Ben F. Pierce Gore (SBN 128515) 1 E-FILING PRATT & ASSOCIATES 2 1901 S. Bascom Avenue, Suite 350 Campbell, CA 95008 3 Telephone: (408) 429-6506 Fax: (408) 369-0752 4 pgore@prattattorneys.com 5 (Co-counsel listed on signature page) 6 Attorneys for Plaintiff RICHARD W. WICHING CLERK, U.S. DISTRICT COURT 7 NORTHERN DISTRICT OF CALIFORNIA 8 IN THE UNITED STATES DISTRICT COURT 9 FOR THE NORTHERN DISTRICT OF CALIFORNIA 10 SAN JOSE DIVISION 11 Case NCV12-01828 12 TRICIA OGDEN, individually and on 13 behalf of all others similarly situated, CLASS ACTION AND REPRESENTATIVE 14 ACTION Plaintiff, 15 COMPLAINT FOR DAMAGES, v. **EQUITABLE AND INJUNCTIVE RELIEF** 16 BUMBLE BEE FOODS, LLC, JURY TRIAL DEMANDED 17 Defendant. 18 19 20 Plaintiff, through her undersigned attorneys, brings this lawsuit against Bumble Bee Foods, LLC ("Bumble Bee" or "Defendant") as to her own acts upon personal knowledge, and as 21 22 to all other matters upon information and belief. In order to remedy the harm arising from 23 Defendant's illegal conduct, which has resulted in unjust profits, Plaintiff brings this action on 24 behalf of a nationwide class of consumers who, within the last four years, purchased Bumble Bee 25 products labeled "Rich in Natural Omega-3" or "Excellent Source Omega-3" ("Misbranded Food 26 Products"). 27 28

Class Action Complaint

INTRODUCTION

- 1. Every day, millions of Americans purchase and consume packaged foods. Identical federal and California laws require truthful, accurate information on the labels of packaged foods. This case is about a company that flouts those laws. The law, however, is clear: misbranded foods cannot legally be manufactured, held, advertised, distributed or sold. Misbranded food is worthless as a matter of law, and purchasers of misbranded food are entitled to a refund of their purchase price.
- 2. Bumble Bee produces a variety of seafood products, and it is best known for its tuna products. Bumble Bee represents that it is North America's largest branded shelf-stable seafood company. Bumble Bee products include canned and pouched tuna, salmon, shrimp, crab, clams, oysters, sardines, mackerel, and chicken. Bumble Bee also sells ready-to-eat chicken salad, seafood salad, tuna salad and tuna medley meal kits for such products as chicken salad, seafood salad, tuna salad and tuna medley. Bumble Bee sells sardines and other seafood products under such labels as Beach Cliff®, Brunswick® and King Oscar®.
- 3. Bumble Bee recognizes that health claims drive sales and actively promotes the purported health benefits of its products, notwithstanding the fact that such promotion violated California and federal law. For example, on its website Bumble Bee states:

Nourishing Lifestyles

Bumble Bee Promotes Healthy and Sustainable Lifestyles for Consumers

Bumble Bee's core seafood products are an excellent and affordable source of protein, nutrients and Omega 3 fatty acids. The healthy profile of our product portfolio affords Bumble Bee a strong basis from which to support and encourage healthy consumer lifestyles.

http://www.bumblebee.com/about/sustainability/nourishing-life

4. On the website discussion of its King Oscar® brand, Bumble Bee goes even further in promoting the health benefits of its sardine products, specifically focusing on Omega 3:

More and more research suggests that Omega-3's may help:

• Promote heart health by reducing artery-clogging cholesterol and triglycerides (fats) in your bloodstream.

- Lower your risk of heart attack by regulating electrical activity.
- Protect against type-2 diabetes by positively influencing your metabolism and blood pressure.
- Protect you from certain cancers, including breast cancer and leukemia.
- Benefit your immune system and improve inflammatory diseases such as rheumatoid arthritis and psoriasis.
- Improve your mood and support mental health.
- Play a vital role in the development of your baby's eyes and brain very important for pregnant mothers.

All that good stuff and more from the Omega-3's in delicious fish. That's right, fish are the best natural source of the Omega-3's your body needs most. Especially coldwater fish such as brisling sardines, mackerel, herring, and salmon. Another big reason why nutritionists will tell you to eat more seafood – at least twice a week. At King Oscar, we say why stop there?

http://www.kingoscar.com/health/omega-3

- 5. Bumble Bee also makes health nutrient claims directly on the package of its products. For example, the labels on several of Bumble Bee's products have a seal or logo stating "excellent source of Omega 3" and "Rich in Natural Omega-3.".
- 6. If a food manufacturer makes a claim on a food label, the label must meet certain legal requirements that help consumers make informed choices and ensure that they are not misled. As described more fully below, Defendant has made, and continues to make, false and deceptive nutrient content claims in violation of federal and California laws that govern the types of representations that can be made on food labels. These laws recognize that reasonable consumers are likely to choose products claiming to have a health or nutritional benefit over otherwise similar food products that do not claim such benefits. More importantly, these laws recognize that the failure to disclose the presence of risk-increasing nutrients is deceptive because it conveys to consumers the net impression that a food makes only positive contributions to a diet, or does not contain any nutrients at levels that raise the risk of a diet-related disease or health-related condition.
- 7. Identical federal and California laws regulate the content of labels on packaged food. The requirements of the federal Food Drug & Cosmetic Act ("FDCA") were adopted by the California legislature in the Sherman Food Drug & Cosmetic Law (the "Sherman Law"). California Health & Safety Code § 109875, et seq. Under FDCA section 403(a), food is

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"misbranded" if "its labeling is false or misleading in any particular," or if it does not contain certain information on its label or in its labeling. 21 U.S.C. § 343(a).

- 8. Under the FDCA, the term "false" has its usual meaning of "untruthful," while the term "misleading" is a term of art. Misbranding reaches not only false claims, but also those claims that might be technically true, but still misleading. If any one representation in the labeling is misleading, then the entire food is misbranded, nor can any other statement in the labeling cure a misleading statement. "Misleading" is judged in reference to "the ignorant, the unthinking and the credulous who, when making a purchase, do not stop to analyze." United States v. El-O-Pathic Pharmacy, 192 F.2d 62, 75 (9th Cir. 1951). Under the FDCA, it is not necessary to prove that anyone was actually misled.
- 9. Other companies that sell similar products with similar Omega 3 nutrient content claims have been found by FDA to be in violation of the laws concerning such claims. On July 15, 2011, the FDA sent a warning letter to Natural Guidance, LLC, informing the company of its failure to comply with the requirements of the Federal Food Drug and Cosmetic Act ("FDCA") and its regulations, all of which have been expressly adopted by California in its Sherman Law (the "FDA Warning Letter," attached hereto as Exhibit 1).
 - 10. The FDA Warning Letter to Natural Guidance, LLC, stated, in pertinent part:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your websites www.naturalguidance.com1 and www.salba.com2, as recently as July 2011, and has determined that your Salba® brand products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the products are drugs because they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans. The marketing of the products with these claims violates the Act. You may find the Act and its implementing regulations through links on FDA's home page at www.fda.gov³.

