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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

SETH SULTAN, Individually and On
Behalf of All Others Similarly Situated,

Plaintiff,

vs.

SCHIFF NUTRITION
INTERNATIONAL, INC., a Delaware
Corporation,

Defendant.

) Case No.:
)
) CLASS ACTION COMPLAINT
) FOR:
)
) (1) Violation of Unfair Competition
) Law (Cal. Bus. & Prof. Code §§
) 17200, *et seq.*);
) (2) Violation of False Advertising
) Law (Cal. Bus. & Prof. Code §§
) 17500, *et seq.*; and,
) (3) Violation of Consumers Legal
) Remedies Act (Cal. Civ. Code §§
) 1750, *et seq.*)

DEMAND FOR JURY TRIAL

1 Plaintiff SETH SULTAN (“Plaintiff”), through his undersigned counsel, on
2 behalf of himself and all persons in the United States similarly situated, alleges the
3 following based on personal knowledge as to allegations regarding Plaintiff’s own
4 acts and experiences, and, as to all other matters, on information and belief,
5 including investigation conducted by Plaintiff’s attorneys.
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7

8 **INTRODUCTION**

9 Plaintiff brings this class action lawsuit against defendant Schiff Nutrition
10 International, Inc. (“Schiff” or “Defendant”), based on its false and fraudulent
11 advertising of MegaRed Omega-3 Krill Oil (“MegaRed”), a dietary supplement.
12

13 1. Defendant is an international company with annual gross sales in the
14 hundreds of millions of dollars.
15

16 2. Defendant manufactures, markets and distributes MegaRed, which is
17 sold in retail stores across the United States.
18

19 3. MegaRed’s key ingredients are the omega-3 fatty acids
20 eicosapentaenoic acid (“EPA”) and docosahexaenoic acid (“DHA”), which some
21 research has suggested may help reduce the risk of coronary heart disease (“CHD”).
22

23 4. Because this research is inconclusive, under Food and Drug
24 Administration (“FDA”) standards wholly adopted by California law the only
25 health claim regarding omega-3 fatty acids that may be made on a nutritional
26 supplement such as MegaRed is the following qualified health claim: “Supportive
27 but not conclusive research shows that consumption of EPA and DHA Omega-3
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1 fatty acids may reduce the risk of coronary heart disease.” For this same reason, the
2 FDA has stated that any claim suggesting a level of omega-3 fatty acids to be useful
3 in achieving a reduction in the risk of CHD for the general healthy population is
4 presumed to be false and misleading.
5

6 5. Defendant’s packaging, labels, website and other marketing materials
7 violate these clear standards which were adopted in the interest of public health. As
8 a result, MegaRed is a misbranded product under California law.
9

10 6. In bold letters on the top of its package MegaRed proclaims “May
11 Reduce The Risk of Coronary Heart Disease,” and in the middle of the package
12 appears the slogan upon which MegaRed has built its brand, “Just 1 Small Softgel
13 Per Day.” The suggestion that one MegaRed softgel per day will help to prevent
14 CHD is false and misleading as a matter of law. Moreover, this illegal statement is
15 particularly harmful given the very small amount of omega-3 fatty acids actually
16 contained in one MegaRed softgel, which amounts to less than one-fifth the amount
17 of omega-3 fatty acids that the American Heart Association (“AHA”) recommends
18 be consumed daily.
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22 7. MegaRed also makes other claims that go far beyond the qualified
23 health claim authorized by the FDA. On its website for example, MegaRed lists
24 without qualification the various heart-related ailments that the consumption of one
25 softgel per day will supposedly prevent.
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1 8. To create the illusion that its representations are grounded in scientific
2 fact, MegaRed relies upon other claims that are demonstrably untrue. These
3 include, without limitation, the claim that MegaRed has been shown to significantly
4 increase the omega-3 Index within 30 days, a claim which studies by MegaRed's
5 own supplier contradict.
6

7
8 9. MegaRed claims that consumption of one MegaRed softgel provides
9 cardiovascular benefits comparable to consumption of multiple larger fish oil pills
10 and charges an incredible premium over fish oil for this purported benefit, generally
11 in excess of *ten times* the per milligram cost of odorless fish oil capsules. Available
12 studies also strongly suggest this claim is untrue.
13

14 10. Plaintiff purchased MegaRed anticipating that it would provide him
15 with the advertised heart benefits associated with omega-3 fatty acids in a smaller
16 pill, specifically relying on, among other things, the representation that he needed to
17 take "just 1 small softgel per day" to "reduce the risk of coronary heart disease."
18 Had Plaintiff known that MegaRed is misbranded and that these statements are
19 false and misleading as a matter of law, Plaintiff would not have purchased
20 MegaRed or would have paid less for it. Plaintiff also would have taken additional
21 steps to ensure that he received an adequate amount of omega-3 fatty acids in his
22 diet while taking MegaRed.
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25

26 11. MegaRed is indeed a "small pill." However, commensurate with the
27 size of the pill, the amount of omega-3 fatty acids in one MegaRed softgel is also
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1 very small. On information and belief, consumers have and continue to be deceived
2 by MegaRed’s misrepresentations to pay a king’s ransom for a misbranded product
3 that, when taken as advertised, does little or nothing to prevent CHD or otherwise
4 benefit the heart.
5

6 **THE PARTIES**

7 12. Plaintiff Seth Sultan is a citizen and resident of the state of California,
8 County of Orange.
9

10 13. Defendant Schiff Nutrition International, Inc., is a Delaware
11 corporation with its principal place of business in Utah. Schiff is a wholly owned
12 subsidiary of the international consumer products conglomerate, Reckitt Benckiser
13 Group. When in this Complaint reference is made to any act of “Schiff” or
14 “Defendant,” such shall be deemed to mean that officers, directors, agents,
15 employees or representatives of Schiff committed or authorized such acts, or failed
16 and omitted to adequately supervise or properly control or direct its employees
17 while engaged in the management, direction, operation or control of the affairs of
18 Schiff and did so while acting within the scope of their employment or agency.
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22 **JURISDICTION AND VENUE**

23 14. This Court has original jurisdiction of this action under the Class
24 Action Fairness Act of 2005. Pursuant to 28 U.S.C. §§ 1332(d)(2) and (6), this
25 Court has original jurisdiction because the aggregate claims of the putative Class
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1 members exceed \$5 million, exclusive of interest and costs, and at least one of the
2 members of the proposed Class is a resident of a different state than Defendant.

3
4 15. This Court has jurisdiction over Defendant because it is a corporation
5 or other business entity authorized to do business in the state of California and is
6 registered with the California Secretary of State to do sufficient business with
7 sufficient minimum contacts in California and/or otherwise intentionally avails
8 itself of the California market to render the exercise of jurisdiction by the California
9 courts consistent with traditional notions of fair play and substantial justice.

10
11
12 16. Venue is proper in the Central District of California, pursuant to 28
13 U.S.C. 1391, because Defendant regularly conducts business in this District and
14 because a substantial part of the events or omissions giving rise to the claims
15 asserted herein occurred and continue to occur in this District.

16
17 **NATURE OF THE CASE AND COMMON ALLEGATIONS OF FACT**

18 **A. Schiff and Aker BioMarine**

19
20 17. Schiff's website describes the company¹:

21 Schiff Nutrition has been nourishing generations of healthy, active
22 lives since 1936. By applying just the right amount of science to what
23 nature already offers, Schiff Nutrition International, Inc. is leading the
24 way in advanced consumer nutrition. Our portfolio of well-known
25 brands includes MegaRed®, Move Free®, Airborne®, Digestive
Advantage®, Schiff® Vitamins, and Tiger's Milk®.

26 18. Schiff has a history of acquiring and marketing products and product
27 lines in a manner that calls into question whether they know what "just the right
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¹ See <http://www.schiffvitamins.com/about-schiff>, last visited 2/23/2015.

1 amount of science” is when it comes to making health claims regarding those
2 products.

3
4 19. Airborne, for example, was advertised to protect against the common
5 cold until the Center for Science in the Public Interest evaluated Airborne as part of
6 an investigation on cold remedies and found “little or no evidence that the product
7 work[ed].”²

8
9 20. Airborne was subsequently the subject of a significant class action
10 lawsuit that settled for \$23.5 million and the subject of an FTC action that resulted
11 in an additional \$6.5 million being returned to customers.³

12
13 21. Schiff does not currently claim Airborne protects against the common
14 cold.

15
16 22. Schiff improperly advertised their Move Free product, a
17 glucosamine/chondroitin supplement, as an arthritis treatment absent any proof it
18 functioned as such. That product was also the subject of a class action lawsuit filed
19 in 2011 and settled in 2014 for \$5,000,000.⁴

20
21 23. Schiff no longer claims that Move Free is effective in treating arthritis.

