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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

MICHAEL KOSTA, STEVE BATES, SARAH LANGILLE and TREVOR FEWINS, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

DEL MONTE CORPORATION,

Defendant.

Case No. CV 12-01722 YGR

CLASS ACTION AND REPRESENTATIVE ACTION

CONSOLIDATED COMPLAINT FOR DAMAGES, EQUITABLE AND INJUNCTIVE RELIEF

JURY TRIAL DEMANDED

Plaintiffs, Michael Kosta, Steve Bates, Sarah Langille and Trevor Fewins, through their undersigned attorneys, bring this lawsuit against Del Monte Corporation (hereinafter "Del Monte" or "Defendant") as to their own acts upon personal knowledge, and as to all other matters upon information and belief. In order to remedy the harm arising from Defendant's illegal conduct, which has resulted in unjust profits, Plaintiffs bring this action on behalf of a national class of consumers who, within the last four years, purchased a Del Monte canned tomato product, a Del Monte FreshCut vegetable product or a Del Monte Fruit Naturals, SunFresh, SuperFruit or Fruit Bowls fruit product (referred to herein as "Misbranded Food Products").

INTRODUCTION

1. Every day, millions of Americans purchase and consume packaged foods. Identical federal and California laws require truthful, accurate information on the labels of packaged foods. This case is about a company that flouts those laws and sells misbranded food to unsuspecting consumers. The law, however, is clear: misbranded food cannot legally be manufactured, held, advertised, distributed, or sold. Misbranded food is worthless as a matter of law, and purchasers of misbranded food are entitled to a refund of their purchase price.

2. Del Monte is "one of the country's largest producers, distributors, and marketers" of food products with "$3.7 billion in net sales in fiscal 2011." http://www.delmontefoods.com/company/default.aspx

3. While Del Monte has historically focused on thermally treated and/or chemically preserved canned fruit and vegetables while other independent and unrelated Del Monte entities have produced dried and fresh fruit and vegetable products under the Del Monte name, Del Monte recognizes that consumers are increasingly interested in products that were fresh and natural and that consumers are willing, not only to seek out and purchase such fresh and natural products, but were willing to pay a premium for such products

4. Del Monte also recognizes that health claims drive sales, and actively promotes the health benefits of its food products:

> Del Monte offers nutritious foods for main meals and snacking for the entire family, and our broad selection of healthy options is especially appropriate for children. We aim to have a good number of our products provide at least a half a cup of fruits or vegetables per serving and to meet healthy nutrient levels as specified by the FDA. A majority of our products are low in fat and we carry several specialized product lines organic, low-salt and reduced-salt, no sugar added, and light-in-calories for those seeking additional health benefits or following specific dietary regimes.

http://www.delmontefoods.com/cr/default.aspx?page=cr_productintegrity

5. Del Monte's website furthers states, "Del Monte® fruits and vegetables are chock-full of flavor and packed with nutrition which includes plenty of age-fighting, immune-building

and heart-strengthening antioxidants. Let's do right by our bodies by eating more nutritious meals." http://www.delmonte.com/Nutrition/

6. Del Monte makes unlawful claims on both its labels and its website. Del Monte's unlawful claims include, but are not limited to, unlawful Lycopene antioxidant and other nutrient content claims; unlawful claims that products contained no artificial flavors, additives or preservatives claims; representations that products were fresh and natural as well as unlawful health claims. The unlawful claims are described more fully in the Factual Allegations section herein.

7. If a manufacturer, like Del Monte, is going to make a claim on a food label, the label must meet certain legal requirements that help consumers make informed choices and ensure that they are not misled. Del Monte is certainly aware of these requirements. "We may be exposed to product recalls, including voluntary recalls or withdrawals, and adverse public relations if our products are alleged to cause injury or illness or if we are alleged to have mislabeled or misbranded our products or otherwise violated governmental regulations." http://google.brand.edgar-online.com/EFX_dll/EDGARpro.dll?FetchFilingHtmlSection1?SectionID=8241623-89280-173390&SessionID=zEFsFe8pbICAPs7

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

A. Representing food products to be fresh when they have been thermally processed, pasteurized and chemically preserved

B. Representing food products to be "all natural," "100% natural," or natural when they contain significant quantities of chemical preservatives, synthetic chemicals, added artificial color and other artificial ingredients;

C. Representing food products to have a certain standard of identity or to have a particular serving size that is contrary to law;

D. Failing to use the common or usual name of foods required by law;

E. Representing food products to be free of artificial ingredients, additives and preservatives when they in fact contain artificial ingredients, additives and preservatives;

F. Failing to disclose the presence of chemical preservatives and artificial added colors in the ingredient lists of food products as required by law;

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

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

I. Representing foods to be fresh or have a fresh taste when those products have undergone manufacturing processes and contain undisclosed chemical preservatives that preclude any representations about freshness as a matter of law;

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

K. 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\.

9. These practices are not only illegal but they mislead consumers and deprive them of the information they require to make informed purchasing decisions. Thus, for example, a mother who reads labels because she wants to purchase all natural or fresh foods and does not wish to feed her child highly processed foods containing unnatural chemicals would be mislead by Del Monte's practices and labeling

10. Similarly, these laws placed numerous requirements on food companies that were designed to ensure that the claims about their products that they made to consumers were truthful, accurate and backed by acceptable forms of scientific proof. When companies like the Defendant make unlawful nutrient content, or antioxidant or health claims that have been prohibited by regulation, consumers like the Plaintiffs are misled.

11. Identical federal and California laws regulate the content of labels on packaged food. The requirements of the federal Food, Drug & Cosmetic Act ("FDCA") were adopted by the California legislature in the Sherman Food Drug & Cosmetic Law (the "Sherman Law"). California Health & Safety Code § 109875, *et seq.* Under both the Sherman Law and FDCA section 403(a), food is "misbranded" if "its labeling is false or misleading in any particular," or if

it does not contain certain information on its label or in its labeling. California Health & Safety Code § 110660; 21 U.S.C. § 343(a). Under the FDCA, the term "false" has its usual meaning of "untruthful," while the term "misleading" is a term of art. Misbranding reaches not only false claims, but also those claims that might be technically true, but still misleading. If any single representation in the labeling is misleading, the entire food is misbranded, and no other statement in the labeling can cure a misleading statement. "Misleading" is judged in reference to "the ignorant, the unthinking and the credulous who, when making a purchase, do not stop to analyze." *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951). Under the FDCA, it is not necessary to prove that anyone was actually misled.

12. As consumer preferences have begun to favor healthier options, Del Monte has embarked on a health and wellness strategy that seeks to emphasize how its products are good for a consumer and to reposition its products as a healthy option. In furtherance of its health and wellness strategy, Del Monte utilizes unlawful, false and misleading nutrient content and health claims to promote and market its Misbranded Food Products. Del Monte has also sought to appeal to consumer preferences for fresh, natural and functional foods by including unlawful, false and misleading antioxidant claims, nutrient content claims, natural claims and fresh claims on its Misbranded Food Product labels and product related materials. Del Monte has also engaged in a host of unlawful labeling practices designed to conceal those aspects of its foods that are not in line with consumer preferences. Thus, for example, failed to disclose the presence of preservatives and it has understated the serving sizes, calories and sugar and carbohydrate content of its Misbranded Food Products.

13. Del Monte's reason for making such claims and engaging in deceptive and unlawful labeling practices is driven by its pecuniary interests. As stated by Del Monte in the Risk Factors section of the most recent annual report it filed with the S.E.C.:

> *The pet product and food product categories in which we participate are highly competitive and, if we are not able to compete effectively, our results of operations could be adversely affected.*
>
> The pet product and food product categories in which we participate are highly competitive. There are numerous brands and products that compete for shelf space

> and sales, with competition based primarily on quality, breadth of product line, brand awareness, innovation, price, taste, nutrition, variety, packaging and value-added customer services such as inventory management services. We compete with a significant number of companies of varying sizes, including divisions or subsidiaries of larger companies. Our branded products face strong competition from private label products that are generally sold at lower prices…. There are competitive pressures and other factors which could cause our products to lose market share or decline in sales or result in significant price or margin erosion, which would have a material adverse effect on our business, financial condition and results of operations.
>
> *We may be unable to successfully introduce new products, reposition existing products or anticipate changes in pet or consumer preferences, which could adversely affect our results of operations.*
>
> Our future business and financial performance depend, in part, on our ability to successfully introduce new products and improved products, reposition existing products, and anticipate and offer products that appeal to the changing tastes, dietary habits and trends and product packaging preferences of consumers and, their pets, in the market categories in which we compete. … If we are not able to anticipate, identify or develop and market products that respond to changes in pet or consumer preferences or if our new product introductions or repositioned products fail to gain consumer acceptance, we may not grow our business as anticipated. Additionally, demand for our products could decline and our results of operations could be adversely affected.

14. In furtherance of its health and wellness strategy Del Monte has utilized a number of specific unlawful, improper, unauthorized, misleading and false fresh, natural, antioxidant, nutrient content, fresh and no preservative type claims on its products' labels and labeling. These include:

A. Antioxidant claims on the labels of its Del Monte's canned tomato products which fail to meet the minimum regulatory requirements for such antioxidant claims;

B. No artificial ingredients, additives and preservatives claims on the labels of Del Monte's canned food products that contain artificial ingredients, additives and preservatives;

C. "Natural" claims on the labels of Del Monte products that contain ingredients that are not natural; and

D. Nutrient content claims about Del Monte's products when such claims are false and are prohibited by federal and California law; and

E. "Fresh" claims on the labels of Del Monte products that are not fresh.

15. Del Monte recognizes that health and nutrition claims drive food sales, and actively promotes the purported health and nutritional benefits of its Misbranded Food Products, notwithstanding the fact that such promotion violates federal and California law.

16. On its own website, Del Monte has made a number of specific claims about its fruit and vegetable products, including:

> Tomatoes are rich in lycopene, Vitamin C and Vitamin E powerful antioxidants that may play a role in protecting against cancer and heart disease. It seems that almost every day, more research backing the health benefits of tomatoes is discovered. Adding tomatoes and tomato products to your favorite dishes is an easy, delicious way to amp up your healthy diet.
>
> Many vegetables are packed with phytochemicals-powerful plant nutrients like lycopene found in tomatoes and lutein, found in spinach and corn. Vegetables can also be bursting with potassium and fiber that may have a role in protecting against a variety of different diseases. So eating 2 ½ cups a day is important for good health.
>
> Del Monte® fruits and vegetables are chock-full of flavor and packed with nutrition which includes plenty of age-fighting, immune-building and heart-strengthening antioxidants. Let's do right by our bodies by eating more nutritious meals.
>
> Lycopene, a carotenoid found primarily in canned and processed tomatoes, shows promise in preventing heart disease and other types of cancer. It is the pigment that gives the brilliant red color to tomatoes, watermelon and red grapefruit. Research is beginning to show promise that lycopene benefits may have a role in preventing heart disease and certain types of cancer like prostate cancer. Canned tomatoes and tomato products are excellent sources of lycopene because the heat from cooking or canning makes the lycopene more available to your body.
>
> Red colored foods, like tomatoes, red peppers and red grapefruit contain antioxidants like lycopene that may help reduce your risk of heart disease and stroke and possibly cancer.
>
> Superfoods are foods that contain powerful disease fighting nutrients and have significantly more of these good nutrients when compared to other foods. And although they may sound intimidating, the good news about superfoods is that you can find them on your local grocery store shelves. In fact, you may already have some in your pantry and your fridge.
>
> Which foods contain these super nutrients? Most fruits and vegetables contain protective vitamins, minerals and antioxidants, but a few truly stand out as superfoods. And in many cases, the canned product is just as good, if not better,

than the fresh version:

- Tomatoes — especially canned! Tomatoes contain lycopene, an antioxidant that may help protect against cancer and heart disease. Heating the tomato through the canning process helps make this nutrient even more available for your body.
- Grapefruit, Oranges and Citrus fruits — especially red grapefruit! Vitamin C and other antioxidants are found in grapefruit and help strengthen your immune system.
- Spinach — in addition to being a good source of iron, calcium and B vitamins, spinach is loaded with beta carotene thought to help protect against cancer and heart disease. In addition, spinach contains an antioxidant called lutein, a nutrient that helps protect your eyes.
- Corn — The antioxidant lutein is also found in corn and a study from Cornell University found higher levels in canned corn than in fresh.

You may be wondering how the nutrients in superfoods work to your benefit. Simply put, they protect your body from the damage that free radicals can cause to your cells.

To better understand this process, imagine an iron railing that has been exposed to the elements. The rust that forms on the railing is the result of exposure to oxygen. By applying a protective coating to the railing, you block out the rust-inducing oxygen, thus safeguarding the railing from significant damage.

The nutrients in superfoods act in a similar same manner inside your body. Their powerful nutrients, or antioxidants, prevent free radicals, damaged cells that can be problematic, from assaulting your healthy cells. When your body needs to put up its best defense, antioxidants are crucial to your health.

So take a step toward healthier living by eating your fruits and vegetables every day, you'll be on your way to getting the extra protection your body needs.

17. Del Monte's marketing efforts have enabled Del Monte to persuade consumers to purchase its products at premium prices. According to Del Monte's regulatory filings:

Our success depends in part upon our ability to persuade consumers to purchase our branded products versus lower-priced branded and private-label offerings. During economic downturns, consumers may be less willing or able to pay a price premium for our branded products and may shift purchases to lower-priced or other value offerings, which may adversely affect our results of operations.

