus supporting					
10	an award of punitive damages.					
11	203. Plaintiff and the Class are entitled to actual and punitive damages against					
12	Defendant for its violations of the CLRA. In addition, pursuant to Cal. Civ. Code § 1782(a)(2),					
13	Plaintiff and the Class are entitled to an order enjoining the above-described acts and practices,					
14	providing restitution to Plaintiff and the Class, ordering payment of costs and attorneys' fees, and					
15	any other relief deemed appropriate and proper by the Court pursuant to Cal. Civ. Code § 1780.					
16	204. Defendant's actions, representations and conduct have violated, and continue to					
17	violate the CLRA, because they extend to transactions that are intended to result, or which have					
18	resulted, in the sale of goods or services to consumers.					
19	205. Defendant sold Misbranded Food Products nationwide and in California during the					
20	Class Period.					
21	206. Plaintiff and members of the Class are "consumers" as that term is defined by the					
22	CLRA in Cal. Civ. Code §1761(d).					
23	207. Defendant's Misbranded Food Products were and are "goods" within the meaning					
24	of Cal. Civ. Code §1761(a).					
25	208. By engaging in the conduct set forth herein, Defendant violated and continues to					
26	violate Section 1770(a)(5) of the CLRA, because Defendant's conduct constitutes unfair methods					
27	of competition and unfair or fraudulent acts or practices in that it misrepresents the particular					
28	ingredients, characteristics, uses, benefits and quantities of the goods.					
	THIRD AMENDED CLASS ACTION COMPLAINT51CASE NO. 12-CV-02646 (RMW)51					

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

5 210. By engaging in the conduct set forth herein, Defendant violated and continues to 6 violate Section 1770(a)(9) of the CLRA, because Defendant's conduct constitutes unfair methods 7 of competition and unfair or fraudulent acts or practices in that Defendant advertises goods with 8 the intent not to sell the goods as advertised.

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

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

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

21 214. Defendant has failed to provide appropriate relief for its violations of the CLRA
22 within 30 days of its receipt of the CLRA demand notice. Accordingly, pursuant to Sections
23 1780 and 1782(b) of the CLRA, Plaintiff is entitled to recover actual damages, punitive damages,
24 attorneys' fees and costs, and any other relief the Court deems proper.

25 215. Consequently, Plaintiff and the Class are entitled to actual and punitive damages
26 against Defendant for its violations of the CLRA. In addition, pursuant to Cal. Civ. Code §
27 1782(a)(2), Plaintiff and the Class are entitled to an order enjoining the above-described acts and
28 practices, providing restitution to Plaintiff and the Class, ordering payment of costs and attorneys'
27 THIRD AMENDED CLASS ACTION COMPLAINT 52
27 CASE NO. 12-CV-02646 (RMW)

Case5:12-cv-02646-RMW Document62 Filed06/19/13 Page53 of 54

1	fees, and any other relief deemed appropriate and proper by the Court pursuant to Cal. Civ. Code							
2	§ 1780.							
3	JURY DEMAND							
4	216.							
5		<u>F</u>	PRAYER FOR RELIEF					
6 7	WHE	REFORE, Plaintiff, indi	vidually and on behalf of all others similarly situated, and	l on				
7 8	behalf of the	behalf of the general public, prays for judgment against Defendant as follows:						
8 9	А.	For an order certifying	g this case as a class action and appointing Plaintiff and he	er				
10	counsel to rep	present the Class;						
10	В.	For an order awarding	, as appropriate, damages, restitution or disgorgement to					
12	Plaintiff and	the Class;						
12	C.	For an order requiring	Defendant to immediately cease and desist from selling i	ts				
14	Misbranded Food Products in violation of law; enjoining Defendant from continuing to market,							
15	advertise, distribute, and sell these products in the unlawful manner described herein; and							
16	ordering Def	endant to engage in corre	ective action;					
17	D.	For all remedies availa	able pursuant to Cal. Civ. Code § 1780;					
18	E.	For an order awarding	attorneys' fees and costs;					
19	F.	For an order awarding	punitive damages;					
20	G.	For an order awarding	pre-and post-judgment interest; and					
21	H.	For an order providing	g such further relief as this Court deems proper.					
22	Dated	l: June 19, 2013	Respectfully submitted,					
23			<u>/s/ Ben F. Pierce Gore</u> Ben F. Pierce Gore (SBN 128515)					
24			PRATT & ASSOCIATES 1871 The Alameda					
25			Suite 425 San Jose, CA 95126					
26			(408) 369-0800 pgore@prattattorneys.com					
27			Attorneys for Plaintiff					
28								
		ED CLASS ACTION COMPLA CV-02646 (RMW)	AINT	53				