22
23
24
25 ²Cold Remedy Airborne Settles Lawsuit,” WebMD, [http://www.webmd.com/cold-](http://www.webmd.com/cold-and-flu/news/20080304/cold-remedy-airborne-settles-lawsuit)
26 [and-flu/news/20080304/cold-remedy-airborne-settles-lawsuit](http://www.webmd.com/cold-and-flu/news/20080304/cold-remedy-airborne-settles-lawsuit), last visited
27 2/23/2015.

28 ³ *Id.*

⁴ *Lerma, et al. v. Schiff Nutrition International Inc., et al.*, Case No. 3:11-cv-01056
in U.S. District Court for the Southern District of California.

1 24. Most of Schiff’s revenues derive from products like MegaRed,
2 Airborne and Move Free.

3
4 25. On information and belief, these products derive their brand value and
5 hefty margins much more from aggressive and effective marketing than from
6 clinical efficacy.

7
8 26. Indeed, in 2011, the last year Schiff reported financial results
9 independently prior to being acquired by Reckitt Benckiser, it spent over
10 \$21,000,000 on advertising and marketing and only \$4,000,000 on research and
11 development.⁵

12
13 27. Aker BioMarine (“Aker”) supplies the “Superba Krill Oil” that is used
14 in MegaRed and is cited as the source of the “proprietary” study, discussed *infra*,
15 that is cited on the MegaRed package to support claims concerning the effect of
16 MegaRed on the omega-3 Index.

17
18 28. Aker is not a research institution. Rather, Aker is a for-profit
19 Norwegian fishing and krill oil cultivation company responsible for supplying a
20 large volume of all the world’s krill oil.

21
22 29. Indeed, Aker’s 2011 Annual Report confirmed that Schiff is Aker’s
23 “key partner”:

24
25 The markets in which Aker BioMarine operates continued to grow in
26 2011. In total, Aker BioMarine sold 232 MT of Superba™ Krill in
27 2011 compared to 177 MT in 2010 which is an increase of 31 percent.

28

⁵ See Schiff Nutrition International Fiscal Year 2011 10-K Report.

1 In the international dietary supplement markets, krill has become one
2 of the most noteworthy ingredients in 2011. In particular in the US,
3 krill is now recognized as a key source of omega-3. MegaRed®
4 which is sold and marketed by Schiff Nutrition International, Aker
5 BioMarine's key partner, is now the most-selling omega-3 product in
6 the US. Superba™ Krill from Aker BioMarine is the only omega-3
7 ingredient in MegaRed®.⁶

8 **B. The MegaRed Product Packaging and Associated Marketing**
9 **Materials**

10 30. Defendant aggressively touts the ability of one small MegaRed softgel
11 to reduce the risk of CHD and other heart-related ailments on its product
12 packaging/labeling, website and associated advertising.

13 31. Below is a typical example of the packaging for MegaRed's 500 mg
14 krill oil:

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⁶ See Aker BioMarine Annual Report 2011, p. 21.

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1 32. The packaging of MegaRed’s 300 mg Omega-3 Krill Oil is virtually
2 identical:
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22 33. The back of each package repeats the statement “Just 1 Small Softgel
23 Per Day” on a table comparing the benefits of MegaRed to fish oil. Beneath this
24 table the claim that MegaRed “may reduce the risk of coronary heart disease” is
25 also repeated.

26 34. On the back of each package the following statement also appears:
27 “MegaRed has been shown to significantly increase your Omega-3 Index in just 30
28

1 days.♦ The omega-3 Index is a measure of the amount of omega-3 fatty acids in
2 your body’s cells. A higher omega-3 Index is associated with better cardiovascular
3 health and other health benefits.” As discussed at greater length *infra*, the diamond
4 symbol references a footnote which purports to cite a proprietary study that
5 Defendant refuses to release, and the claimed results of which are contradicted by
6 those studies that are available.
7
8

9 35. In a side compartment within the MegaRed package next to the bottle
10 of MegaRed softgels is a color foldout with similar claims made on both sides. A
11 typical example is reproduced is reproduced below:
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What is Small, Red, Powerful and Supports Cardiovascular Health?



ACTUAL SIZE SOFTGEL SHOWN



COMPARE TO FISH OIL

	Just 1 Small Softgel Per Day	Powerful Antioxidants	Contains Omega-3 Fatty Acids	No Fishy Odor or Aftertaste
 MegaRed® Softgel	✓	✓	✓	✓
 Fish Oil Softgel			✓	

May Reduce the Risk of Coronary Heart Disease[†]

Schiff® MegaRed® contains oil from 100% pure Antarctic krill, tiny crustaceans that thrive in the frigid waters of the Antarctic. MegaRed® provides a combination of omega-3 fatty acids, phospholipids and critical antioxidants to support heart and joint health.*

Unlike fish oil, MegaRed® omega-3 fatty acids are mainly absorbed and carried to the body's cells in phospholipid form. Phospholipids form the structural basis of cell membranes, so MegaRed® phospholipids with omega-3 fatty acids are easily recognized, incorporated and utilized by the body.

Just one small, easy-to-swallow softgel per day. Quality tested for purity.

For more information, visit www.SchiffMegaRed.com or call 1-800-526-6251

* THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.

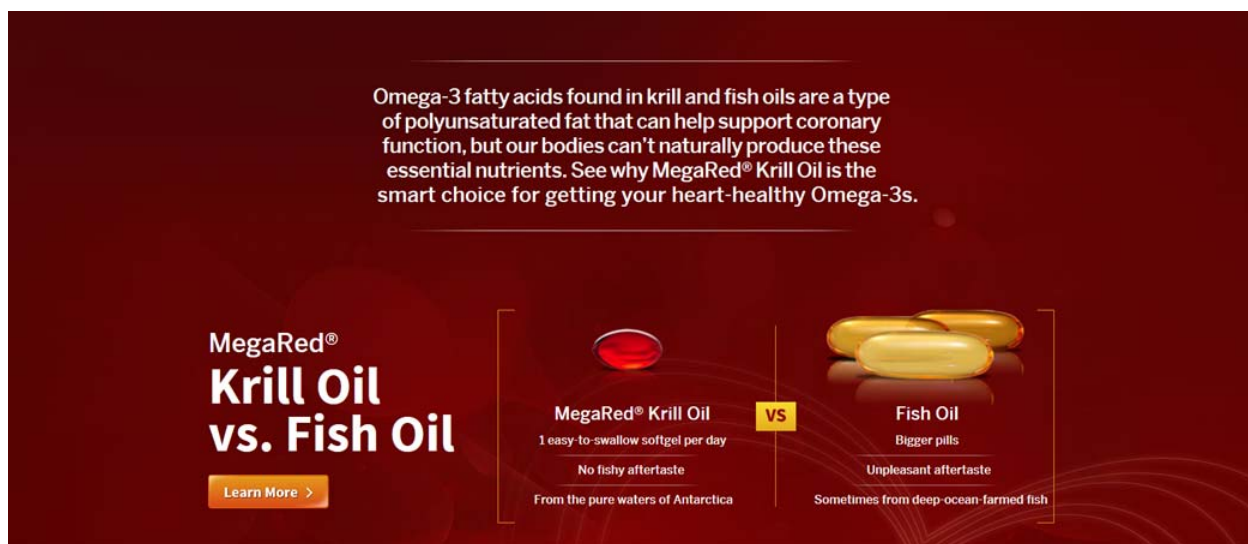
[†]Supportive, but not conclusive research shows that consumption of EPA and DHA Omega-3 fatty acids may reduce the risk of coronary heart disease.

© 2011 Schiff Nutrition Group, Inc.

469104342.8

1 36. Defendant’s website (referenced on the foldout) and associated
2 advertising embellish these claims with additional information and catch phrases
3 intended to tout the potency and efficacy of its product.
4