Our branded products generally command a price premium as compared to the prices of the private-label products with which they compete. Additionally, our branded products in our Consumer Products segment generally command a price premium as compared to the prices of the branded products with which they compete. The current premium for our products may limit our ability to effectively implement price increases. Additionally, these price premiums may increase in the future, particularly if we implement price increases. The

> willingness of consumers to pay a price premium for our branded products depends on a number of factors, including the effectiveness of our marketing programs, the continuing strength of our brands and general economic conditions. During periods of challenging economic conditions, consumers may be less willing or able to pay a price differential for our branded products, notwithstanding our marketing programs or the strength of our brands, and may shift purchases away from our branded products to lower-priced offerings or forgo purchases of our products altogether. If the price premium for our branded products exceeds the amount consumers are willing to pay, whether due to economic conditions or otherwise, our sales would suffer and our revenues and results of operations could be adversely affected. In addition consumers may migrate to higher-value, larger-sized packages of our branded products (which tend to have lower margins than our smaller-sized offerings), which could also have an adverse effect on our results of operations.

18. Del Monte claims it has adopted responsible marketing and advertising policies. Del Monte claims to understand the importance of regulatory compliance and communicating responsibly about its products. According to Del Monte's regulatory filings:

> *Government regulation could increase our costs of production and increase legal and regulatory expenses.*
>
> Manufacturing, processing, labeling, packaging, storing and distributing pet products and food products are activities subject to extensive federal, state and local regulation, as well as foreign regulation. In the United States, these aspects of our operations are regulated by the U.S. Food and Drug Administration ("FDA"), the United States Department of Agriculture ("USDA") and various state and local public health and agricultural agencies. On January 4, 2011, the FDA Food Safety Modernization Act, which is intended to ensure food safety, was enacted. This Act provides direct recall authority to the FDA and includes a number of other provisions designed to enhance food safety, including increased inspections by the FDA of domestic and foreign food facilities and increased review of food products imported into the United States. ….Failure to comply with all applicable laws and regulations, including, among others, Proposition 65, could subject us to civil remedies, including fines, injunctions, recalls or seizures, as well as potential criminal sanctions, which could have a material adverse effect on our business, financial condition and results of operations….
>
> *If our products are alleged to cause injury or illness or fail to comply with governmental regulations, we may suffer adverse public relations, need to recall our products and experience product liability claims.*
>
> We may be exposed to product recalls, including voluntary recalls or withdrawals, and adverse public relations if our products are alleged to cause injury or illness or if we are alleged to have mislabeled or misbranded our products or otherwise violated governmental regulations. ….Consumer concerns (whether justified or not) regarding the safety of our products could adversely affect our business. A product recall or withdrawal could result in substantial and unexpected

> expenditures, destruction of product inventory, and lost sales due to the unavailability of the product for a period of time, which could reduce profitability and cash flow. In addition, a product recall or withdrawal may require significant management attention. Product recalls may also result in adverse publicity, hurt the value of our brands, lead to a decline in consumer confidence in and demand for our products, and lead to increased scrutiny by federal and state regulatory agencies of our operations, which could have a material adverse effect on our brands, business, results of operations and financial condition. ….

19. Nevertheless, Del Monte has made, and continues to make, unlawful, false and deceptive claims on its Misbranded Food Products in violation of identical federal and California laws that govern the types of representations that can be made on food labels. In particular, in making its unlawful antioxidant claims on its Misbranded Food Products, Defendant has violated nutrient content labeling regulations and misbranding laws mandated by identical federal and California laws. In making its natural and fresh claims, Defendant has violated a number of other food labeling and misbranding laws mandated by identical federal and California laws including those prohibiting false or misleading label claims.

20. Defendant has made, and continues to make, unlawful claims on the food labels of its Misbranded Food Products that are prohibited by identical federal and California laws and which render these products misbranded. Under federal and California law, Defendant's Misbranded Food Products, including Defendant's canned fruit and vegetable products including its canned tomato products, cannot legally be manufactured, advertised, distributed, held or sold. Defendant's false and misleading labeling practices stem from its global marketing strategy. Thus, the violations and misrepresentations are similar across product labels and product lines. Thus, for example, the Defendant unlawfully utilized its false fresh representations and antioxidant claims on a wide range of products described below.

PARTIES

21. Plaintiff Michael Kosta is a resident of Santa Rosa, California who purchased Del Monte diced tomatoes, Del Monte FreshCut vegetable products and Del Monte Fruit Natural products in California during the four (4) years prior to the filing of this Complaint (the "Class Period").

22. Plaintiff Steve Bates is a resident of Campbell, California who purchased Del Monte diced tomatoes, Del Monte FreshCut vegetable products and Del Monte Fruit Natural and SunFresh products in California during the four (4) years prior to the filing of this Complaint (the "Class Period").

23. Plaintiff Sarah Langille is a resident of Malvern, Iowa who purchased Del Monte's Fruit Naturals, SunFresh, SuperFruit and/or Fruit Bowls in Iowa during the Class Period.

24. Plaintiff Trevor Fewins is a resident of Benicia, California who purchased and consumed Del Monte Del Monte's Fruit Naturals, SunFresh, SuperFruit and/or Fruit Bowls in California during the Class Period.

25. Defendant Del Monte Corporation is a California corporation with its principle place of business at One Maritime Plaza, San Francisco, California 94111.

26. California law applies to all claims set forth in this Complaint because Plaintiff lives in California and purchased Del Monte products there. Also, Defendant Del Monte Corporation is a California entity with its principal place of business in California. All of the misconduct alleged herein was contrived in, implemented in, and has a shared nexus with California. The formulation and execution of the unlawful practices alleged herein, occurred in, or emanated from California. Accordingly, California has significant contacts and/or a significant aggregation of contacts with the claims asserted by Plaintiff and all Class members.

JURISDICTION AND VENUE

27. This Court has original jurisdiction over this action under 28 U.S.C. § 1332(d) because this is a class action in which: (1) these are over 100 members in the proposed class; (2) at least one member of the proposed class is a citizen of a different state from Defendant; and (3) the claims of the proposed class members exceed $5,000,000 in the aggregate.

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

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

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

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

FACTUAL ALLEGATIONS

A. Identical California And Federal Laws Regulate Food Labeling

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

33. 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.

34. In addition to its blanket adoption of federal labeling requirements, California has also enacted a number of laws and regulations that adopt and incorporate specific enumerated federal food laws and regulations. For example, food products are misbranded under California Health & Safety Code § 110660 if their labeling is false and misleading in one or more particulars; they are misbranded under California Health & Safety Code § 110665 if their labeling fails to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q) and

regulations adopted thereto; they are misbranded under California Health & Safety Code § 110670 if their labeling fails to conform with the requirements for nutrient content and health claims set forth in 21 U.S.C. § 343(r) and regulations adopted thereto; they are misbranded under California Health & Safety Code § 110705 if words, statements and other information required by the Sherman Law to appear on their labeling are either missing or not sufficiently conspicuous; they are misbranded under California Health & Safety Code § 110725 if they fail to bear labels clearly stating the common or usual name of each ingredient they contain; they are misbranded under California Health & Safety Code § 110735 if they are represented as having special dietary uses but fail to bear labeling that adequately informs consumers of their value for that use; and they are misbranded under California Health & Safety Code § 110740 if they contain artificial flavoring, artificial coloring and chemical preservatives but fail to adequately disclose that fact on their labeling.

B. FDA Enforcement History

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

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

> FDA's research has found that with FOP labeling, people are less likely to check the Nutrition Facts label on the information panel of foods (usually, the back or side of the package). It is thus essential that both the criteria and symbols used in front-of-package and shelf-labeling systems be nutritionally sound, well-designed to help consumers make informed and healthy food choices, and not be false or misleading. The agency is currently analyzing FOP labels that appear to be misleading. The agency is also looking for symbols that either expressly or by implication are nutrient content claims. We are assessing the criteria established by food manufacturers for such symbols and comparing them to our regulatory criteria.
>
> It is important to note that nutrition-related FOP and shelf labeling, while

> currently voluntary, is subject to the provisions of the Federal Food, Drug, and Cosmetic Act that prohibit false or misleading claims and restrict nutrient content claims to those defined in FDA regulations. Therefore, FOP and shelf labeling that is used in a manner that is false or misleading misbrands the products it accompanies. Similarly, a food that bears FOP or shelf labeling with a nutrient content claim that does not comply with the regulatory criteria for the claim as defined in Title 21 Code of Federal Regulations (CFR) 101.13 and Subpart D of Part 101 is misbranded. We will consider enforcement actions against clear violations of these established labeling requirements. . .
>
> … Accurate food labeling information can assist consumers in making healthy nutritional choices. FDA intends to monitor and evaluate the various FOP labeling systems and their effect on consumers' food choices and perceptions. FDA recommends that manufacturers and distributors of food products that include FOP labeling ensure that the label statements are consistent with FDA laws and regulations. FDA will proceed with enforcement action against products that bear FOP labeling that are explicit or implied nutrient content claims and that are not consistent with current nutrient content claim requirements. FDA will also proceed with enforcement action where such FOP labeling or labeling systems are used in a manner that is false or misleading.

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

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

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

> In the early 1990s, the Food and Drug Administration (FDA) and the food industry worked together to create a uniform national system of nutrition labeling, which includes the now-iconic Nutrition Facts panel on most food packages. Our citizens appreciate that effort, and many use this nutrition information to make food choices. Today, ready access to reliable information about the calorie and nutrient content of food is even more important, given the prevalence of obesity and diet-related diseases in the United States. This need is highlighted by the announcement recently by the First Lady of a coordinated national campaign to reduce the incidence of obesity among our citizens,

particularly our children.

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

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

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

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

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

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

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

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

42. In these letters dealing with unlawful nutrient content claims, the FDA indicated that as a result of the same type of claims utilized by the Defendant, products were in "violation of the Federal Food, Drug, and Cosmetic Act … and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101)" and were "misbranded within the meaning of section 403(r)(1)(A) because the product label bears a nutrient content claim but does not meet the requirements to make the claim." Similarly, letters for unlawful "all natural" claims similar to those at issue here, indicated that the products at issue were "misbranded under section 403(a)(1) of the Act" because their labels were "false and misleading."

43. The warning letters were hardly isolated as the FDA has issued over 10 other warning letters to other companies for the same type of food labeling claims at issue in this case.

44. 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. Del Monte did not change the labels on its Misbranded Food Products in response to the warning letters sent to other companies.

45. Defendant also has ignored 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. Despite all warnings, Defendant's Misbranded Food Products continue to run afoul of FDA guidance as well as identical federal and California law.

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

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

C. Defendant's Food Products Are Misbranded

1. Del Monte's Unlawful Schemes To Mislead Consumers That Its Canned, Thermally Treated, Pasteurized, And Chemically Preserved Fruits And Vegetables Were "Fresh."

48. Due to the enormous growth in popularity of fresh fruits, vegetables, and produce, Del Monte engaged in a series of unlawful schemes to deceive consumers into erroneously believing that Del Monte's canned, thermally treated, pasteurized, and chemically preserved fruits and vegetables were "fresh." These schemes and the unlawful practices Del Monte undertook in furtherance of these schemes are detailed below.

a. Defendant's Labeling And Marketing Of Its Fruit Products Violates California Law

49. In violation of California law, Del Monte willfully set out to mislead consumers into erroneously believing Del Monte's fruit products were fresh when they were not. It did this so it could increase it profit margins by charging premium prices for products that would not have commanded those prices had their true nature been revealed and not concealed by Del Monte. In furtherance of this plan, Del Monte not only willfully chose to violate a number of identical California and federal laws and regulations of which it was aware, it actually conducted market research to determine how successful it and its marketing was at misleading consumers into believing its products were something that they were not.

50. As detailed below, in order to fool its customers, Del Monte undertook a series of illegal acts and unlawful labeling practices to further its sales of and profits from its "Fruit Naturals," "SunFresh," "Superfruit," and "Citrus Bowls" fruit products (collectively, the

"Misbranded Fruit Products"). Del Monte has promoted the Del Monte Misbranded Fruit Products with materially false and/or misleading statements and practices.

51. These included 1) taking thermally treated, pasteurized, and chemically preserved canned fruit products and packing them in glass and plastic containers in a manner similar to fresh cut fruit; 2) failing to correctly identify or label such canned fruit products as canned or pasteurized as required by law; 3) placing a false "must be refrigerated" statement on such shelf-stable canned fruit in violation of FDA labeling guidance; 4) placing the canned fruit products in the refrigerated section of the produce section of the grocery store adjacent to real fresh cut fruit and often under banners that stated "Fresh Cut Fruit" or something similar; 7) failing to disclose that certain ingredients were preservatives as required by law; and 8) placing sell by dates in non-conspicuous spots such as the bottom of the container to prevent consumers from noticing that the sell by dates were up to 21 months later.

52. These actions and practices were willful and intentional. Del Monte was aware of its legal requirements and the applicable laws, regulations, policies and regulatory guidance. It just chose to disregard them because it felt it could maximize its profits and achieve above-average margins by violating them. Del Monte was equally aware that consumers were being misled but rather than stop its misleading practices it sought to continue them after first gauging how effective its deception of consumers had actually been. In doing so, Del Monte violated a number of California and federal laws including the identical California and federal misbranding provisions that focus on products whose labeling are false or misleading in any particular or which omit any labeling requirements mandated by law or regulation.

