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13 Attorneys for Plaintiffs AMARIN PHARMA, INC.  
AND AMARIN PHARMACEUTICALS IRELAND,  
14 LTD.

15 UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

16 AMARIN PHARMA, INC. AND  
17 AMARIN PHARMACEUTICALS  
18 IRELAND, LTD.

19 Plaintiffs,

20 v.

21 COROMEGA HEALTH, INC.,

22 Defendant.  
23  
24  
25  
26  
27  
28

Case No. '18CV2481 BEN NLS

**COMPLAINT FOR  
DECLARATORY AND  
INJUNCTIVE RELIEF**

**DEMAND FOR JURY TRIAL**

1           Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland, Ltd. (“Amarin”)  
 2 bring this action against The Coromega Company, Inc. (“Coromega”) and allege  
 3 the following:

#### 4           **NATURE OF ACTION**

5           1.       Amarin brings this action to stop Coromega from engaging in false  
 6 and misleading advertising by promoting its omega-3 products, which are  
 7 marketed as dietary supplements, as reducing the risk of cardiovascular disease and  
 8 as being comparable to, or substitutes for, Amarin’s Food and Drug Administration  
 9 (FDA)-approved prescription drug, Vascepa® (icosapent ethyl). Among other  
 10 things, Coromega falsely and deceptively advertises that its omega-3 “dietary  
 11 supplements” are effective in treating or preventing cardiovascular disease and that  
 12 they confer the same disease-related benefits as Amarin’s Vascepa®. Last month,  
 13 Amarin reported the results of its REDUCE-IT™ trial, a landmark, more than \$360  
 14 million cardiovascular outcomes study, which showed that Vascepa reduced, by  
 15 approximately 25%, the risk of major adverse cardiovascular events (“MACE”) (a  
 16 composite of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke,  
 17 coronary revascularization, or unstable angina requiring hospitalization) in at-risk  
 18 patients on statin therapy. *See REDUCE-IT Cardiovascular Outcomes Study of*  
 19 *Vascepa® (Icosapent Ethyl) Capsules Met Primary Endpoint*, AMARIN CORP. Sept.  
 20 24, 2018, [https://investor.amarincorp.com/news-releases/news-release-](https://investor.amarincorp.com/news-releases/news-release-details/reduce-ittm-cardiovascular-outcomes-study-vascepar-icosapent)  
 21 [details/reduce-ittm-cardiovascular-outcomes-study-vascepar-icosapent](https://investor.amarincorp.com/news-releases/news-release-details/reduce-ittm-cardiovascular-outcomes-study-vascepar-icosapent) (hereinafter  
 22 “REDUCE-IT Press Release”), submitted herewith as Exhibit 1. Among other  
 23 things, Coromega has made false and misleading claims that the REDUCE-IT  
 24 results support the efficacy of its omega-3 “dietary supplements” in reducing  
 25 cardiovascular disease in the general population when that is not true. The  
 26 REDUCE-IT results are limited to Vascepa, and they cannot be extrapolated to  
 27 omega-3 products like Coromega’s that are materially different based on, for  
 28 example, composition, dosage, and regulatory status.

1           2.       Section 43(a) of the Lanham Act protects those engaged in commerce  
2 from precisely this type of unfair competition and false advertising by creating a  
3 cause of action for those like Amarin who are harmed by it. *See* 15 U.S.C. §  
4 1125(a)(1).

5           3.       Under California law, products that purport to treat or prevent disease  
6 are “drugs,” and manufacturers of such products must demonstrate that their drugs  
7 are safe and effective in order to obtain regulatory approval to market them.  
8 Although Coromega touts its products as being effective at treating and preventing  
9 cardiovascular disease, upon information and belief, Coromega has not  
10 demonstrated their safety and efficacy to FDA or the State of California. Nor, on  
11 information and belief, has Coromega demonstrated to FDA or the State of  
12 California that its products are manufactured in compliance with stringent  
13 manufacturing requirements applicable to drug products that are designed to ensure  
14 drugs deliver the effects demonstrated in their clinical trials. Coromega’s false and  
15 deceptive advertising, as well as its violation of California’s drug approval  
16 requirements, distracts patients from seeking appropriate medical attention, diverts  
17 limited healthcare resources from proven medications, poses serious risks to the  
18 safety and health of the consuming public, and harms Amarin, a legitimate  
19 manufacturer of an FDA-approved omega-3 prescription drug.