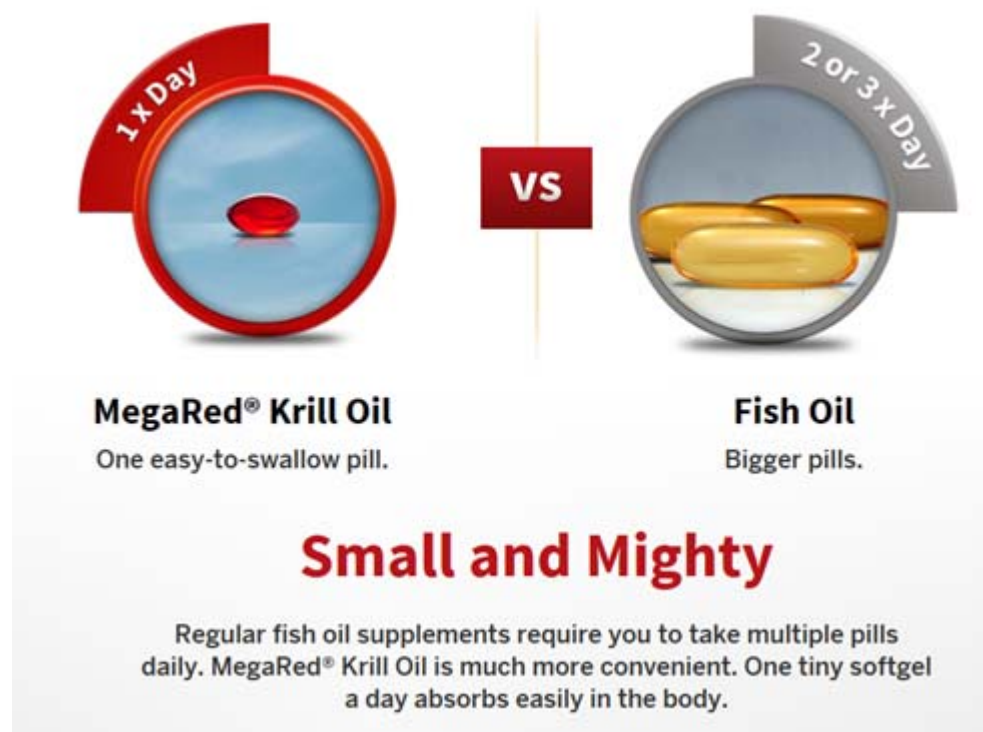
5 37. In addition to repeating the slogan “Just 1 Small Softgel Per Day,”
6 Defendant’s website contains images skillfully crafted to drive home Defendant’s
7 message. For example, the following image appears on the home page of
8 Defendant’s site suggesting that one MegaRed softgel per day provides the omega-
9 3 fatty acids that our bodies need but cannot produce⁷:
10
11



21 38. Similarly, in a section of Defendant’s site titled “Why Omega-3 Krill
22 Oil” the following image appears⁸:
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28 ⁷ See <http://www.megared.com>, last visited 2/23/2015.

⁸ See <http://www.megared.com/why-omega-3-krill-oil>, last visited 2/23/2015.



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39. In an article on its website titled “O Yes! Why Omega-3s Are Your Heart’s Best Friend” MegaRed emphasizes the ability of its product to provide a level of Omega-3 fatty acids necessary to substitute for not eating omega-3 rich foods and the associated disease prevention benefits. MegaRed states⁹:

The Big Benefits

Scientists first noticed a connection between Omega-3 fatty acids and health back in the 1970’s when they compared people living in Scandinavia with Greenland Eskimos. Researchers found that even though they ate a diet very high in fat, the Inuit had far better heart and immune health than their European counterparts. Why? Because the fat in the Inuit diet, which consisted primarily of whale, seal, salmon and other cold-water seafood, was rich in Omega-3s. Since then, study after study has confirmed that Omega-3s have a potent, positive effect on heart disease by:

⁹ See <http://www.megared.com/articles/why-omega-3s-are-your-hearts-best-friend>, last visited 2/23/2015.

- 1 ● Helping prevent irregular heart beat
- 2 ● Reducing the plaque inside artery walls
- 3
- 4 ● Decreasing levels of triglycerides (blood fat)
- 5 ● Lowering blood pressure
- 6 ● Reducing inflammation throughout the body, including blood
- 7 vessels

8 **Good Sources of Omega-3**

9 Since our bodies don't produce them naturally, we have to rely on diet
10 to get Omega-3s. While certain plant and nut oils contain them, the
11 best food sources of Omega-3s are fatty cold-water fish such as
12 mackerel, herring, lake trout, salmon, anchovies and tuna. The
13 American Heart Association recommends that adults eat at least two
14 servings of cold-water fish per week to get adequate amounts of
15 Omega-3s.

16 For those who can't, or would rather not, dig into fish on a regular
17 basis, supplements like MegaRed Krill Oil can provide you with
18 Omega-3s to help keep your heart healthy for years to come.

19 40. MegaRed marketing materials and advertisements appearing across the
20 internet, in stores and elsewhere contain identical or similar representations,
21 including the claim "Small Pill. Big Heart Health Benefits." For example, the
22 following appeared in a promotion sponsored by well-known healthcare personality
23 Dr. Oz¹⁰:

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28 ¹⁰ See <http://www.usacouponsavings.com/dr-ozs-schiff-megared-giveaway-1st-8000>, last visited 2/23/2015.

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41. Through labeling and advertisements such as those featured above Defendant has built a powerful brand relied upon by tens of thousands of consumers to supply omega-3 fatty acids often not present in the American diet.

C. The Governing Law Concerning Health Claims

42. The Food, Drug and Cosmetic Act of 1938 (“FDCA”) provides the FDA with the authority to oversee the safety of food, drugs and cosmetics. 21 U.S.C. §301, *et seq.* In 1990 the FDCA was amended by the Nutrition Labeling and Education Act to specifically direct the FDA to issue regulations authorizing health claims for foods and dietary supplements after reviewing and evaluating the scientific evidence. Public Law 101-535 (Nov. 8, 1990). Pursuant to this directive,

1 the FDA has promulgated regulations that spell out in detail what health claims
2 may be made on the labels of foods and dietary supplements. FDA regulations
3
4 define a “health claim” as follows:

5 *Health claim* means any claim made on the label or in labeling of a
6 food, including a dietary supplement, that expressly or by
7 implication, including “third party” references, written statements
8 (*e.g.*, a brand name including a term such as “heart”), symbols (*e.g.*,
9 a heart symbol) or vignettes, characterizes the relationship of any
10 substance to a disease or health-related condition. Implied health
11 claims include those statements, symbols, vignettes, or other forms
12 of communication that suggest, within the context in which they are
13 presented, that a relationship exists between the presence or level of
14 a substance in a food and a disease or health-related condition.

15 21 C.F.R. 101, Subpart A, §101.14(a)(1) (emphasis in original).

16 43. In addition to defining the term “health claim,” the FDA delineates the
17 specific requirements for making a health claim, listing twelve categories of
18 permissible health claims, and the particular requirements for each type of claim.

19 21 C.F.R. 101, Subpart E, §§ 101.72-101.83. This regulation is carefully crafted to
20 require that health claims be presented in a qualified and contextualized manner so
21 that consumers are not misled. For example, a health claim associating diets low in
22 saturated fat and cholesterol with reduced risk of coronary heart disease must,
23 among other things, state that coronary heart disease risk depends on many factors
24 and state that diets low in saturated fat and cholesterol “may” or “might” reduce the
25 risk of heart disease. *See Id.* at §101.75(c).
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1 44. Crucially, the FDA regulations make clear that the specific health
2 claims delineated in 21 C.F.R. 101, Subpart E are the *only* health claims that may
3 be made on the label of a food or nutritional supplement:
4

5 *Prohibited health claims.* No express or implied health claim may
6 be made on the label or in labeling for a food, regardless of whether
7 the food is in conventional food form or dietary supplement form,
8 unless: (1) The claim is specifically provided for in subpart E of this
9 part; and (2) The claim conforms to all the general provisions of this
10 section as well as to all specific provisions in the appropriate section
11 of subpart E of this part...

12 21 C.F.R. 101 Subpart A §101.14(e) (emphasis in original).

13 45. The clear purpose of this statutory scheme is to prevent unqualified
14 health claims that are likely to deceive consumers.

15 46. In its January 6, 1993 final rule concerning a health claim for the
16 relationship between omega-3 fatty acids and CHD, the FDA announced its
17 decision not to authorize the use of health claims relating to an association between
18 omega-3 fatty acids and CHD. 58 Fed. Reg. 2682 (1993). Consequently, a health
19 claim regarding the relationship between omega-3 fatty acids and CHD is not
20 included on among the approved health claims set forth in 21 C.F.R. 101, Subpart
21 E. The FDA’s decision was based upon its conclusion that there was not a
22 significant scientific agreement among experts to support a health claim for omega-
23 3 fatty acids and CHD. *Id.*

24 47. In 1999, the U.S. Court of Appeals for the District of Columbia Circuit
25 directed the FDA to reconsider the health claim “Consumption of omega-3 fatty
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1 acids may reduce the risk of coronary heart disease” in dietary supplement labeling.
2 *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir 1999).

3
4 48. In response to the Court’s request, the FDA ultimately elected to
5 exercise its enforcement discretion to approve a very limited health claim related to
6 omega-3 fatty acids and heart disease.

7
8 49. By letter dated October 31, 2000 the FDA stated that it considered the
9 following claim to be “appropriately qualified”:

10
11 The scientific evidence about whether omega-3 fatty acids may reduce
12 the risk of coronary heart disease (CHD) is suggestive, but not
13 conclusive. Studies in the general population have looked at diets
14 containing fish and it is not known whether diets or omega-3 fatty
15 acids in fish may have a possible effect on a reduced risk of CHD. It is
16 not known what effect omega-3 fatty acids may or may not have on
17 risk of CHD in the general population.¹¹

18
19 50. Then approximately four years later by letter dated September 8, 2004,
20 the FDA authorized the following slightly shorter qualified health claim for dietary
21 supplements concerning the relationship between omega-3 fatty acids and CHD,
22 ***which is the only omega-3 health claim that may be made on a nutritional***
23 ***supplement today:***

24 Supportive but not conclusive research shows that consumption of
25 EPA and DHA omega-3 fatty acids may reduce the risk of coronary
26 heart disease.¹²

27
28 ¹¹ See FDA Letter Regarding Dietary Supplement Health Claim for Omega-3 Fatty
Acids and Coronary Heart Disease, October 31, 2000.