53. According to the FDA's Compliance Policy Guide, CPG Sec. 562.450 Identity of Foods - Use of Terms Such as Fresh, Frozen, Dried, Canned, Etc.:

> The Federal Food, Drug, and Cosmetic Act requires that food labels bear the common or usual name of the food. The Fair Packaging and Labeling Act requires that a statement of identity appear prominently on the principal display panel. To avoid misrepresentation and provide information needed to assure proper storage, food labels should include in the name or statement of identity appropriate descriptive terms such as pasteurized, canned, frozen, or dried.

> Fresh: The term fresh should not be applied to foods which have been subjected to any form of heat or chemical processing. …
>
> Canned: A food is considered "canned," if it has been hermetically sealed and so processed by heat as to prevent spoilage. Foods which are in metal containers of the types normally used for canning, and are stored and displayed under conditions which do not suggest or imply that the article is other than a canned food need not be labeled "canned." If packed in glass or plastic bottles or jars and stored or displayed under refrigeration which might cause consumers to believe it is fresh, the label designation should include the word "canned," or "pasteurized," as the case may be.

54. In discussing a previous situation similar to the present one, the Compliance Policy Guide further stated that:

> Certain packers of grapefruit juice have asked us to sanction use of the designation "grapefruit juice" without modifying terms, irrespective of whether the juice was pasteurized, canned, or otherwise processed. Investigation indicated that "canned" grapefruit juice, packed in glass, was being refrigerated and displayed under conditions which implied it was fresh. We advised the packers that to avoid deception, the name should include the word "canned" when the product was so packed, stored, and displayed (particularly if displayed under refrigeration) as to imply or suggest that it was fresh juice.

55. It is beyond dispute that Del Monte's Misbranded Fruit Products such as Del Monte's Fruit Naturals Tropical [Fruit] Medley purchased by the Plaintiffs were "canned" fruit. These products were hermetically sealed and so processed by heat as to prevent spoilage. It is also clear that Del Monte undertook the exact practices with which the FDA took issue. For example, the label of Del Monte's Fruit Natural Tropical Medley failed to identify the product as a canned item or to reveal that the product was pasteurized. The product itself was packed in a clear plastic cup and placed in the refrigerated section of the produce department. Despite the fact that the product was shelf-stable and did not require refrigeration having been pasteurized and preserved with ascorbic acid, citric acid and calcium chloride, it bore a false "must be refrigerated" claim that was unwarranted factually or pursuant to the FDA's Guidance On Labeling Of Foods That Need Refrigeration By Consumers.

56. The FDA's Guidance On Labeling Of Foods That Need Refrigeration By Consumers makes clear that the term "must be refrigerated" "should not be used" on foods like the Misbranded Fruit Products "to avoid confusion."

57. This statement is false and/or misleading in that these processed products do not require refrigeration. The statement is intended to falsely convey, and does falsely convey, to consumers that the Del Monte Misbranded Fruit Products are fresh. The products which Del Monte has labeled as "Must Be Refrigerated" are capable of maintaining an extended shelf life without refrigeration. In fact, some products which Del Monte has labeled as "Must Be Refrigerated" are comparable to other Del Monte fruit products that are sold in the non-refrigerated canned and prepared fruit section of grocery stores, and/or Del Monte products that are labeled with different phrases such as "Best If Refrigerated" or "Refrigerate After Opening." For example, Del Monte used to sell its Fruit Natural products in cans until it decided it could achieve higher profits and above-average margins if it began to market the Fruit Natural products as fresh type products.

58. Del Monte has deliberately falsely labeled its fruit products as "Must Be Refrigerated" in order to convey to the trade, retailers, and consumers the false message that its fruit products are "fresh," and/or the equivalent of "fresh." The use of this label is also designed to secure placement of the Del Monte Misbranded Fruit Products in or near the fresh produce section of grocery stores and other food retailers, next to the Fresh Del Monte and other fresh fruit products.

59. Del Monte is using misleading packaging for its Misbranded Fruit Products lines, including its Fruit Naturals Tropical Medley product, which is packaged in plastic containers identical to the containers used by other producers for cut fresh produce, rather than in packaging typically used for canned or processed foods.

60. Del Monte deliberately packaged its Misbranded Fruit Product lines in such containers in order to (i) take advantage of retailers' and consumers' common understanding that fresh fruit and produce are packaged in this manner; (ii) mislead the public into believing that its processed fruit products are, in fact, fresh; and (iii) secure product placement in or around the refrigerated fresh produce sections of food retailers, alongside the fresh fruit, vegetable and produce products sold by Fresh Del Monte.

61. Del Monte’s false and misleading labeling and advertising caused consumers like

Plaintiffs to rely on Del Monte's labeling, and reasonably believe that Del Monte Misbranded Fruit Products are "fresh" fruit, contain the same essential nutrients as fresh fruit, and have the same nutritional value as fresh fruit.

62. The ingredients statement of Del Monte's Fruit Natural Tropical Medley also failed to disclose the fact that certain chemicals were acting as preservatives as Del Monte 1) intentionally chose not to use the term preservative to describe the function of the ascorbic acid and instead used the phrase "to protect color" because it felt consumers would react negatively to the word preservative; and 2) failed to describe how other preservatives in the product like calcium chloride and citric acid were functioning in the product. In addition, the product's sell by date was placed on the rim of the container where it was obscured by an overlapping container lid.

63. The false claims made by Del Monte through its marketing, labels, and packaging constitute false advertising.

64. The Del Monte Misbranded Fruit Products have been produced, packaged, labeled and marketed to consumers and retailers in a false and misleading way that portrays the products as either "fresh" or the equivalent of fresh-cut fruit products.

65. The claims made by Del Monte about these products were literally false, false by necessary implication, and/or misleading because Del Monte's processed products do not contain the same essential nutrients as fresh fruits, nor are the Del Monte Misbranded Fruit Products nutritionally equivalent to fresh fruit.

66. Del Monte engaged in identical unlawful practices with respect to all of its Misbranded Fruit Products. Del Monte's false labeling and other practices misled the Plaintiffs into believing the Misbranded Food Products were fresh and equivalent to fresh fruit when they were not.

67. Del Monte's false and/or misleading claims and packaging deceived consumers like the Plaintiffs. Plaintiffs were misled by the absence of any disclosure the products were canned or pasteurized, the deceptive packaging and placement of the products, the products' names, the ingredient descriptions, the obscured sell by date, and the false "must be refrigerated

claim. In relying on Del Monte's marketing and labeling and its false statements, Plaintiffs were acting reasonably under the circumstances. In fact, they acted exactly how Del Monte expected and planned.

68. Given the thermal processing and the chemical preservation of Del Monte FreshCut vegetables and SunFresh fruit, any representations of freshness or fresh flavor including the use of the brand names are deceptive and misleading.

69. Upon information and belief Del Monte's labeling practices related to freshness have been challenged by the FDA and other companies.

70. Plaintiffs and reasonable consumers expect that when Del Monte made a representation on its products' labels that such products had a fresh taste or made representations as to its freshness that such a representations were not contrary to regulatory requirement for making such claims. Plaintiffs and reasonable consumers also expect that when a manufacturer represented that its fruit or vegetable products were fresh that those fruit or vegetable products were fresh and had not been chemically preserved or subjected to processes inconsistent with a freshness claim.

71. Plaintiffs saw and reasonably relied on Del Monte's label representation of freshness and its other representations of freshness and fresh taste and they based their purchasing decisions in substantial part on the belief that such products were fresh, would have a fresh taste and had not been subjected to chemical preservation or processes inconsistent with a freshness claim.

72. Plaintiffs did not know, and had no reason to know, that Defendant's Misbranded Food Products contained chemical preservatives and had undergone processes inconsistent with a freshness claim because the Defendant made false representations of freshness on its label and labeling of its products. Moreover, as discussed below, the Defendant falsely represented that its products were free of artificial ingredients & preservatives and 2) failed to disclose those chemical preservatives and artificial ingredients as required by California and federal law.

73. Consumers are thus misled into purchasing Defendant's products with false and misleading labeling statements and ingredient descriptions, which violate California law and the

regulations related to clams related to freshness contained in 21 C.F.R. §§ 101.95 which has been adopted as law by California.

74. Had Plaintiffs been aware that the Misbranded Food Products they purchased contained chemical preservatives and artificial ingredients and thus were not truly fresh as falsely represented they would not have purchased the products, or paid a premium for them. Plaintiffs had other alternatives that lacked such ingredients and Plaintiff also had cheaper alternatives.

75. Because of their false labels and other representations about freshness Defendant's Misbranded Food Products are in this respect misbranded under identical federal and California law. Misbranded products cannot be legally sold and are legally worthless. Plaintiffs and members of the Class who purchased these products paid an unwarranted premium for these products. Because Del Monte's representations of freshness are misleading and in violation of 21 C.F.R. § 101.95, which has been adopted by California, consumers are misled into purchasing and paying a premium for Defendant's products that are not fresh as falsely represented on their labeling and through other means such as their packaging and placement.

b. Defendant Violates California Law By Making Unlawful Fresh Claims On Its Products' Labels

76. California law regulates the use of the word "fresh" in connection with food. Pursuant to 21 C.F.R. § 101.95 which has been adopted by the State of California:

> the word "fresh," when used on the label or in labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation. The restrictions on the use of the term "fresh" "pertain to any use of the subject terms …. in a brand name and use as a sensory modifier" such as "fresh taste."

77. Similarly, according to the FDA's Compliance Policy Guide, CPG Sec. 562.450 Identity of Foods - Use of Terms Such as Fresh, Frozen, Dried, Canned, Etc., "[t]he term fresh should not be applied to foods which have been subjected to any form of heat or chemical processing."

78. The Defendant violates these provisions by falsely representing that its Misbranded Food Products are fresh or have a fresh taste when they have been thermally processed, preserved and contain chemical preservatives.

79. For example, Defendant has a line of "FreshCut" vegetable products that misrepresent in numerous ways including their name that they are fresh. Despite the fact that the product has been thermally processed and contains chemical preservatives like calcium chloride, the label of the Del Monte canned lima beans purchased by the Plaintiffs represents that the beans are "Guaranteed * Picked Fresh * Packed Fresh" and contain "No Preservatives" and that the product is "Packed From Fresh Lima Beans" and states that:

> Del Monte® Green Lima Beans are picked fresh at the peak of flavor, then packed fresh to lock in their rich, tender taste. With no artificial additives or preservatives, you get unsurpassed *FreshCut*® flavor – Guaranteed!

80. Similarly, despite the fact that the product has been thermally processed and contains chemical preservatives like calcium chloride, the label of the Del Monte canned sliced beets purchased by the Plaintiffs represents that the beets are "Guaranteed * Picked Fresh * Packed Fresh" and contain "No Preservatives" and that the product is "Packed From Fresh Beets" and states that:

> Del Monte Sliced Beets are the highest standard in freshness and flavor because they are packed from fresh beets. Picked Fresh. Packed Fresh. Unsurpassed flavor you can taste in every bite. That's the *FreshCut*® guarantee.

81. Such deceptive and false label claims and statements are found on Del Monte's other FreshCut canned vegetable products.

82. In addition, to its FreshCut canned vegetables, Del Monte uses brand names like SunFresh to falsely convey the freshness of its fruit products, despite the fact that these products have been pasteurized and are chemically preserved with a number of chemicals including sodium benzoate, potassium sorbate, citric acid and ascorbic acid.

83. Given the thermal processing and the chemical preservation of Del Monte FreshCut vegetables and SunFresh fruit, any representations of freshness or fresh flavor including the use of the brand names are deceptive and misleading.

84. Upon information and belief Del Monte's labeling practices related to freshness have been challenged by the FDA and other companies.

85. Plaintiffs and reasonable consumers would expect that when the Defendant made a representation on its products' labels that such products had a fresh taste or made representations as to its freshness that such a representations were not contrary to regulatory requirement for making such claims. Plaintiffs and reasonable consumers would also expect that when a manufacturer represented that its fruit or vegetable products were fresh that those fruit or vegetable products were fresh and had not been chemically preserved or subjected to processes inconsistent with a freshness claim.

86. Plaintiffs saw and reasonably relied on the Defendant's label representation of freshness and its other representations of freshness and fresh taste and they based their purchasing decisions in part on the belief that such products were fresh, would have a fresh taste and had not been subjected to chemical preservation or processes inconsistent with a freshness claim.

87. Plaintiffs did not know, and had no reason to know, that Defendant's fruit and vegetable products contained chemical preservatives and had undergone processes inconsistent with a freshness claim because the Defendant made false representations of freshness on its label and labeling of its products. Moreover, as discussed below, the Defendant falsely represented that its products were free of artificial ingredients & preservatives and failed to disclose those chemical preservatives and artificial ingredients as required by California and federal law.

88. Consumers are thus misled into purchasing Defendant's products with false and misleading labeling statements and ingredient descriptions, which violate California law and the regulations related to clams related to freshness contained in 21 C.F.R. §§ 101.95 which has been adopted as law by California.

89. Had Plaintiffs been aware that the Misbranded Food Products they purchased contained chemical preservatives and artificial ingredients and thus were not truly fresh as falsely represented they would not have purchased the products, or paid a premium for them. Plaintiffs had other alternatives that lacked such ingredients and Plaintiff also had cheaper alternatives.

90. Because of their false label representations about freshness Defendant's Misbranded Food Products are in this respect misbranded under identical federal and California law. Misbranded products cannot be legally sold and are legally worthless. Plaintiffs and members of the Class who purchased these products paid an unwarranted premium for these products. Because Del Monte's representations of freshness are misleading and in violation of 21 C.F.R. § 101.95, which has been adopted by California, consumers are misled into purchasing and paying a premium for Defendant's products that are not fresh as falsely represented on their labeling.