Some examples of claims taken from your website at www.naturalguidance.com4, include:

From your webpage titled "Salba - A Superior Source of Omega-3s" at www.salba.com/superior source⁶:

"Omega-3s Benefits ...

- Child Depression
- Breast, Colon, and Prostate Cancer
- Coronary Heart Disease
- Diabetes management
- · Cardiovascular Heart Disease"

Your Salba® brand products are not generally recognized as safe and effective for the above referenced uses and therefore, the products are new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505(a) of the Act [21 U.S.C. § 355(a)], a new drug may not be legally marketed in the U.S. without an approved New Drug Application (NDA). FDA approves new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Furthermore, because your Salba® brand products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; adequate directions for use cannot be written so that a layperson can use these products safely for their intended uses. Thus, your products are also misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352 (f)(1)] in that the labeling for these drugs fails to bear adequate directions for use.

Misbranded Products

Even if your Salba products were not unapproved new drugs, your Salba Whole Seed Super-grain – 16 oz., Salba Ground Seed-9.5 oz., Salba Seed Oil (12oz), Salba Seed Oil Softgels, and Salba Whole Food Bars (Cranberry Nut, Mixed Berry, and Tropical Fruit) would be misbranded under section 403 of the Act [21 U.S.C. 343] because their labeling includes unauthorized nutrient content claims. A claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with an FDA regulation authorizing the use of such a claim. Characterizing the level of a nutrient in food labeling of a product without complying with specific requirements pertaining to nutrient content claims for that nutrient misbrands the product under section 403(r)(1)(A) of the Act.

1. Nutrient content claims that use the defined terms "rich in," "high," or "excellent source of" may be used in the labeling of a food only if the food contains 20 percent or more of the daily value (DV) of that nutrient per reference amount customarily consumed (RACC), as required by 21 CFR 101.54(b)(1). Such claims may not be made about a nutrient for which there is no established DV.

However, your website, <u>www.naturalguidance.com</u>⁷, includes such a claim for specific nutrients even though the food does not contain 20 percent or more of the DV per RACC of these nutrients, in accordance with 21 CFR 101.54(b)(1):

2. Although various nutrient content claims for ALA, DHA, and EPA omega-3 fatty acids have been statutorily authorized through the notification procedure in section 403(r)(3)(C) of the Act [21 U.S.C. § 343(r)(3)(C)], the claims for Omega-3 on your

websites do not meet the requirements for any of these claims. Specifically, among other requirements, the claims authorized under the notification procedure must specify whether the claim is referring to ALA, DHA, or EPA omega-3 fatty acids.¹

The following are examples of unauthorized Omega-3 claims on your website, www.salba.com⁸, which can be found on each product's webpage:

Salba Seed Oil (12 oz.) and Salba Seed Oil Softgels (90 ct.)

• "[N]ature's richest source of Omega-3s."

Salba Whole Food Bars (Tropical Fruit Cranberry Nut, and Mixed Berry)

• "Salba - nature's richest plant-based source of Omega-3s..."

In addition, the following are examples of unauthorized Omega-3 claims on your website, www.naturalguidance.com, which can be found on each product's webpage:

Salba Whole Food Bars (Tropical Fruit, Cranberry Nut, and Mixed Berry)

• "Salba is nature's richest vegetarian source of ... omega-3s."

Salba Ground Seed - 9.5 oz. and Salba Whole Seed Super-Grain - 16 oz.

• "Richest Source of Omega-3s ... in Nature."

11. The Omega 3 claims listed above that are on Bumble Bee's King Oscar website establish that Bumble Bee's products are drugs under section 201(g)(1)(B) of the FDCA [21 U.S.C. § 321(g)(1)(B)], because they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. However, Bumble Bee's products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" as defined by section 201(p) of the FDCA [21 U.S.C. § 321(p)]. A new drug may not be legally marketed in the United States without prior approval from the FDA as described in section 505(a) of the FDCA [21 U.S.C. § 355(a)]. Bumble Bee's marketing of its products with these claims violates the FDCA. Further, because Bumble Bee's products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions for use cannot be written so that a layperson can use these products safely for their intended uses. As such, Bumble Bee's products are misbranded under section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)] in that the labeling for its drugs fails

to bear adequate directions for use.

Bumble Bee has made and continues to make food label claims that are prohibited by federal and California law. Bumble Bee has made, and continues to make, food label claims that are prohibited by federal and California law. Under federal and California law, Defendant's misbranded food products cannot legally be manufactured, advertised, distributed, held or sold. Defendant's false and misleading labeling practices stem from their global marketing strategy. Thus, the violations and misrepresentations are similar across product labels and product lines.

13. Defendant's violations of law are numerous and include: (1) the illegal advertising, marketing, distribution, delivery and sale of Defendant's Misbranded Food Products to

U.S.C. 343] because their labeling includes unauthorized Omega 3 nutrient content claims.

12. Bumble Bee's products are also misbranded under Section 403 of the FDCA [21

PARTIES

packaging and labeling that are mandated by law.

consumers; (2) the failure to properly disclose the high levels of fat, saturated fat and cholesterol

in their Misbranded Food Products on the Misbranded Food Products' packaging and labeling as

required by law; and (3) the failure to include statements on the Misbranded Food Products

- 14. Plaintiff Tricia Ogden is a resident of San Jose, California who purchased Defendant's Misbranded Food Products in California during the four (4) years prior to the filing of this Complaint (the "Class Period").
- 15. Defendant Bumble Bee is a Delaware corporation with its principal place of business at 9655 Granite Ridge Dr., Suite 100, San Diego, CA 92123.
- 16. Defendant is a leading producer of retail seafood products. It sells its misbranded food products to consumers through grocery and other retail stores throughout the United States and California.

JURISDICTION AND VENUE

17. This Court has original jurisdiction over this action under 28 U.S.C. § 1332(d) because this is a class action in which: (1) there are over 100 members in the proposed class;

- (2) members of the proposed class have a different citizenship from Defendants; and (3) the claims of the proposed class members exceed \$5,000,000 in the aggregate.
- 18. The Court has jurisdiction over the federal claim alleged herein pursuant to 28 U.S.C. § 1331, because it arises under the laws of the United States.
- 19. The Court has jurisdiction over the California claims alleged herein pursuant to 28 U.S.C. § 1367, because they form part of the same case or controversy under Article III of the United States Constitution.
- 20. Alternatively, the Court has jurisdiction over all claims alleged herein pursuant to 28 U.S.C. § 1332, because the matter in controversy exceeds the sum or value of \$75,000, and is between citizens of different states.
- 21. The Court has personal jurisdiction over Defendant because a substantial portion of the wrongdoing alleged in this Complaint occurred in California, Defendant is authorized to do business in California, has sufficient minimum contacts with California, and otherwise intentionally avails itself of the markets in California through the promotion, marketing and sale of merchandise, sufficient to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.
- 22. Because a substantial part of the events or omissions giving rise to these claims occurred in this District and because the Court has personal jurisdiction over Defendants, venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (b).

