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

12
13 MICHAEL KOSTA, individually and on
14 behalf of all others similarly situated,

Plaintiff,

15 v.

16 DEL MONTE CORPORATION,

17 Defendant.

Case No.

C12-01722^{LB}

CLASS ACTION AND REPRESENTATIVE ACTION

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

JURY TRIAL DEMANDED

18
19 Plaintiff, Michael Kosta, through his undersigned attorneys, brings this lawsuit against
20 Del Monte Corporation (hereinafter "Del Monte" or "Defendant") as to his own acts upon
21 personal knowledge, and as to all other matters upon information and belief. In order to remedy
22 the harm arising from Defendant's illegal conduct, which has resulted in unjust profits, Plaintiff
23 brings this action on behalf of a national class of consumers who, within the last four years,
24 purchased a Del Monte canned tomato product, a Del Monte FreshCut vegetable product or a Del
25 Monte Fruit Naturals product (referred to herein as "Misbranded Food Products").

26 **INTRODUCTION**

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

Class Action Complaint

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FILED

APR - 5 2012

RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND

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

5 2. Del Monte is "one of the country's largest producers, distributors, and marketers"
6 of food products with "\$3.7 billion in net sales in fiscal 2011."

7 <http://www.delmontefoods.com/company/default.aspx>

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

10 Del Monte offers nutritious foods for main meals and snacking for the entire
11 family, and our broad selection of healthy options is especially appropriate for
12 children. We aim to have a good number of our products provide at least a half a
13 cup of fruits or vegetables per serving and to meet healthy nutrient levels as
14 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.

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

16 4. Del Monte's website furthers states, "Del Monte® fruits and vegetables are chock-
17 full of flavor and packed with nutrition which includes plenty of age-fighting, immune-building
18 and heart-strengthening antioxidants. Let's do right by our bodies by eating more nutritious
19 meals." <http://www.delmonte.com/Nutrition/>

20 5. Del Monte makes unlawful claims on both its labels and its website. Del Monte's
21 unlawful claims include, but are not limited to, unlawful Lycopene antioxidant and other nutrient
22 content claims; "free of artificial ingredients & preservatives" claims; representations that
23 products were fresh and natural as well as unlawful health claims. The unlawful claims are
24 described more fully in the Factual Allegations section herein.

25 6. If a manufacturer, like Del Monte, is going to make a claim on a food label, the
26 label must meet certain legal requirements that help consumers make informed choices and
27 ensure that they are not misled. Del Monte is certainly aware of these requirements. "We may be
28 exposed to product recalls, including voluntary recalls or withdrawals, and adverse public

1 relations if our products are alleged to cause injury or illness or if we are alleged to have
2 mislabeled or misbranded our products or otherwise violated governmental regulations.”
3 http://google.brand.edgar-online.com/EFX_dll/EDGARpro.dll?FetchFilingHtmlSection1?Section
4 [ID=8241623-89280-173390&SessionID=zEFsFe8pbICAPs7](http://google.brand.edgar-online.com/EFX_dll/EDGARpro.dll?FetchFilingHtmlSection1?Section)

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

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

19 9. As consumer preferences have begun to favor healthier options, Del Monte has
20 embarked on an apparent health and wellness strategy that seeks to emphasize how its products
21 are good for a consumer and to reposition its products as a healthy option. In furtherance of its
22 health and wellness strategy, Del Monte utilizes unlawful, false and misleading nutrient content
23 and health claims to promote and market its Misbranded Food Products. Del Monte has also
24 sought to appeal to consumer preferences for natural and functional foods by including unlawful,
25 false and misleading antioxidant claims, nutrient content claims, natural claims and fresh claims
26 on its Misbranded Food Product labels and product related materials.

27 10. Del Monte’s reason for making such claims is driven by its pecuniary interests. As
28 stated by Del Monte in the Risk Factors section of the most recent annual report it filed with the

1 S.E.C.:

2 *The pet product and food product categories in which we participate are highly*
3 *competitive and, if we are not able to compete effectively, our results of*
4 *operations could be adversely affected.*

5 The pet product and food product categories in which we participate are highly
6 competitive. There are numerous brands and products that compete for shelf space
7 and sales, with competition based primarily on quality, breadth of product line,
8 brand awareness, innovation, price, taste, nutrition, variety, packaging and value-
9 added customer services such as inventory management services. We compete
10 with a significant number of companies of varying sizes, including divisions or
11 subsidiaries of larger companies. Our branded products face strong competition
12 from private label products that are generally sold at lower prices.... There are
13 competitive pressures and other factors which could cause our products to lose
14 market share or decline in sales or result in significant price or margin erosion,
15 which would have a material adverse effect on our business, financial condition
16 and results of operations.

17 *We may be unable to successfully introduce new products, reposition existing*
18 *products or anticipate changes in pet or consumer preferences, which could*
19 *adversely affect our results of operations.*

20 Our future business and financial performance depend, in part, on our ability to
21 successfully introduce new products and improved products, reposition existing
22 products, and anticipate and offer products that appeal to the changing tastes,
23 dietary habits and trends and product packaging preferences of consumers and,
24 their pets, in the market categories in which we compete. ... If we are not able to
25 anticipate, identify or develop and market products that respond to changes in pet
26 or consumer preferences or if our new product introductions or repositioned
27 products fail to gain consumer acceptance, we may not grow our business as
28 anticipated. Additionally, demand for our products could decline and our results
of operations could be adversely affected.