20           4.       California’s Unfair Competition Law (“UCL”) also exists to prevent  
21 these unscrupulous practices by “prohibiting unfair, dishonest, deceptive,  
22 destructive, fraudulent and discriminatory practices by which fair and honest  
23 competition is destroyed or prevented.” Cal. Bus. & Prof. Code §§ 17001, 17200.

24           5.       California regulates the manufacture and sale of prescription drugs  
25 under the state’s Sherman Food, Drug, and Cosmetic Law (the “Sherman Law”).  
26 As relevant here, the Sherman Law specifies that “[n]o person shall sell, deliver, or  
27 give away any new drug” that has not been approved by FDA or by the State of  
28 California. Cal. Health & Safety Code § 111550(a)–(b). A “drug” is defined to

1 include any product that is “used or intended for use in the diagnosis, cure,  
2 mitigation, treatment, or prevention of disease.” Cal. Health & Safety Code §  
3 109925.

4 6. Amarin introduced Vascepa®, an FDA-approved prescription drug, in  
5 2012, after over a decade of clinical trials and development. Vascepa’s active  
6 ingredient, icosapent ethyl, is the ethyl ester form of eicosapentaenoic acid.  
7 Eicosapentaenoic acid is the omega-3 fatty acid commonly known as “EPA.”  
8 Vascepa is approved for use as an adjunct to diet to reduce triglyceride levels in  
9 adult patients with severe hypertriglyceridemia. *See Vascepa® Full Prescribing*  
10 *Information*, 1 (2017) [https://www.vascepa.com/assets/pdf/Vascepa\\_PI.pdf](https://www.vascepa.com/assets/pdf/Vascepa_PI.pdf),  
11 (hereinafter “Vascepa Full Prescribing Information”), submitted herewith as  
12 Exhibit 2.

13 7. Vascepa is materially different from Coromega’s omega-3 products  
14 because, on information and belief with respect to Coromega’s products: (1)  
15 Vascepa has been proven to lower cardiovascular risk, based on the more than  
16 \$360 million REDUCE-IT cardiovascular outcomes study, whereas the Coromega  
17 products have not; (2) Vascepa is an FDA-approved drug designated by FDA as a  
18 new chemical entity based on its unique molecular structure, whereas the  
19 Coromega products are marketed as “dietary supplements,” *see* FDA Letter to  
20 Robert A. Dormer, May 31, 2016, [http://www.fdalawblog.net/wp-](http://www.fdalawblog.net/wp-content/uploads/archives/docs/VASCEPA%20-%20Exclusivity%20Determination%20on%20Remand.pdf)  
21 [content/uploads/archives/docs/VASCEPA%20-](http://www.fdalawblog.net/wp-content/uploads/archives/docs/VASCEPA%20-%20Exclusivity%20Determination%20on%20Remand.pdf)  
22 [%20Exclusivity%20Determination%20on%20Remand.pdf](http://www.fdalawblog.net/wp-content/uploads/archives/docs/VASCEPA%20-%20Exclusivity%20Determination%20on%20Remand.pdf) (hereinafter “Dormer  
23 Letter”), submitted herewith as Exhibit 3 (designating Vascepa as a new chemical  
24 entity); (3) Vascepa contains only purified EPA (icosapent ethyl), whereas the  
25 Coromega products contain a mix of EPA, docosahexaenoic acid (“DHA”), and  
26 other fatty acids; (4) because omega-3 fatty acids are highly prone to oxidation,  
27 Vascepa is manufactured, encapsulated, and packaged through a stringent and  
28 complex FDA-regulated process designed to effectively eliminate impurities and