FACTUAL ALLEGATIONS

A. Identical California And Federal Laws Regulate Food Labeling

- 23. Food manufacturers are required to comply with federal and state laws and regulations that govern the labeling of food products. First and foremost among these is the Federal Food, Drug and Cosmetics Act ("FDCA") and its labeling regulations, including those set forth in 21 C.F.R. § 101.
- 24. Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements as its own and indicated that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on

or after that date shall be the food regulations of this state." California Health & Safety Code

also enacted a number of laws and regulations that adopt and incorporate specific enumerated

federal food laws and regulations. For example, food products are misbranded under California

Health & Safety Code § 110660 if their labeling is false and misleading in one or more

particulars; are misbranded under California Health & Safety Code § 110665 if their labeling fails

to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q) and

regulations adopted thereto; are misbranded under California Health & Safety Code § 110670 if

their labeling fails to conform with the requirements for nutrient content and health claims set

forth in 21 U.S.C. § 343(r) and regulations adopted thereto; are misbranded under California

Health & Safety Code § 110705 if words, statements and other information required by the

Sherman Law to appear on their labeling are either missing or not sufficiently conspicuous; are

misbranded under California Health & Safety Code § 110735 if they are represented as having

special dietary uses but fail to bear labeling that adequately informs consumers of their value for

that use; and are misbranded under California Health & Safety Code § 110740 if they contain

artificial flavoring, artificial coloring and chemical preservatives but fail to adequately disclose

25. In addition to its blanket adoption of federal labeling requirements, California has

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Defendant's Food Products Are Misbranded В.

that fact on their labeling.

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

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

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- 28. Section 403(r)(1)(A) of the FDCA governs the use of expressed and implied nutrient content claims on labels of food products that are intended for sale for human consumption. See 21 C.F.R. § 101.13.
- 29. An "expressed nutrient content claim" is defined as any direct statement about the level (or range) of a nutrient in the food (e.g., "low sodium" or "contains 100 calories"). See 21 C.F.R. § 101.13(b)(1).
- 30. An "implied nutrient content claim" is defined as any claim that: (i) describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or (ii) suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat"). 21 C.F.R. § 101.13(b)(2)(i-ii).

C. <u>Defendant Makes Unlawful Omega 3 Nutrient Content Claims</u>

- 31. Where a particular nutrient does not have an established daily value (DV) under FDA regulations, food producers may not state on their food labels that their food product is a "good source" of the nutrient, or use a comparable phrase, such as "excellent source" or "rich in." 21 C.F.R. 101.54.
- 32. Federal and California regulations regulate omega 3 claims as a particular type of nutrient content claim. Because omega 3 does not have an established daily value (DV), food producers may not state on their labels that their products are a "good source" of Omega 3, or use a synonym conveying the same message. 21 CFR 101.54. If food producers employ an Omega 3 nutrient content claim, the claim must have been statutorily authorized and must specify whether the claim is referring to ALA, DHA, or EPA omega 3 fatty acids.
- 33. Defendant has violated 21 C.F.R. § 101.54 by representing that its products are an "excellent source" of omega 3 or "rich in" omega 3 and by failing to specify whether its omega 3 nutrient content claims are referring to ALA, DHA or EPA omega 3 fatty acids. For example, certain Bumblebee products claim to be an "excellent source of Omega 3" or "naturally rich in

Omega 3" but they fail to disclose that Omega 3 has no established Daily Value pursuant to FDA regulations. Thus, these products violate 21 C.F.R. § 101.54.

- 34. The types of misrepresentations made above would be considered by a reasonable consumer when deciding to purchase Defendant's products. The failure to comply with the labeling requirements of 21 C.F.R. § 101.54 renders Defendant's products misbranded as a matter of federal and California law. Misbranded products cannot be legally sold and are legally worthless.
- 35. 21 C.F.R. § 101.13 provides the general requirements for nutrient content claims, which California has expressly adopted. *See* California Health & Safety Code § 110100. 21 C.F.R. § 101.13 requires that manufacturers include certain disclosures when a nutrient claim is made and, at the same time, the product contains certain levels of unhealthy ingredients, such as fat and sodium.
- 36. 21 C.F.R. § 101.13(h)(1) provides that: "If a food ... contains more than 13.0 g of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less ... per 50 g ... then that food must bear a statement disclosing that the nutrient exceeding the specified level is present in the food...."
- 37. 21 C.F.R. § 101.13 also sets forth the manner in which that disclosure must be made, as follows:
 - (4)(i) The disclosure statement "See nutrition information for ____ content" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, and in a size no less than that required by $\S101.105(i)$ for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclosure statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch, unless the package complies with $\S101.2(c)(2)$, in which case the disclosure statement may be in type of not less than one thirty-second of an inch.
 - (ii) The disclosure statement shall be immediately adjacent to the nutrient content claim and may have no intervening material other than, if applicable, other information in the statement of identity or any other information that is required to be presented with the claim under this section (e.g., see paragraph (j)(2) of this section) or under a regulation in subpart D of this part (e.g., see §§101.54 and 101.62). If the nutrient content claim appears on more than one panel of the label, the disclosure statement shall be adjacent to the claim on each panel except for the

38. To appeal to consumer preferences, Bumble Bee has repeatedly made unlawful nutrient content claims on products containing disqualifying levels of fat, sodium and cholesterol.

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

These nutrient content claims were unlawful because they failed to include disclosure statements required by law that are designed to inform consumers of the inherently unhealthy nature of those

products in violation of 21 C.F.R. § 101.13(h), which has been incorporated in California's

Sherman Law.

39. Certain Bumble Bee food products bearing the "excellent source of Omega 3" and "Rich in Natural Omega-3" labels make such claims despite disqualifying levels of unhealthy components without proper disclosure. For example, Bumble Bee's "Tuna Salad Original with Crackers Kit" has eighteen grams of fat per labeled serving but does not bear a statement that fat exceeding the specified level is present. As another example, Bumble Bee's "King Oscar Sardines Mediterranean Style" have 110 milligrams of cholesterol per labeled serving but do not bear a statement that cholesterol exceeding the specified level is present. The failure to include the required disclosure statement renders the products at issue misbranded as a matter of law. Misbranded products cannot be legally held or sold and are legally worthless.