11. In furtherance of its health and wellness strategy Del Monte has utilized a number
of specific unlawful, improper, unauthorized, misleading and false antioxidant, nutrient content,
fresh and "100% natural" claims on its products' labels and labeling. These include:

- 24 A. Antioxidant claims on the labels of its Del Monte's canned tomato
25 products which fail to meet the minimum regulatory requirements for
26 such antioxidant claims;
- 27 B. "Free of artificial ingredients & preservatives" claims on the labels of Del
28 Monte's canned tomato products that contain artificial ingredients and
preservatives;

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

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

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

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

9 13. Del Monte has made a number of specific claims about its fruit and vegetable
10 products, including:

11 Tomatoes are rich in lycopene, Vitamin C and Vitamin E powerful antioxidants
12 that may play a role in protecting against cancer and heart disease. It seems that
13 almost every day, more research backing the health benefits of tomatoes is
14 discovered. Adding tomatoes and tomato products to your favorite dishes is an
15 easy, delicious way to amp up your healthy diet.

16 Many vegetables are packed with phytochemicals-powerful plant nutrients like
17 lycopene found in tomatoes and lutein, found in spinach and corn. Vegetables can
18 also be bursting with potassium and fiber that may have a role in protecting
19 against a variety of different diseases. So eating 2 ½ cups a day is important for
20 good health.

21 Del Monte® fruits and vegetables are chock-full of flavor and packed with
22 nutrition which includes plenty of age-fighting, immune-building and heart-
23 strengthening antioxidants. Let's do right by our bodies by eating more nutritious
24 meals.

25 Lycopene, a carotenoid found primarily in canned and processed tomatoes, shows
26 promise in preventing heart disease and other types of cancer. It is the pigment
27 that gives the brilliant red color to tomatoes, watermelon and red grapefruit.
28 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

1 although they may sound intimidating, the good news about superfoods is that
2 you can find them on your local grocery store shelves. In fact, you may already
3 have some in your pantry and your fridge.

4 Which foods contain these super nutrients? Most fruits and vegetables contain
5 protective vitamins, minerals and antioxidants, but a few truly stand out as
6 superfoods. And in many cases, the canned product is just as good, if not better,
7 than the fresh version:

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

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

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

28 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.

14. 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.*

1 Our branded products generally command a price premium as compared to the
2 prices of the private-label products with which they compete. Additionally, our
3 branded products in our Consumer Products segment generally command a price
4 premium as compared to the prices of the branded products with which they
5 compete. The current premium for our products may limit our ability to
6 effectively implement price increases. Additionally, these price premiums may
7 increase in the future, particularly if we implement price increases. The
8 willingness of consumers to pay a price premium for our branded products
9 depends on a number of factors, including the effectiveness of our marketing
10 programs, the continuing strength of our brands and general economic conditions.
11 During periods of challenging economic conditions, consumers may be less
12 willing or able to pay a price differential for our branded products,
13 notwithstanding our marketing programs or the strength of our brands, and may
14 shift purchases away from our branded products to lower-priced offerings or
15 forgo purchases of our products altogether. If the price premium for our branded
16 products exceeds the amount consumers are willing to pay, whether due to
17 economic conditions or otherwise, our sales would suffer and our revenues and
18 results of operations could be adversely affected. In addition consumers may
19 migrate to higher-value, larger-sized packages of our branded products (which
20 tend to have lower margins than our smaller-sized offerings), which could also
21 have an adverse effect on our results of operations.

15. 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*

1 *our products and experience product liability claims.*

2 We may be exposed to product recalls, including voluntary recalls or withdrawals,
3 and adverse public relations if our products are alleged to cause injury or illness
4 or if we are alleged to have mislabeled or misbranded our products or otherwise
5 violated governmental regulations. ...Consumer concerns (whether justified or
6 not) regarding the safety of our products could adversely affect our business. A
7 product recall or withdrawal could result in substantial and unexpected
8 expenditures, destruction of product inventory, and lost sales due to the
9 unavailability of the product for a period of time, which could reduce profitability
10 and cash flow. In addition, a product recall or withdrawal may require significant
11 management attention. Product recalls may also result in adverse publicity, hurt
12 the value of our brands, lead to a decline in consumer confidence in and demand
13 for our products, and lead to increased scrutiny by federal and state regulatory
14 agencies of our operations, which could have a material adverse effect on our
15 brands, business, results of operations and financial condition.

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

24 17. Defendant has made, and continues to make, unlawful claims on the food labels of
25 their Misbranded Food Products that are prohibited by federal and California law and which render
26 these products misbranded. Under federal and California law, Defendant's Misbranded Food
27 Products, including Defendant's canned tomato products, cannot legally be manufactured,
28 advertised, distributed, held or sold. Defendant's false and misleading labeling practices stem
29 from its global marketing strategy. Thus, the violations and misrepresentations are similar across
30 product labels and product lines.

PARTIES

31 18. Plaintiff Michael Kosta is a resident of Santa Rosa, California who purchased Del
32 Monte diced tomatoes, Del Monte FreshCut vegetable products and Del Monte Fruit Natural

1 products in California during the four (4) years prior to the filing of this Complaint (the "Class
2 Period").