1 isolate and protect the fragile single-molecule active ingredient from degradation,  
2 whereas the Coromega products are not; (5) Vascepa was developed as a  
3 prescription only drug to be administered at a high dosage and has a demonstrated  
4 safety profile at that high dosage, whereas the Coromega products are sold in lower  
5 dosages; (6) Vascepa is marketed for use in populations for which it has been  
6 proven to be safe and effective (e.g., adult patients with severe  
7 hypertriglyceridemia), whereas the Coromega products are marketed to the general  
8 public (including children and diseased populations); (7) Vascepa is not mixed  
9 with other ingredients, whereas all of the Coromega products are mixed with  
10 multiple other ingredients, such as pasteurized egg yolk, natural flavor, ascorbic  
11 acid, and stevia leaf extract, and (8) Vascepa is sold in capsules, whereas the  
12 Coromega products are sold in liquid form. Vascepa is the only omega-3  
13 prescription drug that is pure EPA.

14 8. On September 24, 2018, Amarin announced the results of its  
15 REDUCE-IT clinical trial, a global study of 8,179 statin-treated adults with  
16 elevated cardiovascular risk. REDUCE-IT demonstrated to a statistically  
17 significant level that taking 4 grams of Vascepa a day reduced, by approximately  
18 25%, the risk of MACE. *See* REDUCE-IT Press Release, Exhibit 1. The  
19 REDUCE-IT results demonstrate that Vascepa, a relatively low cost drug from a  
20 consumer perspective, could potentially help healthcare professionals save millions  
21 of lives by preventing MACE in appropriate patients.

22 9. Amarin developed Vascepa legally and invested the significant  
23 resources necessary to conduct clinical trials to show that the drug is effective in  
24 reducing triglyceride levels in adult patients with severe hypertriglyceridemia, and  
25 then to submit that data to FDA for review and approval. Amarin also invested  
26 significant resources in the REDUCE-IT trial and is in the process of preparing a  
27 submission to FDA for review and approval of the results. All told, the cost of  
28

1 Amarin’s clinical trials exceeded \$450 million. The total cost for the REDUCE-IT  
2 trial alone exceeded \$360 million.

3 10. The REDUCE-IT trial studied only Vascepa and its results are  
4 Vascepa-specific. The study cannot be generalized to other omega-3 products,  
5 including dietary supplements, which come in many different dosages and omega-  
6 3 fatty acid compositions. Yet, only nine days after September 24, 2018, when  
7 Amarin announced the REDUCE-IT results, Coromega issued its own press release  
8 falsely and misleadingly stating that the results of the REDUCE-IT trial support  
9 the efficacy of Coromega’s different, non-prescription omega-3 products for  
10 reducing cardiovascular risk in the general population.

11 11. Coromega’s press release falsely and misleadingly stated, for  
12 example: “Thanks to results from Amarin’s Reduce-It clinical study, we have great  
13 news on how omega-3s can positively affect those at risk for heart attack and  
14 stroke.” *See Breaking News: High EPA Omega-3 Proving to Decrease Heart*  
15 *Attack Risk*, THE SQUEEZE (Oct. 3, 2018) (hereinafter “Coromega Press Release”),  
16 [https://www.coromega.com/blog-1/breaking-news-high-epa-omega-3-proving-to-](https://www.coromega.com/blog-1/breaking-news-high-epa-omega-3-proving-to-decrease-heart-attack-risk?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE)  
17 [decrease-heart-attack-](https://www.coromega.com/blog-1/breaking-news-high-epa-omega-3-proving-to-decrease-heart-attack-risk?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE)  
18 [risk?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuv](https://www.coromega.com/blog-1/breaking-news-high-epa-omega-3-proving-to-decrease-heart-attack-risk?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE)  
19 [D\\_BwE](https://www.coromega.com/blog-1/breaking-news-high-epa-omega-3-proving-to-decrease-heart-attack-risk?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE), submitted herewith as Exhibit 4. The press release also falsely and  
20 misleadingly states that “[o]ur product Coromega Max has a powerful 2,400mg of  
21 Omega-3 fatty acids including both DHA and EPA. This proves to be an optimal  
22 amount for maximum health benefits for the heart, body and mind.” *Id.*

23 12. By making these false and misleading statements, as well as others in  
24 its press release and on its website as described below, Coromega is violating the  
25 Lanham Act as well as the false advertising provisions in the Sherman Law, in  
26 violation of the UCL.