¹² See September 9, 2004 FDA Letter Responding to Health Claim Petition dated
June 23, 2003 (Wellness petition): Omega-3 Fatty Acids and Reduced Risk of
Coronary Heart Disease (Docket No. 2003Q-0401).

1 51. In the very same enforcement discretion letter in which the FDA
2 authorized the above qualified health claim, it specifically considered whether a
3 daily dietary intake should be stated as this is generally required for health claims
4 under 21 C.F.R. Section 101.14(d)(2)(vii). The FDA concluded that this
5 requirement did not apply to the qualified health claim for omega-3 fatty acids and
6 reduced risk of CHD because “the scientific evidence did not support the
7 establishment of a recommended daily dietary intake level *or even a possible level*
8 *of effect.*” *Id.* at 26 (emphasis added). The FDA went on to conclude:

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12 ***Therefore, the agency continues to consider any label or labeling***
13 ***suggesting a level of omega-3 fatty acids to be useful in achieving a***
14 ***reduction in the risk of CHD for the general healthy population to be***
15 ***false and misleading under section 403(a) of the act.***” *Id.* (emphasis
16 added).

17 52. The sum and substance of the FDA’s regulatory position is that, to the
18 extent a qualified health claim is allowed with regard to Omega-3 fatty acids and
19 heart disease, such a claim cannot suggest that a particular dosage, amount or level
20 is useful in obtaining the claimed result. Any claim that does so is presumptively
21 false and misleading under section 403(a) of the FDCA.

22 53. As discussed in greater detail below, in light of the foregoing,
23 Defendant’s MegaRed is a misbranded product under applicable California law. By
24 way of this Complaint, Plaintiffs seek to impose requirements that are identical to
25 and do not exceed the federal requirements.
26
27
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1 54. Specifically, California’s Sherman Law incorporates “[a]ll food
2 labeling regulations and any amendments to those regulations adopted pursuant to
3 the FDCA” as “the food labeling regulations of this state.” Cal. Health & Saf. Code
4 § 110100(a).
5

6 55. Moreover, the Sherman Law specifically adopts and incorporates
7 specific federal food and drug laws and regulations. Under the Sherman Law,
8 “[a]ny food is misbranded if its labeling does not conform with the requirements
9 for nutrient content or health claims as set forth in Section 403(r) (21 U.S.C. Sec.
10 343(r)) of the federal act and the regulations adopted pursuant thereto.” Cal. Health
11 & Saf. Code § 110670. Similarly, a food product is “misbranded if its labeling does
12 not conform with the requirements for nutrition labeling as set forth in Section
13 403(q) (21 U.S.C. § 343(q)) of the federal act and the regulations adopted pursuant
14 thereto.” Cal. Health & Saf. Code § 110665.
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18 56. The Sherman Law further states that “any food is misbranded if its
19 labeling is false or misleading in any particular.” Cal. Health & Saf. Code §
20 110660.
21

22 57. State law claims based on a dietary supplement’s non-conforming,
23 misleading, or deceptive label are expressly permitted when they impose legal
24 obligations identical to the FDCA and corresponding FDA regulations, including
25 FDA regulations concerning health claims.
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1 58. Defendant’s conduct thus constitutes a violation of California law for
2 which Plaintiffs and class members are entitled to seek redress under the Unfair
3 Competition Law (“UCL”), Consumers Legal Remedies Act (“CLRA”), and the
4 False Advertising Law (“FAL”).
5

6 **D. MegaRed is a Misbranded Product Under the Governing Law**
7

8 59. MegaRed blatantly and unabashedly violates the rule that omega-3
9 claims may not suggest a relationship between a particular level of consumption
10 and the prevention of CHD.
11

12 60. The typical MegaRed label proclaims in bold letters on the top of the
13 package “May Reduce The Risk of Coronary Heart Disease,” and in the middle of
14 the package states “Just 1 Small Softgel Per Day.” These phrases are repeated by
15 MegaRed on the back of its packaging and on its website and associated
16 advertising. The meaning conveyed by these statements to the reasonable
17 consumer is clear and unmistakable: One small MegaRed softgel contains all the
18 Omega-3 you need to meet your daily requirements and reduce the risk of CHD.
19
20 Indeed, MegaRed says as much on its website:
21

22 Since our bodies don’t produce them naturally, we have to rely on
23 diet to get Omega-3s. While certain plant and nut oils contain
24 them, the best food sources of Omega-3s are fatty cold-water fish
25 such as mackerel, herring, lake trout, salmon, anchovies and tuna.
26 The American Heart Association recommends that adults eat at
27 least two servings of cold-water fish per week to get adequate
28 amounts of Omega-3s.

1 For those who can't, or would rather not, dig into fish on a regular
2 basis, supplements like MegaRed* Krill Oil can provide you with
3 Omega-3s to help keep your heart healthy for years to come.¹³

4 61. MegaRed's statement "Just 1 Small Softgel Per Day" clearly suggests
5 a level of omega-3 fatty acids to be useful in achieving a reduction in CHD in the
6 context within which it is presented. Consequently, this statement as well as all
7 other similar statements on its labels, website and associated advertising are
8 presumptively false and misleading and constitute misbranding under FDA
9 standards wholly adopted by California.
10

11
12 62. In addition, the claims upon which MegaRed has built its brand – such
13 as "Small Pill. Big Heart Health Benefits" -- go far beyond the limited qualified
14 health claim authorized by the FDA.
15

16 63. The MegaRed website boldly claims that "study after study" has
17 supposedly confirmed Omega-3 fatty acids have a "potent, positive effect on heart
18 disease" by preventing or ameliorating numerous heart-related ailments including
19 irregular heartbeat, plaque inside artery walls, blood clotting, triglyceride (blood
20 fat) levels, blood pressure and inflammation throughout the body.¹⁴ It is precisely
21 because the science relating to these claims is inconclusive that the FDA permits
22 only a limited qualified health claim regarding the impact of omega-3 fatty acids on
23
24
25

26 _____
27 ¹³ See <http://www.megared.com/articles/why-omega-3s-are-your-hearts-best-friend>,
last visited 2/23/2015.

28 ¹⁴ See <http://www.megared.com/articles/why-omega-3s-are-your-hearts-best-friend>,
last visited 2/23/2015.

1 CHD. MegaRed does not even pretend to comply with the law, as if the FDA had
2 never spoken on the issue at all.

3
4 64. MegaRed is also misbranded because it contains statements which, on
5 information and belief, are false and made to create the illusion that MegaRed's
6 claims are grounded in scientific fact.

7
8 65. Specifically, the MegaRed label also claims that the use of MegaRed
9 will lead to a tangible and quantifiable health outcome. The back of the MegaRed
10 300 mg and 500 mg packages state:

11
12 MegaRed has been shown to significantly increase your omega-3
13 index in just 30 days.♦ The omega-3 Index is a measure of the amount
14 of omega-3 fatty acids in your body's cells. A higher omega-3 Index
is associated with better cardiovascular health and other health
benefits.

15 66. The diamond symbol included in that quotation references a footnote
16 of sorts at the bottom of the package, in far smaller print, which reads "Proprietary
17 controlled human clinical study of 300 mg MegaRed for improving omega-3 index,
18 Aker BioMarine, 2010."

19
20 67. The plain implication of this citation is that the company has a study
21 that supports the claim that "MegaRed has been shown to significantly increase
22 your omega-3 index in just 30 days."

23
24 68. However, when the study has been requested by customers, Defendant
25 tells them that it is not currently available. On information and belief, this study is
26 not available through Defendant, Aker Biomarine or any other means.
27
28

1 69. As explained above, Defendant is Aker’s “key partner.” It is therefore
2 neither surprising nor unusual that Aker would provide Defendant with the
3 research cited on the label. However, it is unusual that Aker would not publish
4 this study had it actually supported the efficacy of a product so crucial to Aker’s
5 own financial well-being.
6

7
8 70. Moreover, other published studies in which Aker has been involved
9 suggest that no study showing that 300 mg a day of krill oil will “significantly
10 increase your Omega-3 Index” could possibly exist.
11

12 71. One such study is titled “Krill oil supplementation lowers serum
13 triglycerides without increasing low-density lipoprotein cholesterol in adults with
14 borderline high or high triglyceride levels” and was completed in 2013 and
15 published in 2014 in the journal *Nutritional Research*.¹⁵
16

17 72. In this study participants were given either a placebo, 0.5, 1, 2 or 4
18 grams per day of krill oil and omega-3 levels were measured at 6 and 12 weeks. No
19 one in the study was given as little as 300 mg a day of krill oil nor was any study
20 participant’s omega-3 blood level measured after 30 days.
21

22 73. *Those receiving the lowest amount of krill oil (500 mg) who had*
23 *their blood taken after the shortest period of time (6 weeks) showed an increase in*
24

25
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¹⁵ See <http://www.sciencedirect.com/science/article/pii/S0271531713002832>, last visited 2/23/2015.