2. Defendant Makes Unlawful Natural Claims

91. Seeking to profit from consumers' desire for natural food products, Del Monte has falsely represented certain of its fruit and vegetable products as being natural when that is not true. For example, Del Monte has an entire line of "Fruit Naturals" snacks that contain numerous unnatural ingredients. Similarly, Del Monte claims that its tomato sauces are "100% Natural" or that its stewed tomatoes " have been "all natural for over 100 years" despite the fact that these products contain ingredients like citric acid and/or calcium chloride whose inclusion in a product the FDA has informed other tomato companies precludes making a representation that the product is natural. Similarly, Del Monte's stewed tomatoes contain unnatural high fructose corn syrup which also precludes the use of the term natural.

92. Defendant has unlawfully labeled a number of its products as being natural when they actually contain artificial ingredients and/or chemical preservatives. These include the Defendant's Fruit Naturals products. For example, Del Monte's Fruit Naturals No Sugar Added Red Grapefruit contains: Grapefruit, Water, Sorbitol, Ascorbic Acid (To Protect Color), Potassium Sorbate and Sodium Benzoate (To Preserve Quality), Citric Acid, Acesulfame Potassium, Sucralose. Similarly, Del Monte's Fruit Naturals Red Grapefruit contains: Grapefruit, Reconstituted White Grape Juice, Reconstituted Red Grapefruit Juice, Potassium Sorbate and Sodium Benzoate (To Preserve Quality), Ascorbic Acid (To Protect Color), Citric Acid, Color Added. Del Monte's Fruit Naturals Cherry Mixed Fruit contains: Mixed Fruit [Peaches, Pears, Pineapples, Cherries (Cherries, Carmine)], Reconstituted White Grape Juice, Reconstituted Pear

Juice, Ascorbic Acid (To Protect Color), Potassium Sorbate and Sodium Benzoate (Preservatives), Natural Flavors, Citric Acid. Carmine is a dye produced from the crushed bodies of parasitic insects. These products and the rest of the Fruit Naturals product line are anything but natural and it is misleading to represent them as such.

93. Similarly, for example, Del Monte represents that its Cherry Mixed Fruit in Cherry Flavored Light Syrup is made with "all natural, great tasting fruit" but it contains cherries which treats as a defined term: cherries (cherries, carmine) which cannot possibly qualify as all natural fruit due to the artificial color carmine, or cochineal, the dye produced from the crushed bodies of parasitic insects.

94. Defendant has also made the same illegal claims natural on its websites and advertising in violation of federal and California law.

95. Defendant's claims in this respect are false and misleading and the products in this respect are misbranded under federal and California law. Misbranded products cannot be legally sold or held and are legally worthless.

96. Plaintiffs purchased Del Monte's products in reliance on the Defendant's false representations that the products were either "all natural," "100% Natural" or natural. Had the Plaintiffs and the Class known these representations were false they would not have bought the products, or paid a premium for them. Plaintiffs had other alternatives that lacked such ingredients and Plaintiff also had cheaper alternatives.

97. Similarly, Defendant's canned tomato products were misrepresented as being natural and lacking artificial flavors or preservatives despite the fact that the Defendant's canned tomato products lists citric acid as an ingredient, and sometimes also list calcium chloride. The product label for Defendant's Diced Tomatoes, for example, lists both citric acid and calcium chloride.

98. According to standardized requirements for canned tomatoes (21 C.F.R. § 155.190) citric acid may only be used for acidification purposes while calcium chloride may only be used as a firming agent. These uses are both artificial and a form of chemical preservation thus rendering claims that the products were "all natural" or "100% NATURAL" or lacking in

artificial flavors or preservatives false and misleading which results in the Del Monte canned tomato products being misbranded under California law.

99. Upon information and belief, some of Del Monte's competitors in the canned tomato product market also include citric acid and/or calcium chloride as ingredients, but those competitors do not make a natural claim on the product labels.

100. Some of Del Monte's competitors in the canned or packaged tomato product market do not include citric acid or calcium chloride in their tomato products.

101. Del Monte itself through its S&W and Contadina brands produces non-canned tomato products like ketchup that do not contain citric acid or calcium chloride.

102. The FDA has sent warning letters relating to the use of a "Natural" label when a product contains citric acid and/or calcium chloride.

103. The FDA has determined – specifically with respect to canned tomato products – that "the addition of calcium chloride and citric acid to these products preclude use of the term 'natural' to describe this product."

104. In the August 29, 2001, FDA "Hirzel warning letter" the FDA specifically found that "labels for canned tomato products manufactured by" Hirzel were "in violation of Section 403 of the Federal Food Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101- Food Labeling." Among other reasons, the Hirzel warning letter stated in pertinent part:

> [The product] labels bear the term "All NATURAL," but according to the ingredient statements, calcium chloride and citric acid are added to the products. We have not established a regulatory definition for the term "natural," however; we discussed its use in the [preamble] to the food labeling final regulations (58 Federal Register 2407, January 6, 1993). FDA's policy regarding the use "natural," means that nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food. Therefore, the addition of calcium chloride and citric acid to these products preclude use of the term "natural" to describe this product.

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178343.htm

105. Defendant knew or should have known of the Hirzel warning letter. Because the Defendant's products contain the same ingredients prohibited by the FDA in other tomato products, the use of the claim "100% NATURAL" in connection with Defendant's tomato product labels is false and misleading, and therefore these products are misbranded under section 403(a)(1) of the Act.

106. On August 16, 2001, the FDA sent a warning letter to Oak Tree Farm Dairy, Inc. ("Oak Tree warning letter"). The letter "found serious violations" of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations, Part 101 – Food Labeling (21 CFR 101), and stated in pertinent part:

> The term "all natural" on the "OAKTREE ALL NATURAL LEMONADE" label is inappropriate because the product contains potassium sorbate. Although FDA has not established a regulatory definition for "natural," we discussed its use in the preamble to the food labeling final regulations (58 Federal Register 2407, January 6, 1993, copy enclosed). FDA's policy regarding the use of "natural," means nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food. The same comment applies to use of the terms "100 % NATURAL" and "ALL NATURAL" on the "OAKTREE REAL BREWED ICED TEA" label because it contains citric acid.

107. In its rule-making and warning letters to manufacturers, as described herein, the FDA has repeatedly stated its policy to restrict the use of the term "natural" in connection with added color, synthetic substances, and flavors as provided in 21 C.F.R. § 101.22.

108. The FDA has also repeatedly affirmed its policy regarding the use of the term "natural" as meaning that nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food.

109. The FDA considers use of the term "natural" on a food label to be truthful and non-misleading when "nothing artificial or synthetic…has been included in, or has been added to, a food that would not normally be expected to be in the food." *See* 58 FR 2302, 2407, January 6, 1993.

110. Any coloring or preservative can preclude the use of the term "natural" even if the coloring or preservative is derived from natural sources. The FDA distinguishes between natural and artificial flavors in 21 C.F.R. § 101.22.

111. The FDA has sent out numerous warning letters concerning this issue. *See, e.g.*, Exhibit A (August 29, 2001 FDA warning letter to Hirzel Canning Company relating to citric acid or calcium chloride in tomato products); Exhibit B (August 16, 2001 FDA warning letter to Oak Tree Farm Dairy relating to citric acid); and Exhibit C (November 16, 2011 FDA warning letter to Alexia relating to synthetic chemical preservatives). Defendant is aware of these FDA warning letters.

112. Defendant's claims in this respect are false and misleading and the products in this respect are misbranded under federal and California law. Misbranded products cannot be legally sold or held and are legally worthless.

The Plaintiffs and the Class purchased Del Monte's canned tomato products in reliance on the Defendant's false representations that the products were "100% Natural." Had the Plaintiffs known this representation was false they would not have bought the products or paid a premium for them. Plaintiffs had other alternatives that lacked such ingredients and Plaintiff also had cheaper alternatives.

3. Defendant Violates California Law By Making Unlawful And False Claims That Its Misbranded Food Products Are Free Of Artificial Additives And Preservatives And By Failing To Disclose On Its Misbranded Food Products' Labels The Presence Of Preservatives In Those Products As Required By California Law

113. Despite the fact that its Misbranded Food Products contained artificial additives and chemical preservatives and other artificial ingredients, the Defendant falsely represented on the labels of its Misbranded Food Products that they were free of artificial ingredients and preservatives.

114. These representations were demonstrably false and misled consumers such as the Plaintiffs who relied on the statements.

115. For example, Defendant's Del Monte tomato products, such as the diced tomatoes and tomato paste purchased by the Plaintiffs, bore such a false labeling statement. In fact, these products contained a number of chemical preservatives and artificial ingredients such as citric acid and calcium chloride which, as discussed below, fall squarely within the definition of chemical preservatives incorporated into California and federal law.

116. Similarly, for example, the labels of the Del Monte FreshCut lima beans, carrots and beets and the tomato products bought by Plaintiffs stated they had "no preservatives" or "no artificial flavors or preservatives" despite containing the chemical preservatives, citric acid and calcium chloride. Similarly, the labels of the Del Monte FreshCut lima beans, carrots and beets bought by Plaintiffs stated they had "no artificial additives or preservatives" despite the fact that they contained the artificial additive and chemical preservative calcium chloride.

117. According to the standardized requirements for canned tomatoes (21 C.F.R. § 155.190) citric acid may only be used for acidification purposes while calcium chloride may only be used as a firming agent. Given that these uses are both artificial and a form of preservation, the label statements "no preservatives" and "no artificial flavors or preservatives" are both false and misleading and renders the Del Monte canned tomato products misbranded. The same is true for Del Monte's FreshCut vegetable products.

118. Moreover, even if the Defendant had not included false representations that its Misbranded Food Products were free of artificial ingredients & preservatives on its product labels, these products would have still been misbranded as a matter of law because of the Defendant's failure to disclose the presence of such ingredients as mandated by identical California and federal law.

119. Under California law "food is misbranded if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless its labeling states that fact (California Health & Safety Code § 110740). California's law is identical to federal law on this point.

120. Pursuant to 21 C.F.R. § 101.22 which has been adopted by California, "[a] statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the

food or on its container or wrapper, or on any two or all three of these, as may be necessary to render such statement likely to be read by the ordinary person under customary conditions of purchase and use of such food." 21 C.F.R. § 101.22 defines a chemical preservative as "any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties."

121. Defendant's Misbranded Food Products were misbranded because they contained chemical preservatives but failed to disclose that fact.

122. For example, while Defendant's Del Monte brand canned tomato products, such as the diced tomatoes and tomato paste purchased by the Plaintiffs, contain citric acid which is used in those products as an acidulant which is a type of chemical preservative designed to retard spoilage in canned vegetables, their labels fail to disclose the fact that the citric acid is being used as a preservative in those products by including a parenthetical such as (preservative) or (to retard spoilage) after the term citric acid in the ingredient statement. Because Defendant unlawfully fails to indicate these ingredients are being used as chemical preservatives or firming agents a reasonable consumer would have no reason to doubt the preservative free claim as these ingredients could have been used for some other purpose such as flavoring in the case of citric acid but for the limitation on doing so contained in the standard of identity for tomatoes.

123. Similarly, while a number of Defendant's Del Monte brand canned tomato products, such as the diced tomatoes purchased by the Plaintiffs, contain calcium chloride which is used in those products as an firming agent which is a type of chemical preservative designed to prevent canned vegetables from becoming soft and mushy, their labels fail to disclose the fact that the calcium chloride is being used as a preservative in those products by including a parenthetical such as (firming agent) after the term calcium chloride in the ingredient statement.

124. Del Monte also utilized the artificial ingredient high fructose corn syrup in a number of the tomato products purchased by Plaintiffs, including its stewed tomatoes and

flavored diced tomatoes. Despite this fact it included a "no artificial flavors" statement on its label

125. Additionally, a number of Defendant's other products contain artificial colors such as carmine but fail to disclose that this ingredient is being used for artificial coloring purposes, For example, the Defendant's Cherry Mixed Fruit in Cherry Flavored Light Syrup states it is made with "all natural, great tasting fruit" and then states it contains the defined term: cherries (cherries, carmine) which does not reveal that carmine is being used to artificially color the cherries.

126. In fact, Del Monte made a conscious decision not to disclose such information because it felt that if it did so consumers would react negatively to its products. Therefore, it chose either to not disclose the uses for which these preservatives and artificial ingredients were being included in its products or it chose to obscure the fact by using terms like "to preserve quality" or "to protect color" instead of clearly stating these additives were preservatives or artificial coloring or flavoring as required by law. Del Monte did this because it felt that fully disclosing the preservatives function in the product by using the word preservative as required by law would cause consumers to react negatively.

127. Plaintiffs and reasonable consumers would expect that when the Defendant made a representation on its products' labels that such products were "free of artificial ingredients & preservatives" that such a representation was true. Plaintiffs and reasonable consumers would also expect that when Defendant lists its products' ingredients that it would make all disclosures required by law such as the disclosure of chemical preservatives and coloring mandated by identical California and federal law.

128. Plaintiffs saw the Defendant's label representations that its products were "free of artificial ingredients & preservatives" and relied on them in the reasonable expectation that such a representation was true. Plaintiffs based their purchasing decisions in part on the belief that these products did not contain chemical preservatives or artificial ingredients.

129. Plaintiffs did not know, and had no reason to know, that Defendant's Misbranded Food Products contained undisclosed chemical preservatives and other artificial ingredients

because 1) the Defendant falsely represented on its label that the products were "free of artificial ingredients & preservatives" and 2) failed to disclose those chemical preservatives and artificial ingredients as required by California and federal law.