	Case5:12-cv-02646-RMW Document62 Filed06/19/13 Page54 of 54					
1	CERTIFICATE OF SERVICE					
2	I hereby certify that I have on June 19, 2013 filed and served through the Court's ECF					
3	system a true and correct copy of the foregoing.					
4						
5	/s/ Ben F. Pierce Gore Ben F.Pierce Gore					
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	THIRD AMENDED CLASS ACTION COMPLAINT54CASE NO. 12-CV-02646 (RMW)54					

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http://www.twiningsusashop.com/green-tea.html[2/26/2013 4:26:41 PM]

	Case5:12-cv-026	46-RMW Document@8-1 File GUNPOWDER GREEN TEA A rich blend of Green Gunpowder teas from the Orient with a clear fragrance liquor. Vertical and the orient with a clear Order Now Vertical and the orient	ed 08/19/13 Pag	PURE GREEN 100% ORGANIC & FAIR TRADE CERTIFIED™ TEA Pure green tea with a fresh taste, smooth flavour and enticing aroma. Order Now
		GREEN TEA WITH JASMINE 100% ORGANIC & FAIR TRADE CERTIFIED™ TEA Pure green tea perfectly balanced with the unique floral scent of jasmine.		GREEN TEA WITH A HINT OF CITRUS ORGANIC & FAIR TRADE CERTIFIED™ TEA Pure green tea perfectly balanced with the alluring flavour of lemon and orange.
TWININGS TEA EXPLORER		GREEN TEA WITH MINT ORGANIC & FAIR TRADE CERTIFIED™ TEA Pure green tea perfectly balanced with the fresh taste of peppermint. Order Now		

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More inspections. Compliance, Enforcement, and Criminal Investigations Enforcement Actions Warning Letters

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

EXHIBIT 2

12 Case5:12-cv-02646-RNI Wer United States Inc.8/23/10 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 in 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.

 $\frac{1}{8}$ 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. I is your responsibility to ensure that all of your products are in compliance with the laws and regulations

1 1

/12/12

12 Case5:12-cv-02646-RWW Document 2-2 Filed06/19/13 Page3 of 6 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 5/10/11⁹

Links on this page:

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

- Accessibility
- Contact FDA
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- FDA Basics
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CLLS. Department of Health & Human Services

U.S. Food & Drug Administration

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HomeoInspections, Compliance, Enforcement, and Criminal Investigations Enforcement Actions Warning Letters

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

" Department of Health and Human Services

April 20, 2011

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Refer to MIN 11 - 21

Public Health Service

Central Region

...

Food and Drug Administration Minneapolis District Office

Minneapolis, MN 55401 Telephone: (612) 334-4100 FAX: (612) 334-4142

250 Marquette Avenue, Suite 600

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.rishitea.com/store/index.php¹ 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 you 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.gov².

I. Unapproved New Drugs

Examples of disease claims on your website http://www.rishi-tea.com/store/3

index.php include: Ginger, Organic Botanical

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

Green Oolong Tea, 100% Premium Tealeaf Powder

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

Pu-erh Tea

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

• "Regular consumption of Oolong Tea is linked to the reduction of plaque in the arteries, reduction of cholesterol and lowering of blooc sugar."

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm252215.htm



Page 1 of 4

"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."

• "White Tea...contain[5] 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 The above violations are not meant to be an all-inclusive list or denciencies 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 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,

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm252215.htm

Page 2 of 4

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/s/ Gerald J. Berg Director Minneapolis District

Close Out Letter

• Diaspora Tea & Herb Co., LLC - Close Out Letter 2/3/124

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
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- Contact FDA
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- 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

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