27 13. In addition, by marketing its omega-3 products as treating or  
28 preventing cardiovascular disease and as products that are comparable to

1 prescription drugs like Vascepa, the products meet the definition of “drug” under  
2 the Sherman Law, but do not comply with the Sherman Law’s requirements for  
3 such drugs. Specifically, on information and belief, Coromega has never sought  
4 nor obtained approval for these “drugs” from the FDA or the State of California.  
5 Coromega’s omega-3 products are therefore unlawful, unapproved “drugs,” sold in  
6 violation of the Sherman Law and the UCL.

7       14. In skirting the drug approval process, Coromega has improperly  
8 avoided the most risky, expensive, and time-consuming requirements for lawfully  
9 marketing drugs—namely, conducting clinical trials to support an application for  
10 drug approval.

11       15. Flouting California’s drug approval requirements by marketing its  
12 omega-3 products with disease claims—namely, claims that the products treat or  
13 prevent cardiovascular disease and claims that the products are comparable to  
14 prescription drugs like Vascepa—gives Coromega an unfair competitive advantage  
15 over law-abiding pharmaceutical manufacturers like Amarin. Worse, it puts  
16 patients at risk by exposing them to unapproved drugs that are marketed under the  
17 guise of legal “dietary supplements” and encourages consumers to substitute  
18 unproven products for medical treatments they may need under a doctor’s care.

19       16. In addition, the statements in the press release cited above (among  
20 others) are false and misleading for a number of reasons. For example, the  
21 statement falsely and/or misleadingly states or implies—without any  
22 substantiation—that Coromega’s omega-3 dietary supplements, and omega-3  
23 dietary supplements more generally, are effective in treating or preventing heart  
24 disease.

25       17. The results of the REDUCE-IT trial are relevant only to Vascepa and  
26 cannot be extrapolated to support the safety and efficacy of Coromega’s omega-3  
27 dietary supplements in reducing cardiovascular risk. The REDUCE-IT trial  
28 studied the efficacy of a specific prescription *drug* comprised of a unique active

1 ingredient: a single molecule omega-3 fatty acid in ethyl ester form (namely,  
2 EPA). That drug was then administered at a specified dose, 4 grams per day, to a  
3 particular *statin-treated* population identified as being at high risk for  
4 cardiovascular events to evaluate its impact on that population. Thus, the results  
5 cannot be extrapolated to *unproven, non-prescription products* that are marketed as  
6 “dietary supplements” to the *general population* (i.e., a population that is not  
7 taking statins and is not at high risk for cardiovascular events)—particularly when  
8 those supplements have loosely regulated manufacturing controls, *different omega-*  
9 *3 fatty acid compositions, different omega-3 dosages, different dosage forms* (e.g.,  
10 capsule, versus emulsified liquid), and added ingredients.

11 18. Coromega’s statements in the press release (as well as other  
12 statements discussed below) are also false and misleading because they equate  
13 Coromega’s omega-3 products with Vascepa. The products are materially  
14 different. There is no evidence supporting Coromega’s claims that the products are  
15 comparable, much less that Coromega’s products are superior to Vascepa.

16 19. Marketing dietary supplements in a manner that renders them  
17 unapproved drugs, and in a manner that deceives consumers—as Coromega is  
18 doing—can have profound implications for personal and public health. As former  
19 Attorney General Loretta Lynch observed:

20 What many Americans don’t know is that dietary  
21 supplements are not subject to testing by the Food and  
22 Drug Administration before they reach the store  
23 shelves—meaning that every day, millions of Americans  
24 are ingesting substances whose safety and efficacy are  
25 not guaranteed. Some of these supplements are simply a  
26 waste of money, promising results that they can’t deliver  
27 or advertising ingredients that they don’t contain. And  
28 too often, these supplements don’t just abuse consumer



1 trust—they also endanger public health. Some contain  
2 harmful ingredients, causing consumers to fall ill. Others  
3 falsely claim to cure illness and disease, leading patients  
4 to use them as a substitute for the proven therapies they  
5 need. But whether these supplements are deceptive or  
6 dangerous, the fact remains that too many companies are  
7 making a profit by misleading—and in some cases  
8 harming—American consumers.