1 *their Omega-3 level of only 5%, an increase that does not even approach being*
 2 *clinically significant.*

3
 4 74. Although the study states that this small increase was significant, that
 5 conclusion is belied by the data presented which indicate that the change is less
 6 than the margin of error. This conclusion is also belied by the delta value set forth
 7 in the “Statistical Analysis” section of the study which establishes a 15% change as
 8 the measure of clinical significance. 15% is a common value for measuring clinical
 9 significance in clinical studies of this nature.
 10

11
 12 75. MegaRed has since doubled-down on its claim to dramatically increase
 13 the Omega-3 Index in a short period of time including a graph on its website
 14 claiming that taking one 300 mg MegaRed per day will raise the Index by 22% in
 15 30 days and 37% in ninety days. The MegaRed website provides¹⁶:
 16

17 **Percentage change in Omega-3 Index over 90 days of MegaRed®**
 18 **Omega-3 Krill Oil 300 mg use**

19 **30 Days to a Higher**
 20 **Omega-3 Index**

21 The Omega-3 Index is a measure of the amount of
 22 omega-3 fatty acids in your body's cells. A higher
 23 Omega-3 Index is associated with better cardiovascular
 24 health and other health benefits. Clinical studies have
 25 shown taking MegaRed® Omega-3 Krill Oil once daily can
 26 significantly increase your level of Omega-3s in just 30
 27 days.†

28 [Read More About Omega-3s >](#)

*Plus or Minus Standard Error of Measurement
 † A 12-week clinical study was conducted to measure the change in Omega-3 Index among an untreated control group (n=30) and a group that was administered 300 mg of MegaRed® Omega-3 Krill Oil once daily (n=30). Subjects were healthy adult females and males 18–65 years old.

¹⁶ See <http://www.megared.com/how-megared-works>, last visited 2/23/2015.

1 76. Once again a proprietary unpublished study is cited to support these
2 figures that, on information and belief, diverge wildly from the results of any
3 published study, including one published only a year ago by Defendant’s supplier
4 Aker. On information and belief, the referenced study either does not exist or is so
5 “doctored” as to render it scientifically meaningless.
6

7
8 77. As discussed in greater detail below, another Aker study strongly
9 suggests MegaRed’s claim that a single MegaRed softgel is an adequate alternative
10 to the consumption of multiple fish oil pills is also false and misleading.
11

12 **E. The Risk of Harm Posed By MegaRed’s Violations of the Law is**
13 **Great Because of the Comparatively Small Amount of Omega-3**
14 **Fatty Acids Contained within One Small MegaRed Softgel**

15 78. One 300 mg MegaRed softgel provides only 74 mg of EPA + DHA.

16 79. One 500 mg MegaRed “Extra Strength” softgel provides only 94 mg
17 of EPA + DHA.

18 80. On information and belief, all or virtually all of the research and
19 recommendations related to the cardiovascular benefits associated with omega-3
20 fatty acids have involved daily intake and/or supplementation of DHA + EPA well
21 in excess of 100 mg.
22

23 81. In fact, 100 mg a day of EPA + DHA is generally considered
24 insufficient intake. An article that appeared in the journal *Food and Nutrition*
25 *Sciences* in 2013 explained that:
26

27 Dietary intakes of n-3 PUFA are very low in most western societies.
28 Dietary intake data from NHANES (1999-2000) indicate that fish

1 consumption in the US population is inadequate, resulting in a mean
2 intake of only 100 mg/day of EPA and DHA combined [12]. Along
3 with important lifestyle changes, including dietary changes and
4 weight loss, the AHA recommends a daily intake of 500-1000 mg of
5 n-3 PUFA for individuals with borderline high TG (150-199 mg/dL),
6 1000-2000 mg for individuals with high TG (200-499 mg/dL), and
7 2000-4000 mg for individuals with very high TG levels (≥ 500 mg/dL)
8 [1]. For individuals who prefer not to eat fatty fish such as herring,
9 salmon, or sardines, dietary supplements of n-3 PUFA are available as
10 a substitute.¹⁷

11 82. Primary prevention of CHD involves doing something to prevent CHD
12 before the subject gets the disease or knows that he or she has the disease. The
13 AHA recommends that patients without documented CHD eat a variety of fatty fish
14 at least twice a week, including oils and foods rich in alpha-linolenic acid (*e.g.*,
15 flaxseed, canola and soybean oils; flaxseeds and walnuts.) Consuming two
16 servings of fatty fish per week is equivalent to consuming “at least 500 mg per day
17 of EPA + DHA”.¹⁸

18 83. Secondary prevention of CHD involves preventing the first heart
19 attack in a patient with known CHD. The AHA recommends “omega-3 fatty acids
20
21
22

23 ¹⁷ Alan S. Ryan, Stephen S. Porter, Frederick D. Sancilio, “A Dietary Supplement
24 with a High Eicosapentaenoic Acid to Docosahexaenoic Acid Ratio Reduces
25 Triglyceride Levels in Mildly Hypertriglyceridemic Subjects,” published online
26 January 2013, available at <http://sancilio.com/wp-content/uploads/2014/01/SCI-Omega-article.pdf>, last visited 12/2/2014.

27 ¹⁸ Artham, Fish Oil in Primary and Secondary Cardiovascular Prevention, *Ochsner*
28 *Journal* (2008) 8: 49 - 60, pages 49 and 56. See also Lee JH, Omega-3 for
cardioprotection, *Mayo Clin. Pro.* (2008) 83: 324-332; Anand RG, The role of fish
oil in arrhythmia prevention, *J. Cardiopulm. Rehabil. Pre.* (2008) 28(2): 92-98.

1 from fish or fish oil capsules (1,000 mg of EPA + DHA per day) for cardiovascular
2 disease risk reduction.”¹⁹

3
4 84. Therefore, the dose per day of combined EPA + DHA omega-3 fatty
5 acids recommended by the AHA is a minimum of 500 mg for primary prevention of
6 CHD and 1,000 mg for secondary prevention of CHD.

7
8 85. As noted, the 300 mg MegaRed krill oil softgel contains only 50 mg of
9 EPA and 24 mg of DHA for a total of 74 mg of EPA + DHA, and the so-called
10 “Extra Strength” 500 mg MegaRed Softgel contains only 94 mg of EPA + DHA.

11
12 86. Even the highest dose pill of MegaRed, the 1,000 mg MegaRed krill
13 oil softgel, only contains 128 mg EPA and 60 mg DHA for a total of 188 mg of
14 EPA + DHA, which is well below recommended levels of EPA + DHA for
15 primary or secondary prevention of CHD.

16
17 87. The European Food Safety Authority, the European Union’s FDA
18 counterpart with regard to nutritional supplements, allows the statement that “EPA
19 and DHA contribute to the normal function of the heart.” However, in order to
20 make this claim, “information shall be given to the consumer that the beneficial
21 effect is obtained with a daily intake of 250 mg of EPA and DHA.”²⁰

22
23
24 88. A 2010 study by an Aker BioMarine affiliated scientist measuring the
25 effect of krill oil supplementation was published in the journal *Lipids* in 2011. The

26
27 ¹⁹ Fihn SG, *Circulation*, 2012, 126, e354-e471.

28 ²⁰ See http://bio.lonza.com/uploads/tx_mwaxmarketingmaterial/Lonza_Brochures_DHAidThe_Vegetarian_Source.pdf, last visited 2/25/15.

1 paper was titled “Metabolic Effects of Krill Oil are Essentially Similar to Those of
2 Fish Oil but at Lower Dose of EPA and DHA, in Healthy Volunteers.”²¹

3
4 89. Volunteers in that study took a daily dose of **3,000 mg of krill oil** for
5 7 weeks in order to examine its efficacy, a full *ten times* the recommended daily
6 dose of the MegaRed 300 mg softgel, and six times the recommended daily dose of
7 the 500 mg softgel.
8

9 90. That study stated:

10 American Heart Association guidelines for omega-3 and fish for the
11 primary prevention of coronary artery disease are two servings of
12 fish per week. This recommendation will provide 250-500 mg EPA
13 + DHA per day. In the present study we have shown that the daily
14 intake of 3 g krill oil containing 543 mg EPA + DHA increases the
15 plasma level of EPA + DHA to the same extent as intake of fish oil
16 containing 864 mg EPA + DHA.