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

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

12 JURISDICTION AND VENUE

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

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

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

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

28

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

3 **B. FDA Enforcement History**

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

8 30. In October 2009, the FDA issued a *Guidance For Industry: Letter regarding Point*
9 *Of Purchase Food Labeling* ("2009 FOP Guidance"), to address its concerns about front of
10 package labels. The 2009 FOP Guidance advised the food industry: FDA's research has found
11 that with FOP labeling, people are less likely to check the Nutrition Facts label on the information
12 panel of foods (usually, the back or side of the package). It is thus essential that both the criteria
13 and symbols used in front-of-package and shelf-labeling systems be nutritionally sound, well-
14 designed to help consumers make informed and healthy food choices, and not be false or
15 misleading. The agency is currently analyzing FOP labels that appear to be misleading. The
16 agency is also looking for symbols that either expressly or by implication are nutrient content
17 claims. We are assessing the criteria established by food manufacturers for such symbols and
18 comparing them to our regulatory criteria.

19 It is important to note that nutrition-related FOP and shelf labeling, while
20 currently voluntary, is subject to the provisions of the Federal Food, Drug, and
21 Cosmetic Act that prohibit false or misleading claims and restrict nutrient
22 content claims to those defined in FDA regulations. Therefore, FOP and shelf
23 labeling that is used in a manner that is false or misleading misbrands the
24 products it accompanies. Similarly, a food that bears FOP or shelf labeling with
25 a nutrient content claim that does not comply with the regulatory criteria for the
26 claim as defined in Title 21 Code of Federal Regulations (CFR) 101.13 and
27 Subpart D of Part 101 is misbranded. We will consider enforcement actions
28 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

1 laws and regulations. FDA will proceed with enforcement action against
2 products that bear FOP labeling that are explicit or implied nutrient content
3 claims and that are not consistent with current nutrient content claim
4 requirements. FDA will also proceed with enforcement action where such FOP
5 labeling or labeling systems are used in a manner that is false or misleading.

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

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

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

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

26 With that in mind, I have made improving the scientific accuracy and
27 usefulness of food labeling one of my priorities as Commissioner of Food and
28 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

1 healthy ones and, indeed, may be false or misleading.

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

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

17

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

26 I will close with the hope that these warning letters will give food
27 manufacturers further clarification about what is expected of them as they
28 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.

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

35. 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.

36. In these letters 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

1 Act ... and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR
2 101)” and were “misbranded within the meaning of section 403(r)(1)(A) because the product
3 label bears a nutrient content claim but does not meet the requirements to make the claim.”

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

6 38. The FDA stated that the agency not only expected companies that received
7 warning letters to correct their labeling practices but also anticipated that other firms would
8 examine their food labels to ensure that they are in full compliance with food labeling
9 requirements and make changes where necessary. Del Monte did not change the labels on its
10 Misbranded Food Products in response to the warning letters sent to other companies nor did it
11 change its labels on its Misbranded Food Products when it ultimately received a warning letter
12 from the FDA.

13 39. Defendant also has ignored the FDA’s Guidance for Industry, A Food Labeling
14 Guide which details the FDA’s guidance on how to make food labeling claims. Defendant
15 continues to utilize unlawful claims on the labels of its Misbranded Food Products. Despite all
16 warnings, Defendant’s Misbranded Food Products continue to run afoul of FDA guidance as well
17 as federal and California law.

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

20 41. Plaintiff did not know, and had no reason to know, that the Defendant’s
21 Misbranded Food Products were misbranded and bore food labeling claims despite failing to meet
22 the requirements to make those food labeling claims.

23 **C. Defendant’s Food Products Are Misbranded**

24 42. Pursuant to Section 403 of the FDCA, a claim that characterizes the level of a
25 nutrient in a food is a “nutrient content claim” that must be made in accordance with the
26 regulations that authorize the use of such claims. 21 U.S.C. § 343(r)(1)(A). California expressly
27 adopted the requirements of 21 U.S.C. § 343(r) in § 110670 of the Sherman Law.
28

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

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

8 45. 21 C.F.R. § 101.13 provides the general requirements for nutrient content claims,
9 which California has expressly adopted. California Health & Safety Code § 110100.

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

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

19 1. **Defendant Makes Unlawful Nutrient Content Claims**

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

26 49. Only approved nutrient content claims will be permitted on the food label, and all
27 other nutrient content claims will misbrand a food. It should thus be clear which type of claims
28 are prohibited and which are permitted. Manufacturers are on notice that the use of an

1 unapproved nutrient content claim is prohibited conduct. 58 FR 2302. In addition, 21 USC
2 343(r)(2) prohibits using unauthorized undefined terms and declares foods that do so to be
3 misbranded.

4 50. In order to appeal to consumer preferences, Defendant has repeatedly made
5 unlawful nutrient content claims about Lycopene and Lutein and other antioxidants and nutrients
6 that fail to utilize one of the limited defined terms. These nutrient content claims are unlawful
7 because they fail to comply with the nutrient content claim provisions in violation of 21 C.F.R. §§
8 101.13 and 101.54, which have been incorporated in California's Sherman Law. To the extent
9 that the terms used to describe Lycopene or Lutein and unnamed antioxidants are deemed to be a
10 synonym for a defined term like "contain" the claim would still be unlawful because, as these
11 nutrients do not have established daily values, they cannot serve as the basis for a term that has a
12 minimum daily value threshold.