- 40. These regulations are intended to ensure that consumers are not misled to believe that a product that claims, for instance, to be an excellent source of Omega 3, but actually has unhealthy levels of fat or cholesterol, is a healthy choice, because of the presence of Omega 3.
- 41. Plaintiff did not know, and had no reason to know, that Defendant's Misbranded Food Products were misbranded, and bore nutrient claims despite failing to meet the requirements to make those nutrient claims. Plaintiff was equally unaware that Defendant's Misbranded Food Products contained one or more nutrients like fat, sodium, or cholesterol that, according to the FDA, "may increase the risk of disease or health related condition that is diet related."
- 42. Based on the fat and cholesterol content of these products, pursuant to federal and California law, Bumble Bee must include a warning statement adjacent to the Omega 3 nutrient claim that informs consumers of the high levels of fat or cholesterol. No such fat or cholesterol

disclosure statement currently exists on these products. Therefore, they are misbranded as a matter of federal and California law and cannot be sold because they are legally worthless.

D. <u>Defendant Has Violated California Law</u>

- 43. Defendant has violated California Health & Safety Code § 110390, which makes it unlawful to disseminate false or misleading food advertisements, including statements on products and product packaging or labeling or any other medium used to directly or indirectly induce the purchase of a food product.
- 44. Defendant has violated California Health & Safety Code § 110395, which makes it unlawful to manufacture, sell, deliver, hold or offer to sell any falsely advertised food.
- 45. Defendant has violated California Health & Safety Code §§ 110398 and 110400, which make it unlawful to advertise misbranded food or to deliver or proffer for delivery any food that has been falsely advertised.
- 46. Defendant has violated California Health & Safety Code § 110660 because its labeling is false and misleading in one or more ways, as follows:
- a. Defendant's Misbranded Food Products are misbranded under California Health & Safety Code § 110665 because its labeling fails to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q) and the regulations adopted thereto;
- b. Defendant's Misbranded Food Products are misbranded under California Health & Safety Code § 110670 because its labeling fails to conform with the requirements for nutrient content and health claims set forth in 21 U.S.C. § 343(r) and the regulations adopted thereto; and
- c. Defendant's Misbranded Food Products are misbranded under California Health & Safety Code § 110705 because words, statements and other information required by the Sherman Law to appear on their labeling either are missing or not sufficiently conspicuous.
- 47. Defendant has violated California Health & Safety Code § 110760, which makes it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is misbranded.
- 48. Defendant's Misbranded Food Products are misbranded under California Health & Safety Code § 110755 because they purport to be or are represented as for special dietary uses,

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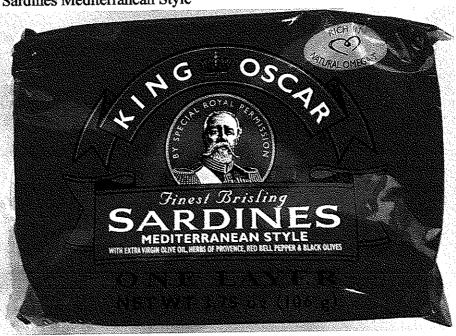
and their labels fail to bear such information concerning their vitamin, mineral and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order to fully inform purchasers as to its value for such uses.

- 49. Defendant has violated California Health & Safety Code § 110765, which makes it unlawful for any person to misbrand any food.
- 50. Defendant has violated California Health & Safety Code § 110770, which makes it unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for deliver any such food.
- 51. Defendant has violated the standard set by 21 C.F.R. § 101.13(h), which has been incorporated by reference in the Sherman Law, by failing to include on their product labels the nutritional information required by law.

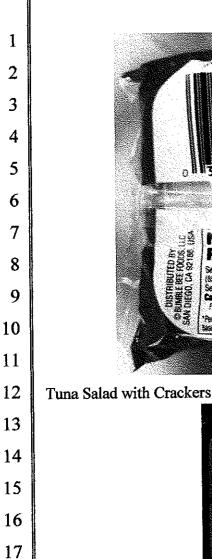
E. Plaintiff Purchased Defendant's Misbranded Food Products

- 52. Plaintiff cares about the nutritional content of food and seeks to maintain a healthy diet.
- 53. Plaintiff purchased Defendant's misbranded food products at issue in this Complaint on occasions during the Class Period.
- 54. Plaintiff purchased the following products:

King Oscar Sardines Mediterranean Style



- 14 -Class Action Complaint





WITH CRACKERS OMEGA-3 Ready To Eat VII WI 3.5 02 (99 g)

- 15 -Class Action Complaint

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55. Plaintiff read the labels on Defendant's Misbranded Food Products, including the Omega 3 claims, where applicable, before purchasing them. Defendant's failure to disclose that there is no established daily value for Omega 3 and failure to disclose the presence of riskincreasing nutrients in connection with its "excellent source" or "rich in" Omega 3 claims was deceptive because it falsely conveyed to the Plaintiff the net impression that the Misbranded Food Products he bought made only positive contributions to a diet, and did not contain any nutrients at levels that raised the risk of diet-related disease or a health-related condition.

- 56. Plaintiff relied on Defendant's package labeling including the "excellent source" and "rich in" Omega 3 nutrient content claim, and based and justified the decision to purchase Defendant's products in substantial part on Defendant's package labeling including the "excellent source" and "rich in" Omega 3 content claims. Plaintiff would have foregone purchasing Defendant's products and bought other products readily available at a lower price.
- 57. At point of sale, Plaintiff did not know, and had no reason to know, that Defendant's products were misbranded as set forth herein, and would not have bought the products had she known the truth about them.
- 58. At point of sale, Plaintiff did not know, and had no reason to know, that Defendant's "excellent source" and "rich in" Omega 3 nutrient content claims were unlawful and unauthorized as set forth herein, and would not have bought the products absent the unlawful "excellent source" and "rich in" Omega 3 nutrient content claim.
- 59. As a result of Defendant's misrepresentations, Plaintiff and thousands of others in the United States purchased the Misbranded Food Products at issue.
- 60. Defendant's labeling, advertising and marketing as alleged herein is false and misleading and was designed to increase sales of the products at issue. Defendant's misrepresentations are part of an extensive labeling, advertising and marketing campaign, and a reasonable person would attach importance to Defendant's representations in determining whether to purchase the products at issue.
- 61. A reasonable person would also attach importance to whether Defendant's products were legally salable, and capable of legal possession, and to Defendants' representations about these issues in determining whether to purchase the products at issue. Plaintiff would not have purchased Defendant's Misbranded Food Products had he known they were not capable of being legally held or sold.

Whether Defendant's unlawful, unfair and/or deceptive practices harmed

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f.