17 91. A consumer would have to take **four 300 mg MegaRed capsules per**
18 **day, or three 500 mg MegaRed capsules per day**, just to get to the **minimum 250**
19 **mg threshold** described in this study. Significantly more would need to be
20 consumed to reach the threshold set by the AHA.

21 92. **Yet, according to the MegaRed label and Defendant’s incessant**
22 **advertising campaign, “Just 1 Small Softgel Per Day” is all you need.**
23
24
25

26 _____
27 21

28 *See*
http://download.springer.com/static/pdf/177/art%253A10.1007%252Fs11745-010-34904.pdf?auth66=1403209214_1f867baebc0afbc762cca7d956372ee&ext=.pdf.

1 93. Notwithstanding the significant doses studied (as compared to a typical
2 MegaRed softgel) the study made the following finding concerning the impact on
3 serum lipids:
4

5 Small changes in the levels of HDL-cholesterol, LDL cholesterol, and
6 TG were observed in all study groups from start to end of the
7 intervention phase, but only the within-group increase in LDL-
8 cholesterol seen in the fish oil group ($p = 0.039$) was statistically
9 significant.

10 94. The study goes on to claim that the krill oil group did exhibit a
11 statistically significant increase in the ratio of HDL cholesterol (aka “good
12 cholesterol”) and triglycerides but again the conclusion is belied by the data which
13 indicates that the change was less than the margin of error. Moreover, on
14 information and belief, the change was not clinically significant even if it could be
15 characterized as statistically relevant.
16

17 95. This study strongly suggests that MegaRed’s claims concerning the
18 impact of taking one 300 mg or 500 mg MegaRed per day cannot be true.
19

20 96. This study also strongly suggests that MegaRed’s claim to provide an
21 adequate alternative to consumption multiple fish oil pills is false and misleading.
22 Even accepting, *arguendo*, that this study showed omega-3 supplementation to have
23 a clinically significant effect (which it did not) it concludes that 543 mg of EPA +
24 DHA from krill oil was equivalent to 846 EPA + DHA from fish oil, which is a
25 factor of 1.55 (*i.e.*, less than two). However, most if not all fish oil supplements
26 sold on the market today possess two or more times the EPA+DHA per pill than
27
28

1 MegaRed. Consequently, for one MegaRed softgel to substitute for two fish oil
2 pills, it would have to have a potency of four or more times that of fish oil. Aker
3 Biomarine’s study strongly suggests this is not the case, and, on information and
4 belief, krill oil has nowhere near this level of potency as compared to fish oil.
5

6 **PLAINTIFFS’ FACTS**

7
8 97. Plaintiff SETH SULTAN is a health-conscious individual who seeks to
9 maintain a daily diet which provides an appropriate level of nutrition.

10 98. Periodically over the last four years Plaintiff purchased MegaRed
11 Omega-3 Krill Oil in 500 mg doses from various retail stores. For example, on July
12 13, 2012 Plaintiff purchased MegaReds’s 500 mg Omega-3 Krill Oil at a Costco in
13 Laguna Niguel, California.
14

15 99. Before Plaintiff purchased MegaRed Omega-3 Krill Oil in 500 mg
16 strength, he purchased MegaRed Omega-3 Krill oil in 300 mg strength.
17

18 100. At the time of purchase Plaintiff read the product’s packaging,
19 including the statements “May Reduce The Risk of Coronary Heart Disease” and
20 “Just 1 Small Softgel Per Day”. At or prior to the time of purchase Plaintiff also
21 read and relied upon other statements by MegaRed, including claims that MegaRed
22 raises the Omega-3 Index, lowers triglycerides and c-reactive proteins, and provides
23 an exceptionally powerful small pill with benefits comparable to multiple larger
24 fish oil pills. Plaintiff also read the foldout contained within the MegaRed box.
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101. MegaRed’s representations caused Plaintiff to believe that he could satisfy his daily need for omega-3 fatty acids by taking just one MegaRed softgel per day and receive the claimed benefits, including a reduction in the risk of CHD.

102. Plaintiff paid a premium for MegaRed over other products such as fish oil in reliance on these representations.

103. Had Plaintiff known at the time that MegaRed is a misbranded product under California law and that a single MegaRed softgel does not necessarily satisfy a daily omega-3 requirement or provide the advertised benefits, Plaintiff would not have purchased MegaRed or would have paid less for the product. Plaintiff would also have taken additional measures to ensure he received the necessary level of omega-3 fatty acids in his diet.

104. Plaintiff’s reliance was reasonable in light of MegaRed’s representations.

105. On information and belief, like Plaintiff, as a direct result of MegaRed’s misbranding, tens of thousands of consumers have paid a premium for MegaRed believing that consumption of one MegaRed softgel per day necessarily satisfies a daily nutritional requirement for omega-3 fatty acids linked to reduction of CHD and other heart-health benefits.

1 **CLASS ACTION ALLEGATIONS**

2 106. Plaintiff brings this action on behalf of himself and all others similarly
3 situated pursuant to Federal Rules of Civil Procedure 23(a),23(b)(2) and/or
4 23(b)(3).
5

6 107. All claims alleged herein arise under California law for which Plaintiff
7 seeks relief authorized by California law.
8

9 108. The classes Plaintiff seeks to represent (sometimes referred to herein
10 collectively as the “Class”) are defined as follows:
11

12 **Nationwide Class:** All persons in the United States who purchased
13 MegaRed Omega-3 Krill Oil, in 300 mg and/or 500 mg strength,
14 between four years prior to the filing of the Complaint in this action
until the date of certification.

15 **California Sub-Class:** All persons in California who purchased
16 MegaRed Omega-3 Krill Oil, in 300 mg and/or 500 mg strength,
17 between four years prior to the filing of the Complaint in this action
until the date of certification.

18 Excluded from the Class are Defendant, as well as its officers, employees, agents or
19 affiliates and any judge who presides over this action, as well as all past and present
20 employees, officers and directors of Defendant. Also excluded are Plaintiff’s
21 counsel and employees of their law firms. Plaintiff reserves the right to expand,
22 limit, modify or amend this class definition, and to add one or more subclasses, in
23 connection with his motion for class certification, or at any other time, based upon,
24 *inter alia*, changing circumstances and/or new facts obtained during discovery.
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1 109. **Numerosity:** Upon information and belief, the Class is composed of
2 tens of thousands of individuals whose joinder in this action would be
3 impracticable. The disposition of their claims through this class action will benefit
4 Class members, the parties and the Court.
5

6 110. **Existence and Predominance of Common Questions of Fact and**
7 **Law:** There is a well-defined community of interest in questions of law and fact
8 affecting the Class. These questions of law and fact predominate over individual
9 questions affecting individual Class members, including, but not limited to, the
10 following:
11

- 12
- 13 a. Whether Defendant engaged in unlawful, unfair or
14 deceptive business practices by failing to properly label
15 dietary supplements sold to consumers;
16
 - 17 b. Whether Defendant engaged in false advertising by
18 failing to properly label dietary supplements sold to
19 consumers;
20
 - 21 c. Whether MegaRed is a misbranded product under
22 California law;
23
 - 24 d. Whether Defendant made health claims on MegaRed that
25 exceed the permitted qualified health claim concerning
26 Omega-3 and its impact on CHD;
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- e. Whether Defendant made claims in connection with the sale and marketing of MegaRed suggesting a level of Omega-3 fatty acids to be useful in achieving a reduction in the risk of CHD for the general healthy population;
- f. Whether Defendant made false statements concerning the benefits or effects of taking MegaRed, including without limitation the effect on the Omega-3 Index;
- g. Whether Defendant made false, misleading and/or untrue statements via its labeling;
- h. Whether Defendant violated California’s Consumers Legal Remedies Act (Cal. Civil Code §§ 1750, *et seq.*);
- i. Whether Defendant violated California’s Unfair Competition Law (Cal. Bus. & Prof. Code §§ 17200, *et seq.*);
- j. Whether Defendant violated California’s False Advertising Law (Cal. Buss & Prof. Code §§ 17500, *et seq.*);
- k. Whether Defendant violated California’s Sherman Food, Drug, and Cosmetic Law (Cal. Health & Saf. Code §§ 109875, *et seq.*);

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- l. Whether Defendant’s conduct, as alleged herein, was intentional and knowing;
- m. Whether Defendant was unjustly enriched by the sale of misbranded MegaRed Products;
- n. Whether Class members are threatened with irreparable harm or are otherwise entitled to injunctive and other equitable relief, and, if so, the nature of such relief;
- o. Whether Defendant’s unlawful, unfair and/or deceptive practices harmed Plaintiff and the Class;
- p. The method of calculation and extent of damages suffered by Plaintiff and Class Members; and
- q. Whether Plaintiff and Class members are entitled to an award of reasonable attorneys’ fees, prejudgment interest and cost of suit.