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

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

26 53. For example, claims that Del Monte's canned tomato products are "an excellent
27 source of," or "rich in" Lycopene are unlawful because Lycopene does not have an RDI and
28 therefore Defendant's canned tomato products do not meet the minimum nutrient level threshold

1 to make such a claim which is 20 percent or more of the RDI (Reference Daily Intake or
2 Recommended Daily Intake) or the DRV (Daily Reference Value) of Lycopene per reference
3 amount customarily consumed. Claims that Del Monte's canned tomato product "contain
4 Lycopene are unlawful because Lycopene does not have an RDI and therefore Defendant's
5 canned tomato products do not meet the minimum nutrient level threshold to make such a claim
6 which is 10 percent or more of the RDI or the DRV per reference amount customarily consumed.
7 Claims that Del Monte's canned tomato products are "rich in," Vitamin C or Vitamin E are
8 unlawful because Defendant's canned tomato products do not meet the minimum nutrient level
9 threshold to make such a claim which is 20 percent or more of the RDI or the DRV per reference
10 amount customarily consumed. Claims that Del Monte's products like its tomato products are a
11 "good source" of potassium fail to meet the criteria for such a claim as well. 21 C.F.R. §§ 101.13
12 and 101.54. In addition, claims that Del Monte's canned tomato products have "more" Lycopene
13 than other products also fail to meet the minimum nutrient level threshold to make such a claim.

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

16 55. Claims that Del Monte products contain or are made with an ingredient that is
17 known to contain a particular nutrient, or is prepared in a way that affects the content of a
18 particular nutrient in the food, can only be made if it "good source" of the nutrient that is
19 associated with the ingredient or type of preparation. Thus, Del Monte's statements that Lycopene
20 is found in tomatoes trigger a "good source" requirement (10 percent or more of the RDI or the
21 DRV per reference amount customarily consumed) which Lycopene and tomatoes cannot
22 demonstrate. 21 C.F.R. § 101.65(c)(3). Similarly, Del Monte's label claim that its canned tomato
23 products are a "[n]atural source of Lycopene, a powerful antioxidant, and Vitamins A & C"
24 trigger trigger a "good source" requirement (10 percent or more of the RDI or the DRV per
25 reference amount customarily consumed) for Lycopene, Vitamin A, and Vitamin C which cannot
26 be satisfied for Lycopene and which certain canned tomato products like Del Monte's tomato
27 sauce cannot satisfy for Vitamin A or C.

28

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

3 57. Defendant has violated these referenced regulations. Therefore, Defendant's
4 Misbranded Food Products are misbranded as a matter of federal and California law and cannot
5 be sold or held because they are legally worthless.

6 **2. Defendant Makes Unlawful Antioxidant Claims**

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

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

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

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

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

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

26 (5) the antioxidant nutrient must meet the requirements for nutrient content
27 claims in 21 C.F.R. § 101.54(b), (c), or (e) for "High" claims, "Good Source" claims, and "More"
28 claims, respectively. For example, to use a "High" claim, the food would have to contain 20% or

1 more of the Daily Reference Value (“DRV”) or RDI per serving. For a “Good Source” claim, the
2 food would have to contain between 10-19% of the DRV or RDI per serving, *see* 21 C.F.R. §
3 101.54(g)(3); and

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

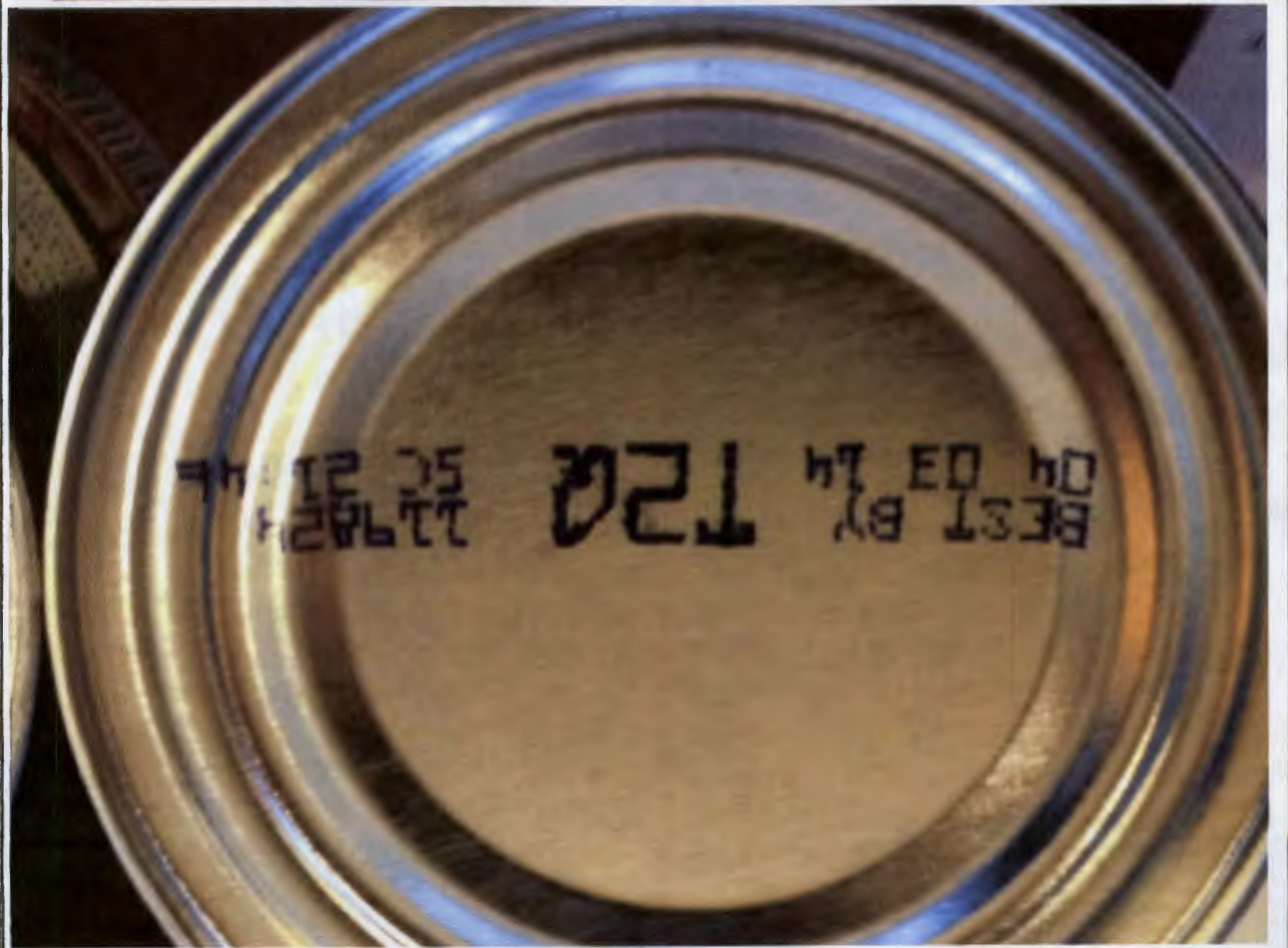
8 60. For example on Del Monte Canned tomato products such as the ones purchased by
9 Plaintiff the label states, “Natural Source of Antioxidants” and contains check marks by the terms
10 “Vitamins A and C” and “Lycopene.” It also says “[n]atural source of Lycopene, a powerful
11 antioxidant, and Vitamins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