Plaintiff and the Classes; and

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

- 67. Typicality: Plaintiff's claims are typical of the claims of the Classes because Plaintiff bought Defendant's Misbranded Food Products during the Class Period. Defendant's unlawful, unfair and/or fraudulent actions concern the same business practices described herein irrespective of where they occurred or were received. Plaintiff and the Class sustained similar injuries arising out of Defendant's conduct in violation of California law. The injuries of each member of the Class were caused directly by Defendant's wrongful conduct. In addition, the factual underpinning of Defendant's misconduct is common to all Class members and represents a common thread of misconduct resulting in injury to all members of the Class. Plaintiff's claims arise from the same practices and course of conduct that give rise to the claims of the Class members and are based on the same legal theories.
- Neither Plaintiff nor Plaintiff's counsel have any interests that conflict with or are antagonistic to the interests of the Class members. Plaintiff has retained highly competent and experienced class action attorneys to represent its interests and those of the members of the Class. Plaintiff and Plaintiff's counsel have the necessary financial resources to adequately and vigorously litigate this class action, and Plaintiff and counsel are aware of their fiduciary responsibilities to the Class members and will diligently discharge those duties by vigorously seeking the maximum possible recovery for the Class.
- 69. Superiority: There is no plain, speedy or adequate remedy other than by maintenance of this class action. The prosecution of individual remedies by members of the Class will tend to establish inconsistent standards of conduct for Defendant and result in the impairment of Class members' rights and the disposition of their interests through actions to which they were not parties. Class action treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently and without the unnecessary duplication of effort and expense that numerous individual actions would engender. Further, as the damages suffered by individual members of the Class may be relatively small, the

expense and burden of individual litigation would make it difficult or impossible for individual members of the Class to redress the wrongs done to them, while an important public interest will be served by addressing the matter as a class action. Class treatment of common questions of law and fact would also be superior to multiple individual actions or piecemeal litigation in that class treatment will conserve the resources of the Court and the litigants, and will promote consistency and efficiency of adjudication.

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

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

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

CAUSES OF ACTION

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

- 73. Plaintiff incorporates by reference each allegation set forth above.
- 74. Defendant's conduct constitutes unlawful business acts and practices.
- 75. Defendant sold Misbranded Food Products nationwide and in California during the Class Period.
- 76. Defendant is a corporation and, therefore, is a "person" within the meaning of the Sherman Law.

- 77. Defendant's business practices are unlawful under § 17200, et seq. by virtue of Defendant's violations of the advertising provisions of Article 3 of the Sherman Law and the misbranded food provisions of Article 6 of the Sherman Law.
- 78. Defendant's business practices are unlawful under § 17200, et seq. by virtue of Defendant's violations of § 17500, et seq., which forbids untrue and misleading advertising.
- 79. Defendant's business practices are unlawful under § 17200, et seq. by virtue of Defendant's violations of the Consumer Legal Remedies Act, Cal. Civil Code § 1750, et seq.
- 80. Defendant sold Plaintiff and the Class Misbranded Food Products that were not capable of being sold or held legally and which were legally worthless.
- 81. As a result of Defendant's illegal business practices, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and to restore to any Class Member any money paid for the misbranded food products.
- 82. Defendant's unlawful business acts present a threat and reasonable continued likelihood of deception to Plaintiff and the Class.
- 83. As a result of Defendant's conduct, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

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

- 84. Plaintiff incorporates by reference each allegation set forth above.
- 85. Defendant's conduct as set forth herein constitutes unfair business acts and practices.
- 86. Defendant sold Misbranded Food Products nationwide and in California during the Class Period.

- 87. Plaintiff and members of the Class suffered a substantial injury by virtue of buying Defendant's Misbranded Food Products that they would not have purchased absent Defendant's illegal conduct as set forth herein.
- 88. Defendant's deceptive marketing, advertising, packaging and labeling of its Misbranded Food Products and its sale of unsalable misbranded products that were illegal to possess was of no benefit to consumers, and the harm to consumers and competition is substantial.
- 89. Defendant sold Plaintiff and the Class Misbranded Food Products that were not capable of being legally sold or held and that were legally worthless.
- 90. Plaintiff and the Class who purchased Defendant's Misbranded Food Products had no way of reasonably knowing that the products were misbranded and were not properly marketed, advertised, packaged and labeled, and thus could not have reasonably avoided the injury suffered.
- 91. The consequences of Defendant's conduct as set forth herein outweigh any justification, motive or reason therefor. Defendant's conduct is and continues to be immoral, unethical, unscrupulous, contrary to public policy, and is substantially injurious to Plaintiff and the Class.
- 92. As a result of Defendant's conduct, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

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

- 93. Plaintiff incorporates by reference each allegation set forth above.
- 94. Defendant's conduct as set forth herein constitutes fraudulent business practices under California Business and Professions Code sections § 17200, et seq.
- 95. Defendant sold Misbranded Food products nationwide and in California during the Class Period.

- 96. Defendant's misleading marketing, advertising, packaging and labeling of the Misbranded Food Products was likely to deceive reasonable consumers, and in fact, Plaintiff and members of the Class were deceived. Defendant has engaged in fraudulent business acts and practices.
- 97. Defendant's fraud and deception caused Plaintiffs and the Class to purchase Defendant's Misbranded Food Products that they would otherwise not have purchased had they known the true nature of those products.
- 98. Defendant sold Plaintiff and the Class misbranded food products that were not capable of being sold or held legally and that were legally worthless.
- 99. As a result of Defendant's conduct as set forth herein, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

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

- 100. Plaintiff incorporates by reference each allegation set forth above.
- 101. Plaintiff asserts this cause of action for violations of California Business and Professions Code § 17500, et seq. for misleading and deceptive advertising against Defendants.
- 102. Defendant sold Misbranded Food Products nationwide and in California during the Class Period.
- 103. Defendant engaged in a scheme of offering Defendant's Misbranded Food Products for sale to Plaintiff and members of the Class by way of, *inter alia*, product packaging and labeling, and other promotional materials. These materials misrepresented and/or omitted the true contents and nature of Defendant's misbranded food products. Defendant's advertisements and inducements were made within California and come within the definition of advertising as contained in Business and Professions Code §17500, *et seq.* in that such product packaging and

labeling, and promotional materials were intended as inducements to purchase Defendant's misbranded food products and are statements disseminated by Defendant to Plaintiff and the Class that were intended to reach members of the Class. Defendant knew, or in the exercise of reasonable care should have known, that these statements were misleading and deceptive as set forth herein.

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

105. Defendant's conduct in disseminating misleading and deceptive statements in California and nationwide to Plaintiff and the Class was and is likely to deceive reasonable consumers by obfuscating the true composition and nature of Defendant's misbranded food products in violation of the "misleading prong" of California Business and Professions Code § 17500, et seq.

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

107. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's misbranded food products by Plaintiff and the Classes.