111. **Typicality:** Plaintiff’s claims are typical of, and are not antagonistic to, the claims of all Class members. Plaintiff and the Class he seeks to represent have all been deceived (or were likely to be deceived) and damaged by Defendant’s false and misleading health claims regarding its MegaRed product as alleged herein. Plaintiff and all Class members have similarly suffered injury, including the loss of money, arising from Defendant’s unfair, unlawful and deceptive conduct, as described herein.

1 112. **Adequacy:** Plaintiff is an adequate representative of the Class
2 because his interests do not conflict with the interests of the Class members he
3 seeks to represent. Plaintiff will fairly and adequately represent and protect the
4 interests of the Class because he is not antagonistic to the Class. Plaintiff has
5 retained counsel who are competent and experienced in the prosecution of
6 consumer fraud and class action litigation.
7
8

9 113. **Superiority:** A class action is superior to other available means for
10 the fair and efficient adjudication of Plaintiff's and Class members' claims.
11 Plaintiff and Class Members have suffered monetary harm as a result of
12 Defendant's unfair, unlawful and fraudulent conduct. Because of the relatively
13 modest size of individual Class members' claims, few, if any, Class members could
14 afford to seek legal redress of the wrongs complained of herein on any individual
15 basis. Absent a class action, Class members and the general public will likely
16 continue to be deceived and suffer monetary losses and the violations of law
17 described herein will continue without remedy, and Defendant will be permitted to
18 retain the proceeds of its misdeeds.
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22 114. All Class members, including Plaintiff, were exposed to one or more
23 of Defendant's misrepresentations or omissions of material fact regarding the health
24 claims made by MegaRed. Due to the scope and extent of Defendant's false
25 advertising scheme, disseminated in a massive, years-long campaign to California
26 consumers via in-store display advertising, internet advertising and print
27
28

1 advertising, it can be reasonably inferred that such misrepresentations or omissions
2 of material fact were uniformly made to all members of the Class. In fact, the false
3 / misleading statements are largely reproduced verbatim on each package and the
4 label of MegaRed. It can be reasonably presumed that all Class members, including
5 Plaintiff, affirmatively acted in response to the material misrepresentations
6 contained in Defendant's false advertising scheme when purchasing MegaRed.
7
8

9 115. As a matter of public policy, this consumer matter should proceed as a
10 consumer class action that will produce several salutary byproducts, including:
11

- 12 a. A deterrent effect upon those sellers who indulge in
13 deceptive practices;
- 14 b. Aid to legitimate business enterprises by curtailing
15 illegitimate competition; and,
- 16 c. Avoidance to the judicial process of the burden of
17 multiple litigation involving identical claims.
18
19

20 116. The Class should be certified and each Class member should be
21 compensated in a manner that will put the Class member in a position the member
22 would be in were it not for Defendant's misconduct.
23

24 **FIRST CAUSE OF ACTION**

25 **Violation of Unfair Competition Law**
26 **(Cal. Bus. & Prof. Code §§ 17200 *et seq.*)**

27 117. Plaintiff incorporates by reference each allegation set forth above.
28

1 118. Plaintiff brings this cause of action on behalf of himself and the
2 Nationwide Class, and alternatively on behalf of the California Sub-Class.

3
4 119. California Business and Professions Code Sections 17200, *et. seq.*
5 defines unfair business competition to include any “unlawful, unfair, or fraudulent
6 business act or practice and unfair, deceptive, untrue, or misleading advertising.”
7
8 Cal. Bus. & Prof. Code § 17200.

9 120. As set forth above, under FDA regulations wholly adopted by
10 California’s Sherman Law, the only health claim concerning Omega-3 fatty acids
11 and CHD that may be made on a dietary supplement is the following qualified
12 health claim: “Supportive but not conclusive research shows that consumption of
13 EPA and DHA Omega-3 fatty acids may reduce the risk of coronary heart disease.”
14 Moreover, a dietary supplement cannot suggest a certain level of omega-3 fatty
15 acids to be useful in achieving a claimed effect. Violating either of these rules
16 constitutes misbranding under section 403(a) of the FDCA and thereby under
17 California’s Sherman Act.
18
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21 121. Further, a dietary supplement bearing a claim that is not properly
22 qualified or consistent with the weight of the evidence is a misbranded food under
23 section 403(r)(1)(B)); a misbranded drug under section 502(f)(1)) and an
24 unapproved new drug under section 505(a)).
25

26 122. A dietary supplement bearing claims that are demonstrably false is
27 also misbranded.
28

1 123. As explained above, MegaRed clearly suggests a certain level of
2 Omega-3 fatty acids – that contained in “Just 1 Small Softgel Per Day” – to be
3 useful in reducing the risk of CHD.
4

5 124. MegaRed also makes health claims that clearly go far beyond the
6 permitted qualified health claim.
7

8 125. And, on information and belief, MegaRed makes claims which are
9 simply not true, including without limitation the claim that MegaRed significantly
10 increases the Omega-3 Index in just thirty days and the claim that a single
11 MegaRed softgel is an adequate substitute for consumption of multiple larger fish
12 oil pills.
13

14 126. The above practices constitute clear violations of California’s Sherman
15 Law and, thereby, “unlawful” business practices or acts under California’s UCL.
16

17 127. Defendant’s labeling and marketing of MegaRed also constitutes an
18 “unfair” business act or practice within the meaning of the UCL because any utility
19 for Defendant’s conduct is outweighed by the gravity of the consequences to
20 Plaintiff and Class Members and because the conduct offends public policy.
21

22 128. As discussed herein, Defendant’s conduct is particularly harmful given
23 the relatively small amount of omega-3 fatty acids contained in one MegaRed
24 softgel. One 300 mg MegaRed softgel has only 74 mg of EPA+DHA, and one 500
25 mg softgel has only 94 mg of EPA+DHA. This is less than one-fifth the amount of
26 omega-3 fatty acids the AHA recommends be consumed daily. Moreover, studies
27
28

1 authored by MegaRed’s own supplier Aker BioMarine suggest daily doses of
2 omega-3 in the amount contained in a single MegaRed would have little to no
3 clinical significance. By misleading consumers to believe they are receiving
4 sufficient omega-3 supplementation by and through MegaRed when the literature
5 strongly suggests that any benefit is available only at a far higher dose, Defendant is
6 potentially endangering the well-being of those who rely on MegaRed, to the
7 exclusion of other products and foods rich in Omega-3 fatty acids.
8

9
10 129. In addition, Defendant’s MegaRed Label and marketing constitutes a
11 “fraudulent” business practice or act within the meaning of the UCL.
12

13 130. A business act or practice is “fraudulent” under the UCL if it is likely
14 to deceive members of the consuming public.
15

16 131. MegaRed’s marketing and advertising materials – including, but not
17 limited to, its packaging and labeling, in-store advertising displays, print
18 advertising and internet advertising – are “fraudulent” within the meaning of the
19 UCL because they have deceived Plaintiff, the Class and are likely to deceive
20 members of the general public into believing that MegaRed provides health benefits
21 that it does not provide.
22

23
24 132. Moreover, there were reasonable alternatives available to Defendant to
25 further its legitimate business interests, other than the conduct described herein. For
26 example, Defendant could have refrained from making unauthorized health claims
27
28

1 that violate California law and instead provided accurate information that places its
2 product in the appropriate context.

3
4 133. As a result of the conduct described above, Defendant has been, and
5 will continue to be, unjustly enriched at the expense of Plaintiff and members of the
6 proposed Class. Specifically, Defendant has been unjustly enriched by obtaining
7 revenues and profits that it would not otherwise have obtained absent its false,
8 misleading and deceptive conduct.

9
10 134. Through its unfair acts and practices, Defendant has improperly
11 obtained money from Plaintiff and the Class, and continues to improperly obtain
12 money from the general public. Plaintiff requests that this Court cause Defendant
13 to restore this money to Plaintiff and all Class members.

14
15 135. Plaintiff also requests that this Court enjoin Defendant from continuing
16 to violate the UCL as discussed herein. Otherwise, Plaintiff, Class Members and
17 members of the general public may be irreparably harmed and/or denied an
18 effective and complete remedy.

19
20
21 **SECOND CAUSE OF ACTION**

22 **Violation of the False Advertising Act**
23 **(Cal. Bus. & Prof. Code §§ 17500, *et seq.*)**

24 136. Plaintiff incorporates by reference each allegation set forth above.