130. Consumers are thus misled into purchasing Defendant's products with false and misleading labeling statements and ingredient descriptions, which do not describe the basic nature of the ingredients, as required by California Health & Safety Code § 110740 and 21 C.F.R. §§ 101.22 which has been adopted as law by California..

131. Had Plaintiffs been aware that the Misbranded Food Products they purchased contained chemical preservatives and artificial ingredients they would not have purchased the products, or paid a premium for them. Plaintiffs had other alternatives that lacked such ingredients and Plaintiff also had cheaper alternatives.

132. Because of their false label representations and omissions about chemical preservatives and artificial ingredients Defendant's Misbranded Food Products are in this respect misbranded under identical federal and California law, including California Health & Safety Code § 110740. Misbranded products cannot be legally sold and are legally worthless. Plaintiffs and members of the Class who purchased these products paid an unwarranted premium for these products.

4. Defendant Makes Unlawful Nutrient Content Claims

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

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

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

136. 21 C.F.R. § 101.13 provides the general requirements for nutrient content claims, which California has expressly adopted. California Health & Safety Code § 110100.

137. 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).

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

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

140. 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 FR 2302. In addition, 21 USC 343(r)(2), whose requirements have been adopted by California, prohibits using unauthorized undefined terms and declares foods that do so to be misbranded.

141. In order to appeal to consumer preferences, Defendant has repeatedly made unlawful nutrient content claims about Lycopene and Lutein and other antioxidants and nutrients

that fail to utilize one of the limited defined terms. These nutrient content claims are unlawful because they fail to comply with the nutrient content claim provisions in violation of 21 C.F.R. §§ 101.13 and 101.54, which are incorporated in California's Sherman Law. To the extent that the terms used to describe Lycopene or Lutein and unnamed antioxidants are deemed to be a synonym for a defined term like "contain" the claim would still be unlawful because, as these nutrients do not have established daily values, they cannot serve as the basis for a term that has a minimum daily value threshold as the defined terms at issue here do.

142. 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.

143. Defendant has repeatedly made unlawful nutrient content claims about Lycopene, Lutein and other antioxidants and nutrients that fail to utilize one of the limited defined terms appropriately. These nutrient content claims are unlawful because they fail to comply with the nutrient content claim provisions in violation of 21 C.F.R. §§ 101.13 and 101.54, which have been incorporated in California's Sherman Law.

144. For example, claims that Del Monte's canned tomato products are "an excellent source of," or "rich in" or "contain" Lycopene are unlawful. They are also false because the terms have defined minimum nutritional thresholds so that, for example, a claim that a product "contains" a nutrient is a claim that the product has at least 10% of the daily value of that nutrient. By using defined terms improperly, Defendant was, in effect, falsely asserting that the products met the minimum nutritional thresholds for the claims in question which its products failed to qualify for. By using undefined terms such as "source" or "found", Defendant was, in effect, falsely asserting that its products met at least the lowest minimum threshold for any nutrient

content claim which would have been 10% of the daily value of the nutrient at issue. Such a threshold represents the lowest level that a nutrient can be present in a food before it becomes deceptive and misleading to highlight its presence in a nutrient content claim.

145. For example, the labels of Del Monte tomato products purchased by the Plaintiffs have utilized two separate unlawful Lycopene antioxidant nutrient content claims. The first was a claim that the particular tomato product was a "Natural Source of Antioxidants" and which contains check marks by the terms "Vitamins A and C" and "Lycopene." The second was a claim that the products were a "[n]atural source of Lycopene, a powerful antioxidant, and Vitamins A & C." Both types of claims are unlawful antioxidant claims nutrient content claims.

146. Both types of label claims are claims are improper nutrient content claims.

147. This has been made clear by prior FDA enforcement actions targeting similar or identical claims. For example on March 24, 2011, the FDA sent Jonathan Sprouts, Inc. a warning letter (Exhibit D) where it specifically targeted a "source" type claim like the one used on the Defendant's tomato products. In that letter the FDA stated:

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

148. It is thus clear that a "source" claim like the one utilized on the labels of Del Monte tomato products such as those purchased by the Plaintiffs are unlawful because the "FDA has not defined the characterization 'source' by regulation" and thus such a "characterization may not be used in nutrient content claims." Such a claim characterizes the fact the tomatoes contain Lycopene at some undefined level. This type of claims is false because it falsely implies that the levels of nutrients in the food are capable of satisfying the minimum nutritional threshold established by regulation.

149. Similarly, claims that Del Monte canned tomato products are an "excellent source" or "rich" in Lycopene are unlawful and false because Del Monte canned tomato products do not meet the minimum nutrient level threshold to make such a claim which is 20 percent or more of the RDI (Reference Daily Intake or Recommended Daily Intake) or the DRV (Daily Reference Value) of Lycopene per reference amount customarily consumed. Claims Similarly, claims that Del Monte's canned tomato products "contain" Lycopene are unlawful and false because Lycopene does not have an RDI and therefore Defendant's canned tomato products do not meet the minimum nutrient level threshold to make such a claim which is 10 percent or more of the RDI or the DRV per reference amount customarily consumed. Claims that Del Monte's canned tomato products are "rich in," Vitamin C or Vitamin E are unlawful because Defendant's canned tomato products do not meet the minimum nutrient level threshold to make such a claim which is 20 percent or more of the RDI or the DRV per reference amount customarily consumed. 21 C.F.R. §§ 101.13 and 101.54. In addition, claims that Del Monte's canned tomato products have "more" Lycopene than other products also fail to meet the minimum nutrient level threshold to make such a claim.

150. Defendant's claims about Lutein also fail to meet the minimum nutrient level threshold to make such a claim.

151. Claims that Del Monte products contain or are made with an ingredient that is known to contain a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, can only be made if it is a "good source" of the nutrient that is associated with the ingredient or type of preparation. Thus, Del Monte's statements on canned tomato product labels that the tomatoes are a "source" of Lycopene trigger a "good source" (10 percent or more of the RDI or the DRV per reference amount customarily consumed) which Lycopene and tomatoes cannot demonstrate. Similarly, Del Monte's label claim that its canned tomato products are a "[n]atural source of Vitamins A & C and Lycopene, a powerful antioxidant" trigger a "good source" requirement (10 percent or more of the RDI or the DRV per reference amount customarily consumed) for Lycopene, Vitamin A, and Vitamin C which cannot

be satisfied for Lycopene and which certain canned tomato products like Del Monte's tomato sauce cannot satisfy for Vitamin A or C.

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

153. Plaintiffs reasonably relied on these nutrient content claims when making their purchase decisions and were misled because they erroneously believed the implicit misrepresentation that the tomato products they were purchasing met the minimum nutritional threshold to make such claims. Plaintiffs would not have purchased these products, or paid a premium for them, had they known that the tomatoes did not in fact satisfy such minimum nutritional requirements with regard to Lycopene, Lutein and other nutrients. Plaintiffs had other alternatives and Plaintiff also had cheaper alternatives.

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

155. Plaintiffs were thus misled by Defendant's unlawful labeling practices and actions into purchasing products they would not have otherwise purchased, or paid a premium for, had they known the truth about those products. Plaintiffs had other alternatives and Plaintiff also had cheaper alternatives.

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

5. Defendant Makes Unlawful Antioxidant Nutrient Content Claims

151. The back panel of Del Monte's product labels for its Defendant's canned tomato products lists citric acid as an ingredient, and sometimes also list calcium chloride. The product label for Defendant's Diced Tomatoes lists both citric acid and calcium chloride.

152. On its product labels, Del Monte touts that its canned tomato products contain antioxidants such as Lycopene. For example, the product label for Defendant's "Diced Tomatoes" states: "Natural Source of Antioxidants" and contains check marks by the terms "Vitamins A and C" and "Lycopene." It also says "[n]atural source of Lycopene, a powerful antioxidant, and Vitamins A & C."

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

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

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

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

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

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

(6) the antioxidant nutrient claim must also comply with general nutrient content claim requirements such as those contained in 21 C.F.R. § 101.13(h) that prescribe the

circumstances in which a nutrient content claim can be made on the label of products high in fat, saturated fat, cholesterol or sodium.

154. For example on Del Monte Canned tomato products such as the ones purchased by Plaintiff the label states, "Natural Source of Antioxidants" and contains check marks by the terms "Vitamins A and C" and "Lycopene." It also says "[n]atural source of Lycopene, a powerful antioxidant, and Vitamins A & C."

155. The antioxidant labeling for Defendant's canned tomato products violates federal and California law.

156. The antioxidant claims on the packages of these products violate federal and California law: (1) because there are no RDIs for Lycopene, the antioxidant being touted, and (2) 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.

157. The FDA has issued at least one warning letter relating to the use of a claim of a Lycopene claim for tomato products indicating that because "[t]here is no established reference value for Lycopene" a nutrient claim for Lycopene is unlawful. As such Lycopene cannot serve as the basis for the type of antioxidant claim made on the Defendant's canned tomato products.

158. In addition to the August 29, 2001 FDA letter sent to the Hirzel Canning Company, the FDA has issued at least 6 other warning letters addressing similar unlawful antioxidant nutrient content claims. Defendant knew or should have known of these FDA warning letters.

159. Ignoring the legal requirements to make antioxidant claims about Lycopene and other antioxidants like Lycopene that is purportedly found in Defendant's tomato products as well as prior enforcement activity and relevant warning letters, the Defendant made multiple unlawful antioxidant claims about its tomato and other vegetable and fruit products.

160. For example, the labels of Del Monte tomato products purchased by the Plaintiffs have utilized two separate unlawful Lycopene antioxidant nutrient content claims. The first was a

claim that the particular tomato product was a "Natural Source of Antioxidants" and which contains check marks by the terms "Vitamins A and C" and "Lycopene." The second was a claim that the products were a "[n]atural source of Lycopene, a powerful antioxidant, and Vitamins A & C." Both types of claims are unlawful antioxidant claims nutrient content claims.

161. This has been made clear by prior FDA enforcement actions targeting similar or identical claims. For example on March 24, 2011, the FDA sent Jonathan Sprouts, Inc. a warning letter where it specifically targeted a "source" type claim like the one used on the Defendant's tomato products. In that letter the FDA stated:

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

162. It is thus clear that a "source" claim like the one utilized on the labels of Del Monte tomato products such as those purchased by the Plaintiffs are unlawful because the "FDA has not defined the characterization 'source' by regulation" and thus such a "characterization may not be used in nutrient content claims." Similarly, a claim that the nutrient Lycopene is "found" in tomatoes is improper because it is either an undefined characterization that a nutrient is found in a food at some undefined level or because it is a synonym for a defined term like "contains" as there is no difference in meaning between the statement "tomatoes contain Lycopene" and the statement "Lycopene is found in tomatoes." Both characterize the fact the tomatoes contain Lycopene at some undefined level. The types of misrepresentations made above would be considered by a reasonable consumer when deciding to purchase the products.

163. Not only do Del Monte's antioxidant, nutrient content regarding the benefits of antioxidants and Lycopene violate FDA rules and regulations, they directly contradict current scientific research, which has concluded: "[T]he evidence today does not support a direct

relationship between tea consumption and a physiological AOX [antioxidant] benefit." This conclusion was reported by Dr. Jane Rycroft, Director of Lipton Tea Institute of Tea, in an article published in January, 2011, in which Dr. Rycroft states:

> Only a few scientific publications report an effect of tea on free radical damage in humans using validated biomarkers in well designed human studies. Unfortunately, the results of these studies are at variance and the majority of the studies do not report significant effects . . .
>
> Therefore, despite more than 50 studies convincingly showing that flavonoids possess potent antioxidant activity *in vitro,* the ability of flavonoids to act as an antioxidant *in vivo* [in humans], has not been demonstrated.
>
> Based on the current scientific consensus that the evidence today does not support a direct relationship between tea consumption and a physiological AOX benefit…
>
> No evidence has been provided to establish that having antioxidant activity/content and/or antioxidant properties is a beneficial physiological effect.

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

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

165. Plaintiffs reasonably relied on these unlawful antioxidant nutrient content claims when making their purchase decisions and were misled because they erroneously believed the implicit misrepresentation that the tomato products they were purchasing met the minimum nutritional threshold to make such antioxidant claims. This threshold represents the lowest level that a nutrient can be present in a food before it becomes deceptive and misleading to highlight its presence in a nutrient content claim. Plaintiffs would not have purchased these products had they known that the tomatoes did not in fact satisfy such minimum nutritional requirements with

regard to Lycopene and unnamed antioxidants. Plaintiffs had other alternatives that lacked such ingredients and Plaintiff also had cheaper alternatives.

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

6. Defendant Makes Unlawful "No Sugar Added" Nutrient Content Claims.

167. Federal and California law regulates "no sugar added" claims as a particular type of nutrient content claim. Specifically, 21 C.F.R. § 101.60 contains special requirements for nutrient claims that use the phrase "no sugar added." Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements of 21 C.F.R. § 101.60 as its own. California Health & Safety Code § 110100.

168. Defendant claims that several of its products have "No Sugar Added." For instance, the labels of Defendant's Fruit Naturals No Sugar Added Red Grapefruit product prominently states "No Sugar Added" on the front of the labels.

169. 21 C.F.R. § 101.60(c)(2) provides in pertinent part, with emphasis added:

> (2) The terms "no added sugar," "without added sugar," or "no sugar added" may be used only if:
>
> (i) No amount of sugars, as defined in §101.9(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging; and
>
> (ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice; and
>
> (iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a food, and a functionally insignificant increase in sugars results; and
>
> (iv) The food that it resembles and for which it substitutes normally contains added sugars; and

> (v) The product bears a statement that the food is not "low calorie" or "calorie reduced" (unless the food meets the requirements for a "low" or "reduced calorie" food) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.