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

108. Plaintiff incorporates by reference each allegation set forth above.

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

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

- 111. Defendant engaged in a scheme of offering Defendant's Misbranded Food Products for sale to Plaintiff and the Class by way of product packaging and labeling, and other promotional materials. These materials misrepresented and/or omitted the true contents and nature of Defendant's Misbranded Food Products. Defendant's advertisements and inducements were made in California and come within the definition of advertising as contained in Business and Professions Code §17500, et seq. in that the product packaging and labeling, and promotional materials were intended as inducements to purchase Defendant's Misbranded Food Products, and are statements disseminated by Defendant to Plaintiff and the Class. Defendant knew, or in the exercise of reasonable care should have known, that these statements were untrue.
- 112. In furtherance of their plan and scheme, Defendant prepared and distributed in California and nationwide via product packaging and labeling, and other promotional materials, statements that falsely advertise the composition of Defendant's Misbranded Food Products, and falsely misrepresented the nature of those products. Plaintiff and the Class were the intended targets of such representations and would reasonably be deceived by Defendant's materials.
- 113. Defendant's conduct in disseminating untrue advertising throughout California and nationwide deceived Plaintiff and members of the Class by obfuscating the contents, nature and quality of Defendant's misbranded food products in violation of the "untrue prong" of California Business and Professions Code § 17500.
- 114. As a result of Defendant's violations of the "untrue prong" of California Business and Professions Code § 17500, et seq., Defendant has been unjustly enriched at the expense of Plaintiff and the Class. Misbranded products cannot be legally sold and are legally worthless.
- 115. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are entitled to an order enjoining such future conduct by Defendant, and such other orders and

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judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

SIXTH CAUSE OF ACTION Consumers Legal Remedies Act, Cal. Civ. Code §1750, et seq.

- 116. Plaintiff incorporates by reference each allegation set forth above.
- 117. This cause of action is brought pursuant to the CLRA. This cause of action does not currently seek monetary damages and is limited solely to injunctive relief. Plaintiff intends to amend this Complaint to seek damages in accordance with the CLRA after providing Defendant with notice pursuant to Cal. Civ. Code § 1782.
- 118. At the time of any amendment seeking damages under the CLRA, Plaintiff will demonstrate that the violations of the CLRA by Defendant were willful, oppressive and fraudulent, thus supporting an award of punitive damages.
- against Defendant for their violations of the CLRA. In addition, pursuant to Cal. Civ. Code § 1782(a)(2), Plaintiff and the Class will be entitled to an order enjoining the above-described acts and practices, providing restitution to Plaintiff and the Class, ordering payment of costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court pursuant to Cal. Civ. Code § 1780.
- 120. Defendant's actions, representations and conduct have violated, and continue to violate the CLRA, because they extend to transactions that are intended to result, or which have resulted, in the sale of goods to consumers.
- 121. Defendant sold Misbranded Food Products nationwide and in California during the Class Period.
- 122. Plaintiff and members of the Classes are "consumers" as that term is defined by the CLRA in Cal. Civ. Code §1761(d).
- 123. Defendant Misbranded Food Products were and are "goods" within the meaning of Cal. Civ. Code §1761(a).

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

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

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

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

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

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

129. Plaintiff incorporates by reference each allegation set forth above.

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

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131. Defendant sold Misbranded Food Products to Plaintiff and the Class that were not capable of being sold or held legally and which were legally worthless. It would be against equity and good conscience to permit Defendant to retain the ill-gotten benefits Defendant received from Plaintiff and the Class, in light of the fact that the products were not what Defendant purported them to be. Thus, it would be unjust and inequitable for Defendant to retain the benefit without restitution to Plaintiff and the Class of all monies paid to Defendant for the products at issue.

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

EIGHTH CAUSE OF ACTION Beverly-Song Act (Cal. Civ. Code § 1790, et seq.)

- 133. Plaintiff incorporates by reference each allegation set forth above.
- 134. Plaintiff and members of the Class are "buyers" as defined by Cal. Civ. Code § 1791(b).
- 135. Defendant is a "manufacturer" and "sellers" as defined by Cal. Civ. Code § 1791(j) & (1).
 - 136. Defendant's food products are "consumables" as defined by Cal. Civ. Code § 1791(d).
- 137. Defendant's nutrient and health content claims constitute "express warranties" as defined by Cal. Civ. Code § 1791.2.
- 138. Defendant, through its package labels, creates express warranties by making affirmations of fact and promising that its misbranded food products comply with food labeling regulations under federal and California law.
- 139. Despite Defendant's express warranties regarding its food products, these products do not comply with food labeling regulations under federal and California law.
- 140. Defendant breached its express warranties regarding Defendant's misbranded food products in violation of Cal. Civ. Code § 1790, et seq.
- 141. Defendants sold Plaintiff and members of the Class Defendant's misbranded food products that were not capable of being sold or held legally and which were legally worthless.

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1	142. As a direct and proximate result of Defendant's actions, Plaintiff and the Class have
2	suffered damages in an amount to be proven at trial pursuant to Cal. Civ. Code § 1794.
3	143. Defendant's breaches of warranty were willful, warranting the recovery of civil
4	penalties pursuant to Cal. Civ. Code § 1794.
5	NINTH CAUSE OF ACTION
6	Magnuson-Moss Act (15 U.S.C. § 2301, et seq.)
7	144. Plaintiff incorporates by reference each allegation set forth above.
8	145. Plaintiff and members of the Class are "consumers" as defined by 15 U.S.C. §
9	2301(3).
10	146. Defendant is a "supplier" and "warrantor" as defined by 15 U.S.C. § 2301(4) & (5).
11	147. Defendant's food products are "consumer products" as defined by 15 U.S.C. §
12	2301(1).
13	148. Defendant's nutrient and health content claims constitute "express warranties."
14	149. Defendant, through its package labels, creates express warranties by making
15	affirmations of fact and promising that its misbranded food products comply with food labeling
16	regulations under federal and California law.
17	150. Despite Defendant's express warranties regarding its food products, these products do
18	not comply with food labeling regulations under federal and California law.
19	151. Defendant breached its express warranties regarding its misbranded food products in
20	violation of 15 U.S.C. §§ 2301, et seq.
21	152. Defendant sold Plaintiff and members of the Classes Defendant's misbranded food
22	products that were not capable of being sold or held legally and which were legally worthless.
23	153. As a direct and proximate result of Defendant's actions, Plaintiff and the Class have
24	suffered damages in an amount to be proven at trial.
25	JURY DEMAND
26	Plaintiff hereby demands a trial by jury of her claims.
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1 PRAYER FOR RELIEF 2 WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, and on 3 behalf of the general public, prays for judgment against Defendant as follows: For an order certifying this case as a class action and appointing Plaintiff and her 4 5 counsel to represent the Classes; For an order awarding, as appropriate, damages, restitution or disgorgement to 6 B. 7 Plaintiff and the Class for all causes of action other than the CLRA, as Plaintiff does not seek monetary relief under the CLRA, but intends to amend her Complaint to seek such relief; 8 9 For an order requiring Defendant to immediately cease and desist from selling its C. Misbranded Food Products in violation of law; enjoining Defendant from continuing to market, 10 advertise, distribute, and sell these products in the unlawful manner described herein; and 11 12 ordering Defendant to engage in corrective action; 13 For all equitable remedies available pursuant to Cal. Civ. Code § 1780; D. 14 For an order awarding attorneys' fees and costs; E. 15 For an order awarding punitive damages; F. 16 For an order awarding pre-and post-judgment interest; and G. 17 For an order providing such further relief as this Court deems proper. Η. 18 Respectfully submitted, Dated: April 12, 2012 19 Ben F. Purice Gore 20 Ben F. Pierce Gore (SBN 128515) 21 PRATT & ASSOCIATES 1901 S. Bascom Avenue, Suite 350 22 Campbell, CA 95008 23 Telephone: (408) 429-6506 Fax: (408) 369-0752 24 pgore@prattattorneys.com 25 26 27 28