9 *Attorney General Lynch Discusses Department's Efforts to Protect Consumers*  
10 *From Unsafe Dietary Supplements*, DEPARTMENT OF JUSTICE, OFFICE OF PUBLIC  
11 AFFAIRS, (March 8, 2016), [https://www.justice.gov/opa/pr/attorney-general-lynch-](https://www.justice.gov/opa/pr/attorney-general-lynch-discusses-departments-efforts-protect-consumers-unsafe-dietary)  
12 [discusses-departments-efforts-protect-consumers-unsafe-dietary](https://www.justice.gov/opa/pr/attorney-general-lynch-discusses-departments-efforts-protect-consumers-unsafe-dietary), submitted  
13 herewith as Exhibit 5.

14 20. In addition, marketing dietary supplements in a manner that renders  
15 them unapproved drugs, and that deceives consumers can cause significant  
16 reputational harm to legitimate manufacturers of approved omega-3 prescription  
17 drugs, like Amarin. Consumers encountering Coromega's false advertising who  
18 have paid attention to these and other warnings about dietary supplements may  
19 discredit all omega-3 products including Amarin's, without realizing that Amarin  
20 is selling legitimate, tested products with proven results. On the other hand,  
21 consumers encountering Coromega's false advertising who do not know about the  
22 noted problems with the dietary supplement industry are likely to rely—to their  
23 detriment and Amarin's—on Coromega's false and misleading statements  
24 regarding the efficacy and treatment value of its products.

25 21. Amarin has suffered and is suffering from competitive injuries as a  
26 result of Coromega's unlawful activities. Amarin's drug, Vascepa, competes with  
27 Coromega's omega-3 line of products, which include: (1) Coromega Max Citrus  
28 Burst, (2) Coromega Max Coconut Bliss, (3) Coromega Omega-3 Squeeze

1 (Family), (4) Women’s Health Omega-3 Fish Oil +D, (5) Coromega Omega-3  
2 Mango Squeeze, and (6) Coromega Kids Omega-3 Squeeze.

3 22. Amarin brings this action to stop Coromega from engaging in false  
4 and misleading advertising in violation of the Lanham Act and the UCL and from  
5 illegally promoting and selling unlawful and unapproved drugs in violation of the  
6 Sherman Law.

7 **PARTIES**

8 23. Amarin Pharma, Inc. is a corporation organized and existing under the  
9 laws of the State of Delaware, with its principal place of business located at 1430  
10 Route 206, Bedminster, NJ 07921. Amarin Pharmaceuticals Ireland, Ltd. is  
11 organized under the laws of the Republic of Ireland, with its principal place of  
12 business located at 2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2  
13 Ireland.

14 24. Defendant The Coromega Company, Inc. is a corporation  
15 incorporated in California, with its principal place of business located at 2525  
16 Commerce Way, Vista, California 92081.

17 25. Coromega owns and operates offices in Vista, CA, in San Diego  
18 County.

19 26. Coromega sells its products primarily online, and ships them  
20 throughout California, including in this District, nationwide, and internationally.

21 **JURISDICTION**

22 27. This Court has subject matter jurisdiction under 15 U.S.C. § 1121(a)  
23 and 28 U.S.C. §§ 1331 and 1367.

24 28. This Court has personal jurisdiction over Coromega because  
25 Coromega’s principal place of business is in California and Amarin’s claims arise  
26 out of or relate to Coromega’s contacts with California.

27 29. Venue in this District is proper under 28 U.S.C. § 1391.  
28

**FACTUAL ALLEGATIONS**

**A. Coromega’s False and Misleading Advertising And Promotion Of Its Omega-3 Products.**

30. Coromega manufactures and sells a number of omega-3 “dietary supplements” that purport to effectively treat or prevent cardiovascular disease, among other things. Those products include: (1) Coromega Max Citrus Burst, (2) Coromega Max Coconut Bliss, (3) Coromega Omega-3 Squeeze (Family), (4) Women’s Health Omega-3 Fish Oil +D, (5) Coromega Omega-3 Mango Squeeze, and (6) Coromega Kids Omega-3 Squeeze. *See Coromega Product Labeling*, submitted herewith as Exhibit 6.