170. 21 C.F.R. § 101.60(b)(2) provides that:

> The terms "low-calorie," "few calories," "contains a small amount of calories," "low source of calories," or "low in calories" may be used on the label or in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that: (i)(A) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and does not provide more than 40 calories per reference amount customarily consumed; or (B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and does not provide more than 40 calories per reference amount customarily consumed and, except for sugar substitutes, per 50 g ….(ii) If a food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the caloric content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "celery, a low-calorie food").

171. The principal display panel of Defendant's states: No Sugar Added despite the fact that it has 60 calories per serving and thus cannot qualify as a low calorie food.

172. The labels of Defendant's Fruit Naturals No Sugar Added Red Grapefruit product do not satisfy element (v) of 21 C.F.R. § 101.60(c)(2) and are therefore misbranded under federal and state law.

173. Notwithstanding the fact that 21 C.F.R. § 101.60(c)(2)(v) bars the use of the term "no sugar added" on foods that are not low-calorie unless they bear an express warning immediately adjacent to each use of the terms that discloses that the food is not "low calorie" or "calorie reduced," Defendant has touted its non low-calorie products as having "no sugar added" and chosen to omit the mandated disclosure statements.

174. In doing so, Defendant has ignored the language of 21 C.F.R. § 101.60(c)(1) that states that:

> Consumers may reasonably be expected to regard terms that represent that the food contains no sugars or sweeteners e.g., "sugar free," or "no sugar," as indicating a product which is low in calories or significantly reduced in calories.

175. Because consumers may reasonably be expected to regard terms that represent that

the food contains "no sugar added" or sweeteners as indicating a product which is low in calories or significantly reduced in calories, consumers are misled when foods that are not low-calorie as a matter of law are falsely represented, through the unlawful use of phrases like "no sugar added" that they are not allowed to bear due to its high calorific levels and absence of mandated disclaimer or disclosure statements.

176. The Defendant's actions were particularly deceptive with respect to the Defendant's Fruit Naturals No Sugar Added Red Grapefruit product purchased by Plaintiffs as it actually had 60 calories per stated serving size despite stating it was packed in artificially sweetened water. In contrast, the Defendant's Fruit Naturals Red Grapefruit product packed in 100% juice listed only 50 calories per stated serving size. Thus, a consumer who wished to purchase or consume the lower calorie option would have been misled based on the Defendant's stated serving sizes. Although, as discussed below, this anomalous can perhaps be explained in part by the fact that the Defendant was not being consistent in its stated serving sizes between the two red grapefruit products, it still highlights the deceptive nature of the Defendants unlawful no sugar added claims.

177. The labeling for Defendant's products violates California law and federal law. For these reasons, Defendant's "no sugar added" claims at issue in this Complaint are misleading and in violation of 21 C.F.R. § 101.60(c)(2) and California law, and the products at issue are misbranded as a matter of law. Misbranded products cannot be legally sold and are legally worthless.

178. Defendant has also made the same illegal claims on its websites and advertising in violation of federal and California law.

179. Defendant is in violation despite numerous enforcement actions and warning letters pertaining to several other companies addressing the type of misleading sugar-related nutrient content claims described herein.

180. Plaintiff did not know, and had no reason to know, that Defendant's Misbranded Food Products were misbranded, and bore nutrient content claims despite failing to meet the requirements to make those nutrient content claims.

181. Defendant's products in this respect are misbranded under federal and California law. Many of the Defendant's products that are labeled with a "No Sugar Added" or similar sugar-related nutrient content claim contain disqualifying levels of calories that prohibit the claim from being made absent a mandated disclosure statement warning of the higher caloric level of the products and thus violate 21 CFR §101.60(c)(2).

182. Because of these improper nutrient content claims, Plaintiffs and members of the Class purchased these products and paid a premium for them. The nutrient content claims regulations discussed herein are intended to ensure that consumers are not misled as to the actual or relative levels of nutrients in food products. Defendant has violated these referenced regulations.

183. Plaintiffs reasonably relied on and were thus misled by the Defendant's unlawful labeling practices and actions into purchasing products they would not have otherwise purchased had they known the truth about those products. Plaintiffs had other alternatives and Plaintiff also had cheaper alternatives.

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

7. <u>Defendant Uses Unlawful Serving Sizes To Understate The Caloric Value And Sugar And Carbohydrate Content Of Its Misbranded Food Products</u>.

185. In violation of identical California and federal law, the Defendant has utilized unlawful serving sizes to understate the caloric value of its misbranded food products.

186. A product that is packaged and sold individually and that contains less than 200% of the applicable reference amount is considered a single-serving container, and the entire contents of the package must be labeled as one serving. However, for products with reference amounts of 100 g (or mL) or larger, manufacturers may decide whether a package containing more than 150%, but less than 200%, of the reference amount is 1 or 2 servings. Regardless of package size, a product that is obviously intended to be consumed in one serving *and* products

bearing label descriptions that suggest a single serving (*e.g.*, "singles" or "the perfect size for one").

187. For example, the label of Defendant's 198 gram Fruit Naturals Red Grapefruit in 100% juice states that a serving size is 126 grams or 1/2 cup and that the container has "about 2 servings." It states that a serving has 12 grams of sugar, 13 grams of carbohydrates and 50 calories.

188. All of these statements are improper because the Defendant has used an unlawful serving size that understates all these amounts. As a single serving container the actual serving size was the full 198 grams of food contained in the container. Fruit Naturals products are individually sold snacks meant to be consumed by a single person in a single sitting, are marketed as such and cannot be resealed.

189. Moreover, the reference amount for this type of fruit product is 140 grams and thus at 198 grams the container is less than 150% of the reference amount. As such, the correct serving size was the full 198 grams of food contained in the container.

190. Defendant engaged in similar unlawful practices with all the fruit natural products packed in 100% juice.

191. By utilizing a smaller incorrect serving size the Defendant understated calories, carbohydrates and sugars. This is misleading to consumers such as the Plaintiffs who rely on the nutritional facts table and the information contained therein.

192. Defendant has also made the same illegal claims on its websites and advertising in violation of federal and California law.

193. Defendant is in violation despite numerous enforcement actions and warning letters pertaining to several other companies addressing the type of misleading serving size statements described herein.

194. Plaintiff did not know, and had no reason to know, that Defendant's Misbranded Food Products were misbranded, and bore unlawful serving size claims.

195. Defendant's products in this respect are misbranded under federal and California law. Many of the Defendant's products that are labeled with a false serving size statement.

196. Because of these unlawful serving size statements and nutritional information on which they relied, Plaintiffs and members of the Class purchased these products and paid a premium for them. The serving size regulations discussed herein are intended to ensure that consumers are not misled as to the actual or relative levels of nutrients in food products. Defendant has violated these referenced regulations.

197. Plaintiffs relied on and were thus misled by the Defendant's unlawful labeling practices and actions into purchasing products they would not have otherwise purchased had they known the truth about those products. Plaintiffs had other alternatives and Plaintiff also had cheaper alternatives.

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

8. Defendant Fails to Comply with the Standard of Identity for its Misbranded Products

199. In violation of identical California and federal law, the Defendant failed to comply with the Standard of Identity applicable to certain products it sold.

200. For example, *21 CFR 145.14*, the standard of identity for canned grapefruit does not allow for artificial coloring. Despite this fact, both the regular and no sugar added versions of Defendant's SunFresh canned grapefruit contain added artificial color.

201. While these products are packaged in glass jars, as discussed above, they are actually canned grapefruit. For the reasons stated above.

202. These products are misbranded because they fail to comply with the standard of identity for canned grapefruit.

203. Plaintiffs reasonably relied on and were thus misled by the Defendant's unlawful labeling practices and actions into purchasing products they would not have otherwise purchased, or paid a premium for, had they known the truth about those products. Plaintiffs had other alternatives and Plaintiff also had cheaper alternatives.

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

9. Defendant Makes Unlawful Health Claims

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

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

207. 21 C.F.R. § 101.14, which has been expressly adopted by California, provides when and how a manufacturer may make a health claim about its product. A "Health Claim" means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (*e.g.*, a brand name including a term such as "heart"), symbols (*e.g.*, a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or

level of a substance in the food and a disease or health-related condition (*see* 21 CFR § 101.14(a)(1)).

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

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

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

> Qualifies as both low fat and low saturated fat;
> Contains 480 mg or less of sodium per reference amount and per labeled serving, and per 50 g (as prepared for typically rehydrated foods) if the food has a reference amount of 30 g or 2 tbsps or less;
>
> Does not exceed the disclosure level for cholesterol (*e.g.*, for most individual food products, 60 mg or less per reference amount and per labeled serving size); *and*
>
> Except for raw fruits and vegetables, certain frozen or canned fruits and vegetables, and enriched cereal-grain products that conform to a standard of identity, provides at least 10% of the daily value (DV) of vitamin A, vitamin C, calcium, iron, protein, *or* fiber per reference amount. Where eligibility is based on a nutrient that has been added to the food, such fortification must comply with FDA's fortification policy.
>
> 21 C.F.R. § 101.65(d)(2).

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

212. Del Monte has violated the provisions of § 21 C.F.R. §101.14, 21 C.F.R. §101.65, 21 U.S.C. § 321(g)(1)(D) and 21 U.S.C. § 352(f)(1) by including certain claims on its website. For example, on its website, Del Monte states: "Because of its strong antioxidant properties, Lycopene is believed to help retard the aging process and stave off heart disease, cancer and major degenerative diseases. Some research has found that cooking foods containing Lycopene – tomatoes, for instance – makes the Lycopene more easily absorbed by the body. That would make canned tomatoes one of the better sources of lycopene." http://www.delmonte.com/health-glossary.aspx.

213. The website also states, "Lycopene, a carotenoid found primarily in canned and processed tomatoes, shows promise in preventing heart disease and other types of cancer. It is the pigment that gives the brilliant red color to tomatoes, watermelon and red grapefruit. Research is beginning to show promise that Lycopene benefits may have a role in preventing heart disease and certain types of cancer like prostate cancer. Canned tomatoes and tomato products are excellent sources of Lycopene because the heat from cooking or canning makes the Lycopene more available to your body."
http://www.delmontefoods.com/livingahealthylifestyle/?page=lh_askthenutritionist4

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

215. Plaintiffs saw such claims and relied on the Defendant's health claims which influenced their decision to purchase the Defendant's tomato products. Plaintiffs would not have bought the products had they known the Defendant's claims were unapproved and that the products were thus misbranded.

216. Plaintiffs were misled into the belief that such claims were legal and had passed regulatory muster and were supported by science capable of securing regulatory acceptance. Because this was not the case the Plaintiffs were deceived.

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

218. Plaintiffs were thus misled by the Defendant's unlawful labeling practices and actions into purchasing products they would not have otherwise purchased, or paid a premium for, had they known the truth about those products. Plaintiffs had other alternatives and Plaintiff also had cheaper alternatives.

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

D. Defendant Has Violated California Law

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

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

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

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

224. Defendant has violated California Health & Safety Code § 110403 which prohibits the advertisement of products that are represented to have any effect on enumerated conditions, disorders and diseases including cancer and heart diseases unless it has federal approval.

225. Defendant's Misbranded Food Products are misbranded under California Health & Safety Code § 110660 because their labeling is false and misleading in one or more ways.

226. Defendant's Misbranded Food Products are misbranded under California Health & Safety Code § 110665 because their labeling fails to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q) and the regulations adopted thereto.

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

228. Defendant's Misbranded Food Products are misbranded under California Health & Safety Code § 110705 because words, statements and other information required by the Sherman Law to appear on their labeling either are missing or not sufficiently conspicuous

229. Defendant's Misbranded Food Products are misbranded under California Health & Safety Code § 110740 because they contain artificial flavoring, artificial coloring and chemical preservatives but fail to adequately disclose that fact on their labeling.

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

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

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

233. Defendant has violated the standard set by 21 C.F.R. § 101.2, 101.4, 101.9, 101.12, 101.22 and 102.5 all of which have been adopted and incorporated by reference in the

Sherman Law, by failing to include on their product labels the nutritional information required by law.

234. Defendant has violated the standards set by 21 CFR §§ 101.13, 101.14, 101.54, 101.65 and 101.95 which have been adopted and incorporated by reference in the Sherman Law, by including unauthorized antioxidant and nutrient content and fresh claims on their products.

E. Plaintiffs Purchased Defendant's Misbranded Food Products

235. Plaintiffs care about the nutritional content of food and seek to maintain a healthy diet.

236. Plaintiffs purchased Defendant's Misbranded Food Products at issue in this Amended Complaint, since 2008 and throughout the Class Period.