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U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

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

Natural Guidance, LLC 7/15/11



Department of Health and Human Services

Public Health Service Food and Drug Administration Florida District 555 Winderley Place, Suite 200 Maitland, Florida 32751 Telephone: 407-475-4700 FAX: 407-475-4770

CERTIFIED MAIL RETURN RECEIPT REQUESTED

WARNING LETTER FLA-11-31

July 15, 2011 Mr. Mitchell A. Propster Owner Natural Guidance, LLC Ancient Naturals, LLC 1000 N. Maitland Ave. Maitland, FL 32751

Dear Mr. Propster:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your websites www.naturalguidance.com ¹ and www.salba.com ², as recently as July 2011, and has determined that your Salba® brand products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the products are drugs because they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans. The marketing of the products with these claims violates the Act. You may find the Act and its implementing regulations through links on FDA's home page at www.fda.gov 3.

Some examples of claims taken from your website at www.naturalguidance.com 4 , include:

From your homepage under "Natural Product of the Week - Salba Whole Seed Super-grain - 16oz" after clicking on "More Info":

Salba Whole Seed Super-Grain - 16 oz.

"The Benefits of Using Salba Include: ...

Prevents Blood Sugar Imbalance"

From each product's webpage:

Salba Whole Food Bars (Cranberry Nut, Mixed Berry, and Tropical Fruit)

"Here are the benefits: ...

Prevents Blood Sugar Imbalance"

Some examples of claims on your website www.salba.com⁵, include the following:

From your "About Us" webpage:

"Salba ... is in the field of management of diabetes specifically with Salba, and methods of use in these seeds in lowering blood pressure, blood glucose and post-prandial glycemia.

From your homepage after clicking on "Products" and then selecting each particular product:

Salba Whole Food Bars (Cranberry Nut, Mixed Berry, and Tropical Fruit) "Benefits of Using Salba: ...

Prevents Blood Sugar Imbalance"

From your "Testimonials" webpage:

- "As a nutritional biochemist, I am always looking for new whole foods that my clients can incorporate into their diet.... [i]t (Salba) seems to help with low level depression'
- "My doctor has told me that I need a new heart After a few days of taking Salba, I noticed feeling much more energy.... My cardiologist

- ... is amazed at the complete transformation in my health."
- "Diabetes Under Control ... I have been a diabetic for ten years. My glucose levels have been higher than my doctor and I would like[.] I read about the effectiveness of salba for glucose control I have taken salba gelcaps for six months or so - my glucose is back under control I feel great and less problems with my allergies.
- "Blood Glucose Down 20 Points!"
- "Salba Helps My Hypoglycemia and IBS"
- "I began using Salba last Thursday (Oct. 20th). I have Celiac Disease and was having trouble internally and run into complications at times where I needed to take a laxative I noticed an improvement within two days.
- "Salba is Working Better than My Prescriptions!! I have been on Salba for about four months now. I have type 2 diabetes and was diagnosed about six years ago. I am on a maximum dose of Metfornin and two shots of 10 mcg of Byetta. My blood sugar was still in the 160 - 210 range ... I started mixing 2-3 tablespoons of Salba with oatmeal in the morning ... my blood sugar is between 94 - 114.
- "My Arthritis is Gone! ... I have taken 2 Tbs. (Salba) daily for the last 6 weeks. The arthritis pain in my knees is completely gone!"

From your webpage titled "Salba - A Superior Source of Omega-3s" at www.salba.com/superior_source 6:

- "Omega-3s Benefits ...
- Child Depression
- · Breast, Colon, and Prostate Cancer
- Coronary Heart Disease
- · Diabetes management
- Cardiovascular Heart Disease"

Your Salba® brand products are not generally recognized as safe and effective for the above referenced uses and therefore, the products are new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505(a) of the Act [21 U.S.C. § 355(a)], a new drug may not be legally marketed in the U.S. without an approved New Drug Application (NDA). FDA approves new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Furthermore, because your Salba® brand products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; adequate directions for use cannot be written so that a layperson can use these products safely for their intended uses. Thus, your products are also misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352 (f)(1)] in that the labeling for these drugs fails to bear adequate directions for use.

Misbranded Products

Even if your Salba products were not unapproved new drugs, your Salba Whole Seed Super-grain - 16 oz., Salba Ground Seed-9.5 oz., Salba Seed Oil (12oz), Salba Seed Oil Softgels, and Salba Whole Food Bars (Cranberry Nut, Mixed Berry, and Tropical Fruit) would be misbranded under section 403 of the Act [21 U.S.C. 343] because their labeling includes unauthorized nutrient content claims. A claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with an FDA regulation authorizing the use of such a claim. Characterizing the level of a nutrient in food labeling of a product without complying with specific requirements pertaining to nutrient content claims for that nutrient misbrands the product under section 403(r)(1)(A) of the Act.

1. Nutrient content claims that use the defined terms "rich in," "high," or "excellent source of" may be used in the labeling of a food only if the food contains 20 percent or more of the daily value (DV) of that nutrient per reference amount customarily consumed (RACC), as required by 21 CFR 101.54(b)(1). Such claims may not be made about a nutrient for which there is no established DV.

However, your website, www.naturalguidance.com⁷, includes such a claim for specific nutrients even though the food does not contain 20 percent or more of the DV per RACC of these nutrients, in accordance with 21 CFR 101.54(b)(1):

Salba Whole Food Bars (Tropical Fruit, Cranberry Nut, and Mixed Berry)

"[R]ichest sources of ... magnesium, calcium, iron ...