31. The labeling of all of Coromega’s dietary supplements indicates that the products contain a mix of EPA, DHA, and other omega-3 fatty acids. *See generally Coromega Product Labeling*, Exhibit 6. The fatty acid compositions are materially different from the composition of Vascepa, which is pure EPA.

32. Each of the Coromega omega-3 products appear to be in the form of liquid packets of emulsified fish oil and contain a different dosage of omega-3 fatty acids. The dosage for Coromega Max Citrus Burst is one or two “shots,” which appear to deliver 1,200 mg or 2,400 mg of omega-3 per day, respectively; the dosage for Coromega Max Coconut Bliss is one or two shots, which appear to deliver 1,200 mg or 2,400 mg of omega-3 fatty acids per day, respectively. The dosage for Coromega Omega-3 Squeeze (Family) appears to be 650 mg of omega-3 fatty acids per day. The dosage for Women’s Health Omega-3 Fish Oil +D appears to be 650 mg of omega-3 fatty acids per day. The dosage for Coromega Omega-3 Mango Squeeze appears to be 1,070 mg of omega-3 fatty acids per day; and the dosage for Coromega Omega-3 Kids appears to be 650 mg of omega-3 fatty acids per day. *See Coromega Product Labeling*, Exhibit 6.

1           33. Each of Coromega’s products contains multiple ingredients in  
2 addition to omega-3, such as pasteurized egg yolk, natural flavor, ascorbic acid,  
3 and stevia leaf extract. *See id.*

4           34. Coromega’s website advertises Omega-3 Squeeze for “anyone in the  
5 family,” with a picture of a mother holding a child. *See Shop: Coromega Family,*  
6 COROMEGA,  
7 [https://www.coromega.com/shop?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2](https://www.coromega.com/shop?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE)  
8 [KbQ9BEAAYASAAEgJYuvD\\_BwE](https://www.coromega.com/shop?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE) (last visited Oct. 26, 2018), Exhibit 6, at  
9 0084. The labeling for the product indicates that it is for adults and children over  
10 the age of 4. *See Shop: Coromega Original Squeeze,* COROMEGA,  
11 [https://www.coromega.com/product-page/super-value-](https://www.coromega.com/product-page/super-value-bag?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE)  
12 [bag?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuv](https://www.coromega.com/product-page/super-value-bag?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE)  
13 [D\\_BwE](https://www.coromega.com/product-page/super-value-bag?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE) (last visited Oct. 26, 2018), Exhibit 6, at 0093. Coromega Max Citrus  
14 Burst and Coromega Max Coconut Bliss have labeling indicating that the products  
15 are for adults and children over the age of 4 as well. *See Shop Coromega Max*  
16 *Citrus Burst,* COROMEGA, [https://www.coromega.com/product-page/max-omega-3-](https://www.coromega.com/product-page/max-omega-3-recovery-citrus-burst?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE)  
17 [recovery-citrus-](https://www.coromega.com/product-page/max-omega-3-recovery-citrus-burst?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE)  
18 [burst?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuv](https://www.coromega.com/product-page/max-omega-3-recovery-citrus-burst?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE)  
19 [D\\_BwE](https://www.coromega.com/product-page/max-omega-3-recovery-citrus-burst?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE) (last visited Oct. 26, 2018), Exhibit 6, at 0093. Although the labeling on  
20 Women’s Health Omega-3 Fish Oil +D is not fully visible on the website, upon  
21 information and belief, the labeling indicates that the product may be taken by  
22 adults and children over the age of 4. The full labeling of Coromega Omega-3  
23 Mango Squeeze and Coromega Omega-3 Kids are not fully visible on Coromega’s  
24 website, but based on the websites of third party vendors, these products also have  
25 labels indicating that the products are suitable for adults and children over the age  
26 of 4. *See Coromega Big Squeeze Omega-3 Mango Nectar,* VITACOST,  
27 [https://www.vitacost.com/coromega-big-squeeze-omega-3-mango-nectar-16-fl-](https://www.vitacost.com/coromega-big-squeeze-omega-3-mango-nectar-16-fl-oz?csrc=BPA&utm_campaign=Shopping_Campaign_RLSA&utm_medium=cpc&)  
28 [oz?csrc=BPA&utm\\_campaign=Shopping\\_Campaign\\_RLSA&utm\\_medium=cpc&](https://www.vitacost.com/coromega-big-squeeze-omega-3-mango-nectar-16-fl-oz?csrc=BPA&utm_campaign=Shopping_Campaign_RLSA&utm_medium=cpc&)