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1 61. The antioxidant labeling for Defendant's canned tomato products violates federal
2 and California law. The antioxidant claims on the packages of these products violate federal and
3 California law: (1) because there are no RDIs for Lycopene, the antioxidant being touted, and
4 (2) because Defendant lacks adequate scientific evidence that the claimed antioxidant nutrients
5 participate in physiological, biochemical, or cellular processes that inactivate free radicals or
6 prevent free radical-initiated chemical reactions after they are eaten and absorbed from the
7 gastrointestinal tract.

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

12 63. In addition to the Hirzel letter (Exhibit A), the FDA has issued at least 6 other
13 warning letters addressing similar unlawful antioxidant nutrient content claims. Defendant knew
14 or should have known of these FDA warning letters.

15 64. For these reasons, Defendant's antioxidant claims at issue in this Complaint are
16 misleading and in violation of 21 C.F.R. § 101.54 and California law, and the products at issue
17 are misbranded as a matter of law. Misbranded products cannot be legally manufactured,
18 advertised, distributed, held or sold, and are legally worthless.

19 **3. Defendant Makes Unlawful Natural Claims**

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

28

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

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

7 68. Upon information and belief, some of Del Monte's competitors in the canned or
8 packaged tomato product market do not include citric acid or calcium chloride in their tomato
9 products.

10 69. Del Monte itself produces non-canned tomato products like tomato paste that do
11 not contain citric acid or calcium chloride.

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

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

17 72. On August 29, 2001, the FDA sent a letter to Hirzel Canning Company ("Hirzel
18 warning letter" attached hereto as Exhibit A). The FDA specifically found that "labels for canned
19 tomato products manufactured by" Hirzel were "in violation of Section 403 of the Federal Food
20 Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101-
21 Food Labeling." Among other reasons, the Hirzel warning letter stated in pertinent part:

22 [The product] labels bear the term "All NATURAL," but
23 according to the ingredient statements, calcium chloride and citric
24 acid are added to the products. We have not established a
25 regulatory definition for the term "natural," however; we discussed
26 its use in the [preamble] to the food labeling final regulations (58
27 Federal Register 2407, January 6, 1993). FDA's policy regarding
28 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.

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

2 73. Defendant knew or should have known of the Hirzel warning letter. Because the
3 Defendant's products contain the same ingredients prohibited by the FDA in other tomato
4 products, the use of a natural claim in connection with Defendant's tomato product is false and
5 misleading, and therefore these products are misbranded under section 403(a)(1) of the Act.

6 74. On August 16, 2001, the FDA sent a warning letter to Oak Tree Farm Dairy, Inc.
7 ("Oak Tree warning letter" attached hereto as Exhibit B). The letter "found serious violations" of
8 the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations, Part 101 -
9 Food Labeling (21 CFR 101), and stated in pertinent part:

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

19 <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178712.htm>

20 Defendant knew or should have known of the Oak Tree warning letter.

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

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

27 77. The FDA considers use of the term "natural" on a food label to be truthful and
28 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.

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

4 79. The FDA has sent out numerous warning letters concerning this issue. *See, e.g.*,
5 Exhibit A (August 29, 2001 FDA warning letter to Hirzel Canning Company relating to citric
6 acid or calcium chloride in tomato products) and Exhibit B (August 16, 2001 FDA warning letter
7 to Oak Tree Farm Dairy relating to citric acid). Defendant is aware of these FDA warning letters.