237. Plaintiff Michael Kosta purchased Defendant's Misbranded Food Products, including Del Monte Diced Tomatoes, Del Monte Tomato Sauce, Del Monte FreshCut Sliced Carrots, Del Monte Fruit Naturals Red Grapefruit, Del Monte Fruit Naturals Red Grapefruit No Sugar Added and Del Monte Fruit Naturals Cherry Mixed Fruit. Plaintiff Steve Bates purchased Defendant's Misbranded Food Products, including Del Monte Diced Tomatoes, Tomato Sauce, FreshCut Sliced Carrots, FreshCut French Style Green Beans, FreshCut Lima Beans, FreshCut Cut Green Beans, FreshCut Whole Kernel Corn, FreshCut Sliced Beets, FreshCut Sweet Peas, FreshCut Sweet Corn Cream Style, SunFresh Red Grapefruit, SunFresh Red Grapefruit No Sugar Added, SunFresh Mandarin Orange, Fruit Naturals Red Grapefruit, Fruit Naturals Red Grapefruit (no sugar added), Fruit Naturals Cherry Mixed Fruit, Fruit Naturals Citrus Salad, Fruit Naturals Tropical Medley, Fruit Naturals Mandarin Oranges, Cherry Mixed Fruit in Cherry flavored light syrup, Mandarin Oranges, No Sugar Added, Stewed tomatoes Original Recipe, Stewed tomatoes Italian Recipe, Stewed tomatoes No Salt Added, Diced tomatoes w/Basil, Garlic and Oregano, and Diced tomatoes Zesty Chili Style. Plaintiffs Sarah Languille and Trevor Fewins purchased Del Monte's Del Monte's Fruit Naturals, SunFresh, SuperFruit and/or Fruit Bowls.

238. Plaintiffs read the labels on Defendant's Misbranded Food Products including the Lycopene antioxidant and other nutrient content claims; the no artificial ingredients, additives, flavors and preservatives claims; and the representations that the products were fresh and natural

before purchasing them.

239. Plaintiffs reasonably relied on Defendant's package labeling and packaging and product placement. Plaintiffs read Defendant's website and web claims concerning Defendant's Misbranded Food Products, including the Lycopene antioxidant nutrient content claims; the no artificial ingredients, additives, flavors and preservatives claims, the nutrient content claims related to Lycopene and other nutrients including the no sugar added claim, the antioxidant claims related to Lycopene, the health and disease related claims about tomatoes, and the freshness and fresh taste claims and representations related to Defendant's food products before purchasing them.

240. Plaintiffs reasonably relied on Defendant's package labeling, packaging, product placement, and website and justified the decision to purchase Defendant's Misbranded Food Products in substantial part on Defendant's package labeling and web claims as well as product packaging and product placement., including the Lycopene antioxidant and other nutrient content claims; the no artificial ingredients, additives, flavors and preservatives claims; and the representations that the products were fresh and natural.

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

242. At point of sale, Plaintiffs did not know, and had no reason to know, that Defendant's Lycopene antioxidant and other nutrient content claims; the no artificial ingredients, additives, flavors and preservatives claims, and the representations that the products were fresh and natural on the products' labels or Defendant's website and web claims were unlawful as set forth herein, and would not have bought the products, or paid a premium for them, had they known the truth about them.

243. After Plaintiffs learned that Defendant's Misbranded Food Products are falsely labeled, they stopped purchasing them.

244. As a result of Defendant's misrepresentations, Plaintiffs and thousands of other consumers purchased the products at issue.

245. Defendant's labeling, advertising, and marketing as alleged herein is false and misleading and designed to increase sales of the products at issue. Defendant's misrepresentations are part of an extensive labeling, advertising and marketing campaign, and a reasonable person would attach importance to Defendant's representations in determining whether to purchase the products at issue.

246. A reasonable person would 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. Plaintiffs would not have purchased the Defendant's Misbranded Food Products, or paid a premium for them, had they known they were not capable of being legally sold or held.

247. These Misbranded Food Products 1) whose essential characteristics had been misrepresented by the Defendant; 2) which contained ingredients the Plaintiffs sought to avoid in their food; 3) which had their nutritional and health benefits misrepresented and overstated by the Defendant, and 4) which were misbranded products which could not be resold and whose very possession was illegal; were worthless to the Plaintiffs and as a matter of law.

CLASS ACTION ALLEGATIONS

248. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(b)(2) and 23(b)(3) on behalf of the following class:

> All persons nationwide who, within the last four years, purchased a Del Monte brand canned tomato product, a Del Monte FreshCut vegetable product or a Del Monte Fruit Naturals, SunFresh, SuperFruit or Fruit Bowls fruit product (the "Class").

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

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

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

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

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

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

c. Whether Defendant made unlawful and misleading antioxidant claims with respect to their food products sold to consumers;

d. Whether Defendant made unlawful and misleading nutrient content claims with respect to their food products sold to consumers;

e. Whether Defendant made unlawful and misleading natural and fresh claims with respect to their food products sold to consumers;

f. Whether Defendant failed to disclose the presence of preservatives or falsely represented that products did not contain preservatives or artificial ingredients;

g. Whether Defendant used unlawful and misleading serving size statement, nutritional information and statements of identity;

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

i. Whether Plaintiffs and the Class are entitled to equitable and/or injunctive relief;

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

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

253. Typicality: Plaintiffs' claims are typical of the claims of the Class because Plaintiffs bought Defendant's Misbranded Food Products during the Class Period. Defendant's unlawful, unfair and/or fraudulent actions concern the same business practices described herein irrespective of where they occurred or were experienced. Plaintiffs and the Class sustained similar injuries arising out of Defendant's conduct in violation of California law. The injuries of each member of the Class were caused directly by Defendant's wrongful conduct. In addition, the factual underpinning of Defendant's misconduct is common to all Class members and represents a common thread of misconduct resulting in injury to all members of the Class. Plaintiffs' 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.

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

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

important public interest will be served by addressing the matter as a class action. Class treatment of common questions of law and fact would also be superior to multiple individual actions or piecemeal litigation in that class treatment will conserve the resources of the Court and the litigants, and will promote consistency and efficiency of adjudication.

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

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

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

CAUSES OF ACTION

FIRST CAUSE OF ACTION
Business and Professions Code § 17200, *et seq.*
Unlawful Business Acts and Practices

259. Plaintiffs incorporate by reference each allegation set forth above.

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

261. Defendant sold Misbranded Food Products in California during the Class Period.

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

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

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

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

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

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

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

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

SECOND CAUSE OF ACTION
Business and Professions Code § 17200, *et seq.*
Unfair Business Acts and Practices

270. Plaintiffs incorporate by reference each allegation set forth above.

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

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

273. Defendants' conduct in mislabeling and misbranding its food products originated from and was approved at Del Monte headquarters in California.

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

275. Defendant's deceptive marketing, advertising, packaging and labeling of its Misbranded Food Products and its sale of unsalable Misbranded Food Products that were illegal to possess was of no benefit to consumers, and the harm to consumers and competition is substantial.

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

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

278. The consequences of Defendant's conduct as set forth herein outweighs any justification, motive or reason therefor. Defendant's conduct is and continues to be illegal and contrary to public policy, and is substantially injurious to Plaintiffs and the Class.

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

280. As a result of Defendant's conduct, Plaintiffs and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's

ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiffs and the Class.

THIRD CAUSE OF ACTION
Business and Professions Code § 17200, *et seq.*
Fraudulent Business Acts and Practices

281. Plaintiffs incorporate by reference each allegation set forth above.

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

283. Defendant sold Misbranded Food Products in California during the Class Period.

284. Defendant's misleading marketing, advertising, packaging and labeling of the Misbranded Food Products and misrepresentation that the products were salable, capable of legal possession and not misbranded was likely to deceive reasonable consumers, and in fact, Plaintiffs and members of the Class were deceived. Defendant has engaged in fraudulent business acts and practices.

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

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

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

FOURTH CAUSE OF ACTION
Business and Professions Code § 17500, *et seq.*
Misleading and Deceptive Advertising

288. Plaintiffs incorporate by reference each allegation set forth above.

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

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

291. Defendants' conduct in mislabeling and misbranding its food products originated from and was approved at Del Monte headquarters in California.

292. Defendant engaged in a scheme of offering Misbranded Food Products for sale to Plaintiffs and members of the Class by way of, *inter alia*, product packaging and labeling, and other promotional materials. These materials misrepresented and/or omitted the true contents and nature of Defendant's Misbranded Food Products. Defendant's advertisements and inducements were made within California and come within the definition of advertising as contained in Business and Professions Code §17500, *et seq.* in that such product packaging and labeling, and promotional materials were intended as inducements to purchase Defendant's Misbranded Food Products and are statements disseminated by Defendant to Plaintiffs and the Class that were intended to reach members of the Class. Defendant knew that these statements were misleading and deceptive as set forth herein.

293. 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 ingredients contained in and the nature of Defendant's Misbranded Food Products. Plaintiffs and the Class necessarily and reasonably relied on Defendant's materials, and were the intended targets of such representations.

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

295. 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 Plaintiffs and the Class. Misbranded products cannot be legally sold or held and are legally worthless. Plaintiffs and the Class paid a premium price for the Misbranded Food Products.

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

FIFTH CAUSE OF ACTION
Business and Professions Code § 17500, *et seq.*
Untrue Advertising

297. Plaintiffs incorporate by reference each allegation set forth above.

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

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

300. Defendants' conduct in mislabeling and misbranding its food products originated from and was approved at Del Monte headquarters in California.

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

302. In furtherance of their plan and scheme, Defendant prepared and distributed in California and nationwide via product packaging and labeling, and other promotional materials,

statements that falsely advertise the ingredients contained in Defendant's Misbranded Food Products, and falsely misrepresented the nature of those products. Plaintiffs and the Class were the intended targets of such representations and would reasonably be deceived by Defendant's materials.

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

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

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

SIXTH CAUSE OF ACTION

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

306. Plaintiffs incorporate by reference each allegation set forth above.

307. This cause of action is brought pursuant to the CLRA. Defendant's violations of the CLRA were and are willful, oppressive and fraudulent, thus supporting an award of punitive damages.

308. Plaintiffs and the Class are entitled to actual and punitive damages against Defendant for its violations of the CLRA. In addition, pursuant to Cal. Civ. Code § 1782(a)(2), Plaintiffs and the Class are entitled to an order enjoining the above-described acts and practices, providing restitution to Plaintiffs and the Class, ordering payment of costs and attorneys' fees,

and any other relief deemed appropriate and proper by the Court pursuant to Cal. Civ. Code § 1780.

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

310. Defendant sold Misbranded Food Products in California during the Class Period.

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

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

313. By engaging in the conduct set forth herein, Defendant violated and continues to violate Section 1770(a)(5), of the CLRA, because Defendant's conduct constitutes unfair methods of competition and unfair or fraudulent acts or practices, in that it misrepresents the particular ingredients, characteristics, uses, benefits and quantities of the goods.

314. 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.

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

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

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

318. Pursuant to Section 1782(a) of the CLRA, on May 8, 2012, Plaintiffs' counsel served Del Monte with notice of Del Monte's violations of the CLRA. As authorized by Del Monte's counsel, Plaintiffs' counsel served Del Monte by certified mail, return receipt requested. Del Monte, through its counsel, acknowledged receipt of Plaintiffs' CLRA demand notice, by responding with a letter dated June 8, 2012.

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

320. Plaintiffs make certain claims in this First Amended Complaint that were not included in the original Complaint filed on April 5, 2012, and were not included in Plaintiffs' CLRA demand notice.

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

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

323. Consequently, Plaintiffs and the Class will be entitled to actual and punitive damages against Defendant for its violations of the CLRA. In addition, pursuant to Cal. Civ. Code § 1782(a)(2), Plaintiffs and the Class will be entitled to an order enjoining the above-described acts and practices, providing restitution to Plaintiffs and the Class, ordering payment of

costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court pursuant to Cal. Civ. Code § 1780.

SEVENTH CAUSE OF ACTION
Restitution Based on Unjust Enrichment/Quasi-Contract

324. Plaintiffs incorporate by reference each allegation set forth above.

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

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

327. It would be against equity and good conscience to permit Defendant to retain the ill-gotten benefits they received from Plaintiffs and the Class, in light of the fact that the products were not what Defendant purported them to be. Thus, it would be unjust and inequitable for Defendant to retain the benefit without restitution to Plaintiffs and the Class of all monies paid to Defendant for the products at issue.

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

JURY DEMAND

Plaintiffs hereby demand a trial by jury of their claims.

PRAYER FOR RELIEF

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

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

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

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

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

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

F. For an order awarding punitive damages;

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

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

Dated: June 11, 2013.

Respectfully submitted,

By: Brian Herrington

Brian Herrington
Don Barrett, P.A.
P.O. Box 927
404 Court Square North
Lexington, MS 39095
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uidstrom@eurekalawfirm.com

Attorneys for Plaintiffs

EXHIBIT A

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Hirzel Canning Company 29-Aug-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

August 29, 2001
WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Karl A. Hirzel, President
Hirzel Canning Company
411 Lemoyne Road
Northwood, Ohio 43619

Dear Mr. Hirzel:

During an inspection of you firm on June 13, 2001 our Investigator collected labels for canned tomato products manufactured by your firm. We have limited our review to three of your products, which we have determined to be sufficiently representative of the labeling efficiencies of your products. Our review of the labels collected for the products listed below show that they cause the products to be in violation of Section 403 of th Federal Food Drug , and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101- Food Labeling as follows:

Del Fratelli CONCENTRATED/ITALIAN STYLE TOMATO PUREE No Salt Added (28 OZ. Cm)

The above product is misbranded within the meaning of Section 403 (a)(l) of the Act in that its labeling 1s false or misleading. The term "FRESH-PACKED" used on the principal display panel, which falsely implies that the finished product in the package is ?fresh," when in fact it has been thermally processed. The Food and drug Administration (FDA) would not object to the use of the term "fresh" in the context of a statement such "packed from lies tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

Del Fratelli Fresh & Read CHOPPED TOMATOES ONION & GARLIC (14.5 oz. cans) and Dei ratelli Fresh & Ready CHOPPED MEXICAN TOMATOES & JALAPENOS (14.5 oz. cans)

The above products are misbranded within the meaning of Section 403 a)(1) of the Act in that their labeling is false or misleading. The statement "FRESH- PACKED" on the principal display panel and "Fresh & Ready" in the brand name of the products falsely imply that the finished products i the package are "fresh," when in fact the have been thermally processed. In addition, according to the Ingredient statements, the products conta at east two preservatives. Products that have been thermally processed or that contain preservatives do not meet the definition of "fresh." As stated above, FDA does not object to the use of the term "fresh" in the context of a statement such as "packed from fresh tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

The Dei Fratelli ® ***. CHOPPED MEXICAN TOMATOES & JALAPENOS product is also misbranded under section 403 (r)((l)(A) of the Act because the label bears the nutrient content claim "HEALTHY," but does not meet the requirements for the claim, as defined in 21 CFR 101.65 (d). Based the information m the nutrition label, the CHOPPED MEXICAN TOMATOES & JALAPENOS product contains 590 mg of sodium. A "healthy" claim m be used where, among other thing, the product contains no more than 360 mg of sodium.