1 [utm\\_source=bing&mtp=iEH4v0hUdc%7cpcrid%7c13752925770&msclid=472b5](https://www.vitacost.com/coromega-omega-3-kids?csrc=BPA-)  
2 [83d4e491dc8c67403ecb407e61a&utm\\_term=1100505165491&utm\\_content=Vita](https://www.vitacost.com/coromega-omega-3-kids?csrc=BPA-)  
3 [mins%20%26%20Supplements&gclid=CKmguI2Mot4CFUWkgQodjGQL7w&gcl](https://www.vitacost.com/coromega-omega-3-kids?csrc=BPA-)  
4 [src=ds](https://www.vitacost.com/coromega-omega-3-kids?csrc=BPA-) (last visited Oct. 26, 2018); *Coromega Omega 3 Kids Tropical Orange*,  
5 VITACOST, <https://www.vitacost.com/coromega-omega-3-kids?csrc=BPA->  
6 [&utm\\_campaign=Shopping\\_Campaign\\_RLSA&utm\\_medium=cpc&utm\\_source=b](https://www.vitacost.com/coromega-omega-3-kids?csrc=BPA-)  
7 [ing&mtp=DcVEMlUbdc%7cpcrid%7c13752925770&msclid=80c9b8c63c2e1881](https://www.vitacost.com/coromega-omega-3-kids?csrc=BPA-)  
8 [32fee31563f45cdf&utm\\_term=1100505165430&utm\\_content=Vitamins%20%26](https://www.vitacost.com/coromega-omega-3-kids?csrc=BPA-)  
9 [%20Supplements&gclid=CLjEh4vhpN4CFUfSDQod9IsJ9g&gclidsrc=ds](https://www.vitacost.com/coromega-omega-3-kids?csrc=BPA-) (last  
10 visited Oct. 26, 2018), Exhibit 6, at 0089, 0091.

11 35. Because neither California nor the FDA reviews products marketed as  
12 “dietary supplements” before they are marketed, it is unclear whether the omega-3  
13 content advertised on Coromega’s nutrition labels reflects the actual content found  
14 in Coromega’s “dietary supplements.” Indeed, at least two studies have shown that  
15 a majority of omega-3 products sold as dietary supplements do not contain the  
16 labeled amount of omega-3. See Alison Kleiner, et al., *A Comparison of Actual*  
17 *Versus Stated Label Amounts of EPA and DHA in Commercial Omega-3 Dietary*  
18 *Supplements in the United States*, 95 J. SCI. FOOD & AGRIC. 1260 (abstract) (2015),  
19 submitted herewith as Exhibit 7, (finding that over 70% of the 47 omega-3 dietary  
20 supplements tested did not contain the amount of EPA or DHA claimed on the  
21 label); Jenna Sullivan Ritter et al., *Quality Analysis of Commercial Fish Oil*  
22 *Preparations*, 93 J. SCI. FOOD & AGRIC. 1935 (abstract) (2012), submitted herewith  
23 as Exhibit 8 (finding that over half of the 16 top selling liquid fish oil products in  
24 the U.S., which were sold by nine different manufacturers, did not contain the  
25 amount of EPA and DHA claimed on the label).

26 36. In any event, none of the purported omega-3 dosages in Coromega’s  
27 omega-3 dietary supplements (which are a mix of EPA, DHA, and other  
28

1 ingredients) are as high as the prescription dose of Amarin’s Vascepa drug, which  
2 is 4 grams per day of pure EPA.