2. Although various nutrient content claims for ALA, DHA, and EPA omega-3 fatty acids have been statutorily authorized through the notification procedure in section 403(r)(3)(C) of the Act [21 U.S.C. § 343(r)(3)(C)], the claims for Omega-3 on your websites do not meet the requirements for any of these claims. Specifically, among other requirements, the claims authorized under the notification procedure must specify whether the claim is referring to ALA, DHA, or EPA omega-3 fatty acids. $^{f 1}$

The following are examples of unauthorized Omega-3 claims on your website, www.salba.com8, which can be found on each product's webpage: Salba Seed Oil (12 oz.) and Salba Seed Oil Softgels (90 ct.)

• "[N]ature's richest source of Omega-3s."

Salba Whole Food Bars (Tropical Fruit Cranberry Nut, and Mixed Berry)

"Salba - nature's richest plant-based source of Omega-3s..."

In addition, the following are examples of unauthorized Omega-3 claims on your website, www.naturalguidance.com⁹, which can be found on each product's webpage:

Salba Whole Food Bars (Tropical Fruit, Cranberry Nut, and Mixed Berry)

"Salba is nature's richest vegetarian source of ... omega-3s."

Salba Ground Seed - 9.5 oz. and Salba Whole Seed Super-Grain - 16 oz.

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

However, your websites include "antioxidant claims" that fail to include the names of the nutrients that are the subject of the claim nor do they provide the names of the nutrients with recognized antioxidant activity in accordance with 21 CFR 101.54(g)(2) and (g)(4).

The following are examples of unauthorized nutrient content claims on your website, www.naturalguidance.com 10, that use the term "antioxidant" which can be found on each product's webpage:

Salba Whole Seed Super-Grain - 16 oz. and Salba Whole Food Bars (Cranberry Nut, Mixed Berry, Tropical Fruit)

"30% More Antioxidants than Blueberries"

Another example of an antioxidant claim on you website, www.salba.com 11, which can be found on the product's webpage: Salba Ground Seed - 9.5 oz.

• "With an arsenal of quality nutrients -- Magnesium, Protein, Calcium, Antioxidants, Potassium, Iron, and Folate ..."

Establishment Registration

The Food and Drug Administration has determined that your facilities are subject to the registration requirement in Section 415 of the Act [21 U.S.C. § 350d] and our implementing regulation at 21 CFR Part 1, Subpart H. The failure to register a facility as required is a prohibited act under Section 301(dd) of the Act [21 U.S.C. § 331(dd)]. Our records indicate that, to date, your facility, Natural Guidance LLC, has not been registered with FDA, and that you have failed to update and revise the registration from your previous business, Core Naturals LLC, to Ancient Naturals, LLC.

As the owner, operator, or agent in charge of your facility you should register your facilities with FDA immediately. Registration may be accomplished on-line at http://www.access.fda.gov¹². We strongly encourage the use of electronic registration because it will result in an automatic confirmation of registration and automatic issuance of a registration number.

The violations mentioned above are not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. You should take prompt action to correct the violations described above and prevent their further recurrence. Failure to promptly correct these violations may result in legal action, without further notice, including, but not limited to, seizure and/or injunction.

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

Please send your reply to the Food and Drug Administration, Attention: Carla A. Norris, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have questions regarding any issues in this letter, please contact Ms. Norris at (407) 475-4730.

Sincerely.

Emma R. Singleton Director, Florida District

1 FDA issued a proposed rule (72 FR 66103, November 27,2007) to prohibit some of these nutrient content claims for omega-3 fatty acids.

Links on this page:

- 1. http://www.naturalguidance.com
- 2. http://www.salba.com
- http://www.fda.gov
- 4. http://www.naturalguidance.com
- 5. http://www.salba.com
- 6. http://www.salba.com/superior_source
- 7. http://www.naturalguidance.com
- 8. http://www.salba.com
- 9. http://www.naturalguidance.com
- 10. http://www.naturalguidance.com
- http://www.salba.com
- 12. http://www.access.fda.gov
 - Accessibility
 - Contact FDA
 - Careers
 - FDA Basics
 - FOIA
 - No Fear Act
 - Site Map
 - Transparency
 - Website Policies

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

USA 900

JS 44 CAND (Rev. 12/11)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

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I. (a) PLAINTIFFS TRICIA OGDEN, individu	ally and on behalf of al	l others similarly situ	DEFENDANTS BUMBLE BEE FOO		
(b) County of Residence of First Listed Plaintiff SANTA CLARA (EXCEPT IN U.S. PLAINTIFF CASES)			NOTE:	of First Listed Defendant (IN U.S. PLAINTIFF CASES OF IN LAND CONDEMNATION OF THE TRACT OF LAND INVOL	ASES, USE THE LOCATION OF
(c) Attorneys (Firm Name, A Ben F. Pierce Gore, Prat 350, Campbell, CA 95008	Address, and Telephone Number t & Associates, 1901 S 3, (408) 429-6506	Bascom Avenue,	Eate FLAING (Known)	2-018	28 28
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2 U.S. Government Defendant	4 Diversity (Indicate Citizenship)	o of Parties in Item III)	Citizen of Another State	2	-
			Citizen or Subject of a Foreign Country	3 🗆 3 Foreign Nation	
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☐ 160 Stockholders' Suits ☐ 190 Other Contract ☐ 195 Contract Product Liability ☐ 196 Franchise	☐ 355 Motor Vehicle Product Liability ☐ 360 Other Personal Injury ☐ 362 Personal Injury Med. Malpractice	□ 371 Truth in Lending □ 380 Other Personal Property Damage □ 385 Property Damage Product Liability	720 Labor/Mgmt. Relations 740 Railway Labor Act 751 Family and Medical Leave Act 790 Other Labor Litigation 791 Empl. Ret. Inc.	□ 863 DIWC/DIWW (405(g)) □ 864 SSID Title XVI □ 865 RSI (405(g))	890 Other Statutory Actions 891 Agricultural Acts 893 Environmental Matters 895 Freedom of Information Act 896 Arbitration
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☐ 210 Land Condemnation ☐ 220 Foreclosure ☐ 230 Rent Lease & Ejectment ☐ 240 Torts to Land	☐ 440 Other Civil Rights ☐ 441 Voting ☐ 442 Employment ☐ 443 Housing/	☐ 510 Motions to Vacate Sentence Habeas Corpus: ☐ 530 Generat		or Defendant) B 871 IRS—Third Party 26 USC 7609	Agency Decision G 950 Constitutionality of State Statutes
☐ 245 Tort Product Liability☐ 290 All Other Real Property	Accommodations D 445 Amer. w/Disabilities - Employment 446 Amer. w/Disabilities - Other D 448 Education	☐ 535 Death Penalty ☐ 540 Mandamus & Other ☐ 550 Civil Rights ☐ 555 Prison Condition ☐ 560 Civil Detainee - Conditions of Confinement	1MMIGRATION 462 Naturalization Application 463 Habeas Corpus - Alien Detainee (Prisoner Petition) 465 Other Immigration Actions		
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