Furthermore, the Dei Fratelli ® *** CONCENTRATED/ITALIAN STYLE TOMATO PUREE, CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS products are misbranded under section 403(r)(l)(A) of the Act because the labels bear nutrient content claim that are not authorize by regulation for the Act or are not consistent with an authorizing regulation. The claims include "** *a great source of Vitamins A and C, and the nutrient Lycopene." In the context used on these labels, the term "great source" is considered to be an unauthorized synonym for "high." FDA has define the nutrient content claim "high" in 21 CFR 101.54(b). ?High" can be used on a food label provided the food contains 20 percent or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed.

There is no established reference value for Lycopene; therefore, the claim "*** great source of *** Lycopene" is not authorized. In addition, the Dei Fratelli ® *** CONCENTRATE/ITALIAN STYLE TOMATO PUREE does not contain 20% or more of the RDI of vitamin A and the CHOPPED MEXICAN TOMATOES & JALAPENOS does not contain 20% or more of the RDIs for Vitamin A or C.

Some of the labels for your tomato products have a "NO SALT ADDED" statement on products that are not sodium free. However, the required statement, "not a sodium free food" or "not for control of sodium in the diet" does not appear on the information panel of the labels.

We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result m enforcement action such seizure and/or injunction being initiated by FDA without further notice.

The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject your food products t legal action. It Is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should also be aware that the term "fresh" in the ingredient name "FRESH TOMATOES" should not appear in the ingredient statement as par of the common or usual name of an ingredient. Ingredients must be declared b their common or usual & name, as stated in section 403(I)(2) of the Act and 21 CFR 101.4(a)(l). Optional information, such as the term "fresh? is not permitted.

Also, the Del Fratelli ® *** CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS labels bear the term "All NATURAL," but according to the ingredient statements, calcium chloride and citric acid are added to the products. We have not established a regulatory definition for the term "natural," however; we discussed its use in the ream le to the food labeling final regulations (58 Federal Register 2407, January 6, 1993). FDA?s policy regarding the use "natural", means that nothing artificial or synthetic as been included m, or as been added to, a food that would not normally be expected to be in the food. Therefore, the addition of calcium chloride and citric acid to these products preclude use of the term "natural" to describe this product.

Please advise us in writing within fifteen(15) working days of receipt of this letter of the specific actions you have taken to correct the violations along with copies of the revised labels. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,
Henry Fielden
District Director
Cincinnati District

EXHIBIT B

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Oak Tree Farm Dairy, Inc. 16-Aug-01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
New York District
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED
August 16, 2001
Ref: NYK-2001-113

Richard Classey
Vice President and General Manager
Oak Tree Farm Dairy, Inc.
544 Elwood Road
East Northport, NY 11731

Dear Mr. Classey:

On May 17 and June 5 and 7,2001, we inspected your beverage manufacturing facility located at the above address. During the inspection, we collected a sample of your "OAKTREE REAL BREWED ICED TEA" product and labels for your "OAKTREE FRUIT PUNCH" and "OAKTREE ALL NATURAL LEMONADE" products. Our analysis of the iced tea and review of the labels found serious violations of the Federal Food, Drug, and Cosmetic Act ("the Act") and Title 21, Code of Federal Regulations, Part 101 - ,Food Labeling(21 CFR 101).

The "OAKTREE REAL BREWED ICED TEA" is misbranded under Section 403(i)(2) of the Act in that it contains the color additive "FD&C Red No. 40", but the certified color additive fails to be declared on the product label in the statement of ingredients by its specific name, as required (21 CFR 101.22(k)(1)). The product is also misbranded under Section 403(k) of the Act because it contains an artificial coloring that is not declared on the label.

The "OAKTREE FRUIT PUNCH" is misbranded under Section 403(k) of the Act because it contains sodium benzoate and potassium sorbate, which are not declared on the product label. A food to which a chemical preservative is added must declare the common or usual name of that ingredient and a description of its function, e.g., "preservative", as required by 21 CFR 101.226).

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your product labels. Other label violations can subject the foods to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration ("FDA").

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction.

As you know, during the inspection, our investigator also reviewed the labels and formulations for your "OAKTREE ALL NATURAL LEMONADE" and "OAKTREE FRUIT PUNCH". Your lemonade label fails to declare the ingredient, citric acid, which is declared as an ingredient on the label of the lemonade concentrate used to make your lemonade. Further, your fruit punch label fails to declare the ingredients, grape juice, artificial fruit punch flavor, propylene glycol, sodium benzoate, and potassium sorbate, which are declared as ingredients on the label of the fruit punch concentrate used to make your fruit punch. Also, your fruit punch label declares the ingredients, concentrated pineapple juice, gum arabic, glycerol ester of wood resin, and blue 1.

However, these ingredients are not found in the fruit punch concentrate used to make your fruit punch and are not listed as ingredients in your fruit punch formulation. The investigator discussed these labeling discrepancies with you at the conclusion of the inspection.

The term "all natural" on the "OAKTREE ALL NATURAL LEMONADE" label is inappropriate because the product contains potassium sorbate. Although FDA has not established a regulatory definition for "natural," we discussed its use in the preamble to the food labeling final regulations (58 Federal Register 2407, January 6, 1993, copy enclosed). FDA?s policy regarding the use of "natural," means nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food. The same comment applies to use of the terms" 100 % NATURAL" and "ALL NATURAL" on the "OAKTREE REAL BREWED ICED TEA" label because it contains citric acid.

Further, the declaration of potassium sorbate in the ingredient statement on the "OAKTREE ALL NATURAL LEMONADE" label must be followed by a description of its function, e.g., "preservative", as required by 21 CFR 101.22(j).

You should notify this office in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time within which the corrections will be completed.

Your reply should be directed to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions concerning the violations noted, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,

/s/
Robert L. Hart
Acting District Director

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10903 New Hampshire Avenue
Silver Spring, MD 20993
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U.S Department of Health & Human Services

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EXHIBIT C

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Alexia Foods, Inc 11/16/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, Maryland

WARNING LETTER
NOV 16, 2011

OVERNIGHT MAIL
RETURN RECEIPT REQUESTED

Alex Dzieduszycki, CEO/President
Alexia Foods, Inc.
51-02 21st Street, #3B
Long Island City, New York 11101

Dear Mr. Dzieduszycki:

The U.S. Food and Drug Administration (FDA) has reviewed the labels for your Alexia brand Roasted Red Potatoes & Baby Portabella Mushrooms products. Based on our review, we have concluded that these products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find copies of the Act and the FDA regulations through links in FDA's home page at http://www.fda.gov [1].

Your Alexia brand Roasted Red Potatoes & Baby Portabella Mushrooms product is misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. 343(a)(1)], which states that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. The phrase "All Natural" appears at the top of the principal display panel on the label. FDA considers use of the term "natural" on a food label to be truthful and non-misleading when "nothing artificial or synthetic...has been included in, or has been added to, a food that would not normally be expected to be in the food." [58 FR 2302, 2407, January 6, 1993].

Your Alexia brand Roasted Red Potatoes & Baby Portabella Mushrooms product contains disodium dihydrogen pyrophosphate, which is a synthetic chemical preservative. Because your products contain this synthetic ingredient, the use of the claim "All Natural" on this product label is false and misleading, and therefore your product is misbranded under section 403(a)(1) of the Act.

We note that your Alexia brand products market a number of food products with the "All Natural" statement on the label. We recommend that you review all of your product labels to be consistent with our policy to avoid additional misbranding of your food products.

This letter is not intended to be an all-inclusive review of your products and their labeling. It is your responsibility to ensure that all of your products and labeling comply with the Act and its implementing regulations. You should take prompt action to correct the violations cited in this letter. Failure to do so may result in enforcement action without further notice. Such action may include, but is not limited to, seizure or injunction.

Please respond in writing within fifteen (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 written response should be sent to Latasha 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. If you have any questions, please contact Ms. Robinson at 301-436-1890.

Sincerely yours,
/S/
Michael W. Roosevelt
Acting Director
Office of Compliance

Center for Food Safety
and Applied Nutrition

cc: New York District Office

Links on this page:

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

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EXHIBIT D

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Jonathan's Sprouts Inc. 3/24/11

Department of Health and Human Services

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

WARNING LETTER
NWE-13-11W

VIA UNITED PARCEL SERVICE
OVERNIGHT DELIVERY

March 24, 2011

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

Dear Mr. Sanderson:

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

Unapproved New Drug

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

- "[S]prouts are full of phytochemicals . . . that are powerful allies in protecting us from the growth of cancer cells . . . in lowering cholesterol levels . . . ."
- "Mung Bean Sprouts Identified as Potent Anti-tumor Agent"
- "Studies on canavanine . . . in alfalfa, have demonstrated benefit for pancreatic, colon and leukemia cancers."

- "Alfalfa Sprouts High in Cholesterol Lowering Agent"

- "Saponins [substance found in alfalfa sprouts] lower the bad cholesterol . . . . Animal studies prove their benefit in arteriosclerosis and cardiovascular disease."

- "Phytoestrogens [substance in alfalfa, clover, and mung bean sprouts] . . . prevent . . . osteoporosis. They are also helpful in controlling . . . fibrocystic breast tumors."

- "Research into the possible benefits of phytoestrogens has focused on . . . a) Cancer-breast and prostate in particular . . . c) Osteoporosis d) Heart disease (antioxidant activity) Other potential areas of benefit include diabetes . . . ."

- "The cruciferous sprouts: Broccoli, [lists others] . . . Cancer Fighters"

- "Broccoli . . . may fight cancer."

- "Broccoli sprouts are rich in one class of cancer protecting agents."

- "There is strong evidence that just two or three tablespoons of broccoli sprouts a day can help prevent cancer, gastric cancer, and other diseases."

- "[S]ulforaphane [obtained from a substance in broccoli] prevents tumor growth and kills stomach bacteria that lead to ulcers and stomach cancer. In one study, they showed that feeding broccoli sprouts to rats prevented . . . heart disease, and stroke."

These products are not generally recognized as safe and effective for the above referenced uses; therefore these products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the United States without prior approval from the FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. In addition, your products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; hence adequate directions cannot be written so a layman can use them safely for their intended uses. Therefore, your products are also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fail to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

Unauthorized Health Claims

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

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

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

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

Unauthorized Nutrient Content Claims

Your Organic Alfalfa Sprouts, Organic Broccoli Sprouts, Organic Mung Bean Sprouts, and Organic Clover Sprouts products are misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product labels bear nutrient content claims that are not authorized by regulation or fail to meet the terms of authorizing regulations. Under section 403(r)(2)(A)(i) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient of a type required to be in the labeling misbrands a product under section 403(r)(1)(A) of the Act. Specifically,

1. Your product labels and labeling bear antioxidant nutrient content claims but fail to comply with the requirements for using such a claim. Nutrient content claims using the term "antioxidant" must comply with, among other requirements, the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a reference daily intake (RDI) must have been established for each of the nutrients that are the subject of the claim [21 CFR 101.54(g)(1)], and these nutrients must have recognized antioxidant activity [21 CFR 101.54(g)(2)]. The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) [21 CFR 101.54(g)(3)]. For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity [21 CFR 101.54(g)(4)]. The antioxidant claims found in your product labeling are nutrient content claims because they characterize the level of antioxidants in your product, but they do not comply with 21 CFR 101.54(g)(4) because they do not include the names of the nutrients that are the subject of the claim or link the nutrients with the claim by use of a symbol. This includes the following claims:

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

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

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

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

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

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

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

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

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

5. In accordance with 21 CFR 101.65(c)(2), the phrases "contains the same amount of [nutrient] as a [food]" and "as much [nutrient] as a [food]" may be used on the label or in the labeling of foods, provided that the amount of the nutrient in the reference food is enough to qualify that food as a "good source" of that nutrient, and the labeled food, on a per serving basis, is an equivalent, good source of that nutrient (e.g., "as much fiber as an apple," "Contains the same amount of Vitamin C as an 8 oz. glass of orange juice."). Your products fail to meet the requirements to make this type of implied nutrient content claim, which is contained in your product labeling. Specifically:

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

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

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

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

We acknowledge your firm's efforts in addressing the issues raised in the FDA-483 Inspectional Observations that was issued to you on October 13, 2010 and the specific corrections your letter indicates that you have made. Your corrective actions will be further evaluated during our next inspection of your facility and your response will be filed as a part of the inspectional record for this facility. The above violations are not meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to assure that all of your sprout products are labeled and processed in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We also have the following comments about your product labels:

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

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

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

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

Sincerely,

/S/

Mutahar S. Shamsi

District Director

New England District

Close Out Letter

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

Links on this page:

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