8 80. Defendant has unlawfully labeled a number of its products as being natural when
9 they actually contain artificial ingredients and/or chemical preservatives. These include the
10 Defendant’s Fruit Naturals products. For example, Del Monte’s Fruit Naturals No Sugar Added
11 Red Grapefruit contains: Grapefruit, Water, Sorbitol, Ascorbic Acid (To Protect Color),
12 Potassium Sorbate and Sodium Benzoate (To Preserve Quality), Citric Acid, Acesulfame
13 Potassium, Sucralose. Similarly, Del Monte’s Fruit Naturals Red Grapefruit contains: Grapefruit,
14 Reconstituted White Grape Juice, Reconstituted Red Grapefruit Juice, Potassium Sorbate and
15 Sodium Benzoate (To Preserve Quality), Ascorbic Acid (To Protect Color), Citric Acid, Color
16 Added. Del Monte’s Fruit Naturals Cherry Mixed Fruit contains: Mixed Fruit [Peaches, Pears,
17 Pineapples, Cherries (Cherries, Carmine)], Reconstituted White Grape Juice, Reconstituted Pear
18 Juice, Ascorbic Acid (To Protect Color), Potassium Sorbate and Sodium Benzoate
19 (Preservatives), Natural Flavors, Citric Acid. Carmine is a dye produced from the crushed bodies
20 of parasitic insects. These products and the rest of the Fruit Naturals product line are anything but
21 natural and it is misleading to represent them as such.

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

24 82. A reasonable consumer would expect that when Defendant labels its products as
25 natural the product’s ingredients are “natural” as defined by the federal government and its
26 agencies. A reasonable consumer would also expect that when Defendant labels its products as
27 natural the product ingredients are “natural” under the common use of that word. A reasonable
28

1 consumer would understand that natural products do not contain synthetic, artificial, or
2 excessively processed ingredients.

3 83. Consumers are thus misled into purchasing and paying a premium for Defendant's
4 products with unnatural ingredients that are not natural as falsely represented on their labeling.

5 84. Defendant's products in this respect are misbranded under federal and California
6 law. Misbranded products cannot be legally sold or held and are legally worthless.

7 **4. Defendant Makes Unlawful "Free Of Artificial Ingredients & Preservatives"**
8 **And Fresh Claims**

9 85. According to standardized requirements for canned tomatoes (21 C.F.R. §
10 155.190) citric acid may only be used for acidification purposes while calcium chloride may only
11 be used as a firming agent. Given that these uses are both artificial and a form of preservation, the
12 label statement "free of artificial ingredients & preservatives" is both false and misleading and
13 renders the Defendant's canned tomato products and other products bearing this statement
14 misbranded.

15 86. Defendant makes numerous claims that its products are "fresh." For example,
16 Defendant has a line of "FreshCut" vegetable products that represent in numerous ways they are
17 fresh. On the label of products like the Defendant's FreshCut Sliced Carrots (which contains
18 calcium chloride) is a statement that the products "are the highest standard of freshness and flavor
19 because they are packed fresh. Picked fresh. Packed fresh. Unsurpassed quality you can taste in
20 every bite. That's the FreshCut guarantee." Elsewhere on the labels are statements that the
21 products are "fresh packed."

22 87. Under 21 C.F.R. § 101.95, the word "fresh," when used on the label or in labeling
23 of a food in a manner that suggests or implies that the food is unprocessed, means that the food is
24 in its raw state and has not been frozen or subjected to any form of thermal processing or any
25 other form of preservation. The restrictions on the use of the term "fresh" "pertain to any use of
26 the subject terms in a brand name and use as a sensory modifier" such as "fresh taste." Given
27 the thermal processing of Defendant's products and the addition of the chemicals like calcium
28 chloride, representations that such products are fresh are deceptive and misleading.

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

3 89. Because Del Monte's representations of freshness are misleading and in violation
4 of 21 C.F.R. § 101.95, consumers are misled into purchasing and paying a premium for
5 Defendant's products that are not fresh as falsely represented on their labeling.

6 90. Defendant's products in this respect are misbranded under federal and California
7 law. Misbranded products cannot be legally sold or held and are legally worthless.

8 **5. Defendant Makes Unlawful Health Claims**

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

16 92. 21 C.F.R. § 101.14, which has been expressly adopted by California, provides
17 when and how a manufacturer may make a health claim about its product. A "Health Claim"
18 means any claim made on the label or in labeling of a food, including a dietary supplement, that
19 expressly or by implication, including "third party" references, written statements (*e.g.*, a brand
20 name including a term such as "heart"), symbols (*e.g.*, a heart symbol), or vignettes, characterizes
21 the relationship of any substance to a disease or health-related condition. Implied health claims
22 include those statements, symbols, vignettes, or other forms of communication that suggest,
23 within the context in which they are presented, that a relationship exists between the presence or
24 level of a substance in the food and a disease or health-related condition (see 21 CFR
25 101.14(a)(1)).

26 93. Further, health claims are limited to claims about disease risk reduction, and
27 cannot be claims about the diagnosis, cure, mitigation, or treatment of disease. An example of an
28 authorized health claim is: "Three grams of soluble fiber from oatmeal daily in a diet low in

1 saturated fat and cholesterol may reduce the risk of heart disease. This cereal has 2 grams per
2 serving.”