25 137. Plaintiff brings this cause of action on behalf of himself and the
26 Nationwide Class, and alternatively on behalf of the California Sub-Class.
27

28

1 138. Pursuant to California Business and Professions Code Sections 17500
2 *et seq.*, it is unlawful to engage in advertising “which is untrue or misleading, and
3 which is known, or which by the exercise of reasonable care should be known, to be
4 untrue or misleading.”
5

6 139. As explained above, Defendant’s packaging and associated marketing
7 for MegaRed clearly suggests a particular level of omega-3 fatty acids to be useful
8 in reducing the risk of CHD, a claim which is presumptively false and misleading
9 under governing law. Moreover, MegaRed makes health claims which go far
10 beyond the permitted qualified health claim for omega-3 and CHD, and related
11 claims that are false, including without limitation the claim that MegaRed will
12 significantly increase the omega-3 index in just thirty days and is an adequate
13 substitute for the daily consumption of multiple larger fish oil pills with far greater
14 amounts of EPA + DHA.
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18 140. Defendant is a multi-million dollar company advised by skilled
19 counsel who, on information and belief, are, or by the exercise of reasonable care,
20 should be aware of the governing regulations and their purpose, and the fact that
21 their labeling does not comply with them.
22
23

24 141. Defendant’s product packaging/labeling and associated marketing
25 therefore constitutes untrue and/or misleading advertising within the meaning of
26 Business and Professions Code sections 17500 *et seq.*
27
28

1 142. Plaintiff, individually and on behalf of all others similarly situated,
2 demands judgment against Defendant for restitution, disgorgement, injunctive relief,
3 and all other relief afforded under Business & Professions Code Sections 17500,
4 plus interest, attorneys' fees, and costs
5

6 **THIRD CAUSE OF ACTION**

7 **Violation of the Consumers Legal Remedies Act**
8 **(Cal. Civ. Code §§ 1750 *et seq.*)**

9 143. Plaintiff incorporates by reference each allegation set forth above.

10
11 144. Plaintiff brings this cause of action on behalf of himself and the
12 Nationwide Class, and alternatively on behalf of the California Sub-Class.

13 145. This cause of action is brought pursuant to the Consumers Legal
14 Remedies Act, California Civil Code §§ 1750, *et seq.* (the "CLRA").
15

16 146. The CLRA has adopted a comprehensive statutory scheme prohibiting
17 various deceptive practices in connection with the conduct of a business providing
18 goods, property, or services to consumers primarily for personal, family, or
19 household purposes. The self-declared purposes of the Act are to protect consumers
20 against unfair and deceptive business practices and to provide efficient and
21 economical procedures to secure such protection.
22

23
24 147. Defendant is a "person" as defined by Civil Code Section 1761(c),
25 because it is a corporation as set forth above.
26
27
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1 148. Plaintiff and each member of the proposed Class are “consumers”
2 within the meaning of Civil Code § 1761(d), because they are individuals who
3 purchased MegaRed for personal and/or household use.
4

5 149. Defendant’s MegaRed product is a “good” within the meaning of
6 California Civil Code Section 1761(a) because it is a tangible product bought by
7 Plaintiff and Class Members for personal, family, and/or household use.
8

9 150. Defendant’s sale of MegaRed to wholesalers and retailers throughout
10 California constitutes “transaction[s]” which were “intended to result or which
11 result[ed] in the sale” of goods to consumers within the meaning of Civil Code
12 Sections 1761(e) and 1770(a).
13

14 151. Plaintiff has standing to pursue this claim as he has suffered injury in
15 fact and has lost money as a result of Defendant’s actions as set forth herein.
16

17 152. Section 1770(a)(5) of the CLRA prohibits anyone from “[r]epresenting
18 that goods or services have sponsorship, approval, characteristics, ingredients, uses,
19 benefits, or quantities which they do not have ” As discussed above, Defendant’s
20 labeling and associated marketing for MegaRed clearly suggests a particular level
21 of omega-3 fatty acids to reduce the risk of CHD, a claim which is presumptively
22 false and misleading under governing law. Moreover, MegaRed makes health
23 claims which go far beyond the permitted qualified health claim, and related claims
24 that are false, including without limitation the claim that MegaRed will
25 significantly increase the omega-3 index in just thirty days and is an adequate
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1 substitute for the daily consumption of multiple fish oil pills with far greater
2 amounts of EPA + DHA. Through this conduct Defendant effectively represented
3 that MegaRed has sponsorship, approval, characteristics, uses, and benefits which it
4 does not have under governing law.
5

6 153. Section 1770(a)(7) of the CLRA prohibits anyone from "[r]epresenting
7 that goods or services are of a particular standard, quality, or grade, or that goods
8 are of a particular style or model, if they are of another." By engaging in the
9 conduct complained of herein, Defendant similarly represented MegaRed to be of a
10 particular standard, quality, or grade which it is not under governing law.
11
12

13 154. Section 1770(a)(9) of the CLRA prohibits anyone from "[a]dvertising
14 goods or services with intent not to sell them as advertised." As noted above,
15 Defendant is a multi-million dollar company advised by skilled counsel who, on
16 information and belief, are or by the exercise of reasonable care should be aware of
17 the governing regulations and their purpose, and the fact that the MegaRed label
18 and associated marketing materials do not comply with them. By introducing
19 MegaRed into the stream of commerce notwithstanding this knowledge, Defendant
20 thus intentionally sold misbranded products.
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24 155. Plaintiff has attached hereto, as Exhibit 1, the declaration of venue
25 required by Civil Code Section 1780(d).
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156. Plaintiff seeks an order enjoining the acts and practices described above, restitution of property, and any other equitable relief that the Court deems proper.

157. Plaintiff has provided Defendant with notice of its violations of the CLRA pursuant to California Civil Code § 1782(a). If, within 30 days from the date of Plaintiff’s notice, Defendant fails to provide appropriate relief for its violations of the CLRA, Plaintiff will amend this Complaint to seek monetary, compensatory, and punitive damages, in addition to the injunctive and equitable relief that they seek now.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and on behalf of the other members of the Class, requests that this Court award relief as follows:

- A. An Order certifying that this action may be maintained as a class action, that Plaintiff be appointed Class Representative and that Plaintiff’s counsel be appointed Class Counsel;
- B. A declaratory judgment that MegaRed’s packaging and associated marketing are unlawful;
- C. An Order requiring Defendant, at its own cost, to notify all Class Members of the unlawful and deceptive conduct complained of herein;
- D. An Order permanently enjoining Defendant from engaging in the improper and unlawful activities and practices described herein;

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- E. An Order requiring Defendant to change the product packaging and associated marketing materials for all MegaRed 300 mg and 500 mg products such that they comply with all applicable labeling rules and regulations;
- F. An Order requiring Defendant to engage in corrective advertising regarding the conduct discussed above;
- G. An Order awarding Plaintiff and all members of the Class restitution and/or other relief, including without limitation, disgorgement of all profits and unjust enrichment obtained by Defendant as a result of its unlawful, unfair and fraudulent business practices described herein;
- H. An Order awarding Plaintiff and members of the Class actual and compensatory damages in an amount according to proof for Defendant's conduct alleged herein;
- I. An Order awarding Plaintiff his costs of suit, including reasonable attorneys' fees pursuant to Code of Civil Procedure Section 1021.5 and as otherwise permitted by statute, and pre- and post-judgment interest; and
- J. Such other and further relief as may be deemed necessary or appropriate.

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury of all issues which may be tried by a jury.

Dated: February 25, 2015 GLANCY BINKOW & GOLDBERG LLP

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EXHIBIT 1

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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

SETH SULTAN, Individually and On
Behalf of All Others Similarly Situated,

Plaintiff,

v.

SCHIFF NUTRITION
INTERNATIONAL, INC., a Delaware
corporation,

Defendant.

Case No.:

**DECLARATION OF SETH SULTAN
IN SUPPORT OF PLAINTIFF'S
SELECTION OF VENUE FOR TRIAL
OF CLAIMS ARISING UNDER THE
CALIFORNIA CONSUMERS LEGAL
REMEDIES ACT**

[Cal. Civ. Code § 1780. subd. (d)]

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I, SETH SULTAN, declare under penalty of perjury as follows:

1. I am Plaintiff Seth Sultan in the above-captioned matter. I have personal knowledge of the facts stated in this Declaration and if called as a witness, I could and would competently testify thereto.

2. Pursuant to California Civil Code section 1780(d), this Declaration is submitted in support of Plaintiff's Selection of Venue for the trial of Plaintiff's cause of action alleging violation of California's Consumers Legal Remedies Act.

3. Periodically over the last four years I purchased MegaRed Omega-3 Krill Oil from various retail stores located within the Central District of California. For example, on July 12, 2012, I purchased MegaRed's 500 mg Omega-3 Krill Oil at a Costco in Laguna Niguel, California.

4. Based on the facts set forth herein, this Court is a proper venue for the prosecution of Plaintiff's cause of action alleging violation of California's Consumers Legal Remedies Act because the transaction(s) at issue, or a substantial portion thereof, occurred in the Central District of California.

I declare under penalty of perjury under the laws of the United States of America and the State of California that the forgoing is true and correct. Executed in Trabuco Canyon, California.

DocuSigned by:
Seth Sultan
12680CAC1325459...

2/23/2015

Seth Sultan

Date