3 94. A claim that a substance may be used in the diagnosis, cure, mitigation, treatment,
4 or prevention of a disease is a drug claim and may not be made for a food. 21 U.S.C. §
5 321(g)(1)(D).

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

9 Qualifies as both low fat and low saturated fat;
10 Contains 480 mg or less of sodium per reference amount
11 and per labeled serving, and per 50 g (as prepared for
12 typically rehydrated foods) if the food has a reference
13 amount of 30 g or 2 tbsps or less;

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

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

25 96. 21 C.F.R. § 101.65(d)(2). The FDA’s definition applies separate criteria to use of
26 healthy on raw, single ingredient seafood or game meat products. 21 C.F.R. § 101.65(d)(2)(ii).
27 FDA’s regulation on healthy also encompasses other, derivative uses of health (*e.g.*, healthful,
28 healthier) in food labeling. 21 C.F.R. § 101.65(d).

29 97. Del Monte has violated the provisions of § 21 C.F.R. §101.14, 21 C.F.R. §101.65,
30 21 U.S.C. § 321(g)(1)(D) and 21 U.S.C. § 352(f)(1) by including certain claims on its website. For
31 example, on its website, Del Monte states: “Because of its strong antioxidant properties, Lycopene
32 is believed to help retard the aging process and stave off heart disease, cancer and major
33 degenerative diseases. Some research has found that cooking foods containing Lycopene –
34 tomatoes, for instance – makes the Lycopene more easily absorbed by the body. That would make

1 canned tomatoes one of the better sources of lycopene.” [http://www.delmonte.com/health-](http://www.delmonte.com/health-glossary.aspx)
2 [glossary.aspx](http://www.delmonte.com/health-glossary.aspx).

3 98. The website also states, “Lycopene, a carotenoid found primarily in canned and
4 processed tomatoes, shows promise in preventing heart disease and other types of cancer. It is the
5 pigment that gives the brilliant red color to tomatoes, watermelon and red grapefruit. Research is
6 beginning to show promise that Lycopene benefits may have a role in preventing heart disease and
7 certain types of cancer like prostate cancer. Canned tomatoes and tomato products are excellent
8 sources of Lycopene because the heat from cooking or canning makes the Lycopene more
9 available to your body.”

10 http://www.delmontefoods.com/livingahealthylifestyle/?page=lh_askthenutritionist4

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

18 **D. Defendant Has Violated California Law**

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

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

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

28

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

3 104. Defendant has violated California Health & Safety Code § 110660 because its
4 food products are misbranded in one or more ways, as follows:

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

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

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

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

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

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

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

25 109. Defendant has violated the standards set by 21 CFR §§ 101.13, 101.54, and 101.65
26 which have been adopted by reference in the Sherman Law, by including unauthorized
27 antioxidant and nutrient content claims on their products.

28

1 **E. Plaintiff Purchased Defendant's Misbranded Food Products**

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

4 111. Plaintiff purchased Defendant's Misbranded Food Products at issue in this
5 Complaint, including Defendant's canned tomatoes products, on occasions during the Class
6 Period.

7 112. Plaintiff purchased Defendant's Misbranded Food Products, including Del Monte
8 Diced Tomatoes, Del Monte Tomato Sauce, Del Monte FreshCut Sliced Carrots, Del Monte Fruit
9 Naturals Red Grapefruit, Del Monte Fruit Naturals Red Grapefruit No Sugar Added and Del
10 Monte Fruit Naturals Cherry Mixed Fruit.

11 113. Plaintiff read the labels on Defendant's Misbranded Food Products including the
12 Lycopene antioxidant and other nutrient content claims; the "free of artificial ingredients &
13 preservatives" claim; and the representations that the products were fresh and natural before
14 purchasing them.

15 114. Plaintiff relied on Defendant's package labeling including the Lycopene
16 antioxidant and other nutrient content claims; the "free of artificial ingredients & preservatives"
17 claim; and the representations that the products were fresh and natural, and based and justified
18 the decision to purchase Defendant's Misbranded Food Products in substantial part on
19 Defendant's package labeling including the Lycopene antioxidant and other nutrient content
20 claims; the "free of artificial ingredients & preservatives" claim; and the representations that the
21 products were fresh and natural.

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

25 116. At point of sale, Plaintiff did not know, and had no reason to know, that
26 Defendant's Lycopene antioxidant and other nutrient content claims, the "free of artificial
27 ingredients & preservatives" claim, and the representations that the products were fresh and
28 natural on the products' labels were unlawful as set forth herein, and would not have bought the

1 products had he known the truth about them.

2 117. As a result of Defendant's misrepresentations, Plaintiff and thousands of others in
3 California purchased the products at issue.

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

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

14 **CLASS ACTION ALLEGATIONS**

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

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

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

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

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

28

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

- 6 a. Whether Defendant engaged in unfair, unlawful or deceptive
7 business practices by failing to properly package and label their
8 Misbranded Food Products sold to consumers;
9 b. Whether the food products at issue were misbranded or unlawfully
10 packaged and labeled as a matter of law;
11 c. Whether Defendant made unlawful and misleading antioxidant
12 claims with respect to their food products sold to consumers;
13 d. Whether Defendant made unlawful and misleading nutrient content
14 claims with respect to their food products sold to consumers;
15 e. Whether Defendant made unlawful and misleading natural and
16 fresh claims with respect to their food products sold to consumers;
17 f. Whether Defendant violated California Bus. & Prof. Code § 17200
18 *et seq.*, California Bus. & Prof. Code § 17500 *et seq.*, the
19 Consumer Legal Remedies Act, Cal. Civ. Code. § 1750 *et seq.*, and
20 the Sherman Law;
21 g. Whether Plaintiff and the Class are entitled to equitable and/or
22 injunctive relief;
23 h. Whether Defendant's unlawful, unfair and/or deceptive practices
24 harmed Plaintiff and the Class; and
25 i. Whether Defendant was unjustly enriched by its deceptive
26 practices.
27
28

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

1 arise from the same practices and course of conduct that give rise to the claims of the Class
2 members and are based on the same legal theories.

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

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

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

1 to possess was of no benefit to consumers, and the harm to consumers and competition is
2 substantial.

3 148. Defendant sold Plaintiff and the Class Misbranded Food Products that were not
4 capable of being legally sold or held and that were legally worthless.

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

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

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

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

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

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

22 154. Defendant sold Misbranded Food Products in California and nationwide during the
23 Class Period.

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

26 156. Defendant's misleading marketing, advertising, packaging and labeling of the
27 Misbranded Food Products and misrepresentation that the products were salable, capable of legal
28 possession and not misbranded was likely to deceive reasonable consumers, and in fact, Plaintiff

1 and members of the Class were deceived. Defendant has engaged in fraudulent business acts and
2 practices.

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

6 158. Defendant sold Plaintiff and the Class Misbranded Food Products that were not
7 capable of being sold or held legally and that were legally worthless.

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

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

16 160. Plaintiff incorporates by reference each allegation set forth above.

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

19 162. Defendant sold Misbranded Food Products in California and nationwide during the
20 Class Period.

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

23 164. Defendant engaged in a scheme of offering Misbranded Food Products for sale to
24 Plaintiff and members of the Class by way of, *inter alia*, product packaging and labeling, and
25 other promotional materials. These materials misrepresented and/or omitted the true contents and
26 nature of Defendant's Misbranded Food Products. Defendant's advertisements and inducements
27 were made within California and come within the definition of advertising as contained in
28 Business and Professions Code §17500, *et seq.* in that such product packaging and labeling, and

1 promotional materials were intended as inducements to purchase Defendant's Misbranded Food
2 Products and are statements disseminated by Defendant to Plaintiff and the Class that were
3 intended to reach members of the Class. Defendant knew that these statements were misleading
4 and deceptive as set forth herein.

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

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

15 167. As a result of Defendant's violations of the "misleading prong" of California
16 Business and Professions Code § 17500, *et seq.*, Defendant has been unjustly enriched at the
17 expense of Plaintiff and the Class. Misbranded products cannot be legally sold or held and are
18 legally worthless.

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

23
24 **FIFTH CAUSE OF ACTION**
25 **Business and Professions Code § 17500, *et seq.***
Untrue Advertising

26 169. Plaintiff incorporates by reference each allegation set forth above.

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

1 171. Defendant sold Misbranded Food Products in California and nationwide during the
2 Class Period.

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

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

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

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

24 176. As a result of Defendant's violations of the "untrue prong" of California Business
25 and Professions Code § 17500, *et seq.*, Defendant has been unjustly enriched at the expense of
26 Plaintiff and the Class. Misbranded products cannot be legally sold or held and are legally
27 worthless.

28

1 185. Plaintiff and members of the Class are “consumers” as that term is defined by the
2 CLRA in Cal. Civ. Code §1761(d).

3 186. Defendant’s Misbranded Food Products were and are “goods” within the meaning
4 of Cal. Civ. Code §1761(a).

5 187. By engaging in the conduct set forth herein, Defendant violated and continues to
6 violate Section 1770(a)(5), of the CLRA, because Defendant’s conduct constitutes unfair methods
7 of competition and unfair or fraudulent acts or practices in that they misrepresent the particular
8 ingredients, characteristics, uses, benefits and quantities of the goods.

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

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

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

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

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

28 192. Plaintiff incorporates by reference each allegation set forth above.

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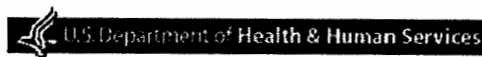
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U.S. Food & Drug Administration

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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 your 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 the Federal Food Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101- Food Labeling as follows:

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

The above product is misbranded within the meaning of Section 403 (a)(1) of the Act in that its labeling is 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 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.

Dei Fratelli Fresh & Ready CHOPPED TOMATOES ONION & GARLIC (14.5 oz. cans) and Dei Fratelli 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 statements "FRESH-PACKED" on the principal display panel and "Fresh & Ready" in the brand name of the products falsely imply that the finished products in the package are "fresh," when in fact they have been thermally processed. In addition, according to the ingredient statements, the products contain at least 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)(1)(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 on the information on the nutrition label, the CHOPPED MEXICAN TOMATOES & JALAPENOS product contains 590 mg of sodium. A "healthy" claim may be used where, among other things, 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)(1)(A) of the Act because the labels bear nutrient content claims that are not authorized 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 defined 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 ® *** CONCENTRATED/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 in enforcement action such as 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 to 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 part of the common or usual name of an ingredient. Ingredients must be declared by their common or usual name, as stated in section 403(I)(2) of the Act and 21 CFR 101.4(a)(1). Optional information, such as the term "fresh" is not permitted.

Also, the Dei 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 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 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

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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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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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