3 37. Coromega has made, and is continuing to make, false and misleading  
4 statements regarding its omega-3 products in advertising and promotional  
5 materials. These false and misleading statements appear to fall into two categories:  
6 (1) unsubstantiated claims that Coromega’s omega-3 products treat or prevent  
7 heart disease; and (2) improper and unsubstantiated comparisons of Coromega’s  
8 omega-3 products to Amarin’s Vascepa (and other prescription drugs).

9 *i. Coromega’s Unsubstantiated Cardiovascular Treatment and*  
10 *Prevention Claims Are False and Misleading.*

11 38. Coromega falsely and/or misleadingly states and implies that  
12 Coromega’s omega-3 products treat or prevent cardiovascular disease. Such  
13 claims made in connection with the marketing of the Coromega omega-3 products  
14 at issue include, for example:

- 15 - “Thanks to results from Amarin’s Reduce-It clinical study, we have great  
16 news on how omega-3s can positively affect those at risk for heart attack and  
17 stroke.” Coromega Press Release, Exhibit 4, at 0071.
- 18 - ““25% risk reduction in at-risk patients for cardiac events with 4 grams of  
19 EPA per day. Dose matters!”” *Id.*
- 20 - “Both acids lower triglyceride issues, reduce inflammation, and have blood-  
21 thinning effects—all of which, in turn, can reduce the risk of future heart  
22 disease.” *Id.* at 0072.
- 23 - “Previous studies on omega-3 oils have used much lower doses. One  
24 example of a prior study using what’s considered a high dose of EPA is the  
25 Japanese JELIS trial. Patients were given 1.8-g daild [sic] and this too  
26 showed a benefit for cardiovascular health.” *Id.* at 0073.
- 27 - “Break out your spy glass and look at the serving size to make sure you  
28 don’t need to take 10 pills, wasting piles of money in the process, just to get

1 the recommended dosage stated by the FDA, recommending 3000mg as of  
 2 2017. For many brands, 3000mg is about 3-4 pills. Coromega MAX  
 3 squeezes are 2400mg per serving!” *The Quality of Your Fish Oil Matters*,  
 4 COROMEGA: THE SQUEEZE (Apr. 19, 2018) [https://www.coromega.com/blog-  
 5 1/the-quality-of-your-fish-oil-matters-1](https://www.coromega.com/blog-1/the-quality-of-your-fish-oil-matters-1) (hereinafter “The Quality of Your  
 6 Fish Oil Matters”), submitted herewith as Exhibit 9, at 0103.

7 39. The first three statements above are false and misleading because, on  
 8 information and belief, Coromega has no reliable studies supporting the claim  
 9 above that omega-3 dietary supplements generally (regardless of product dosage,  
 10 composition, or dosage form, or whether the product contains additional  
 11 ingredients, etc.) can reduce the risk of cardiac events (e.g., “heart attack and  
 12 stroke”) in general healthy populations.

13 40. In fact, three recent meta-analyses published in highly respected  
 14 medical journals show that there is no scientific consensus that omega-3 *dietary*  
 15 *supplements* such as those sold by Coromega have any beneficial effect on  
 16 cardiovascular disease risks, or even cardiovascular health more generally, in  
 17 healthy populations. See David S. Siscovick et al., *Omega-3 Polyunsaturated*  
 18 *Fatty Acid (Fish Oil) Supplementation and the Prevention of Clinical*  
 19 *Cardiovascular Disease: A Science Advisory From the American Heart*  
 20 *Association*, 135 CIRCULATION e867, e880, Table 8 (2017), submitted herewith as  
 21 Exhibit 10,  
 22 <http://circ.ahajournals.org/content/early/2017/03/13/CIR.0000000000000482>  
 23 (“available evidence does not support the use of [omega-3] supplements in the  
 24 general population who are not at high risk for [cardiovascular disease]”); see also  
 25 Ethan M. Balk et al., *Omega-3 Fatty Acids and Cardiovascular Disease: An*  
 26 *Updated Systematic Review*, EVIDENCE REPORT/TECHNOLOGY ASSESSMENT No.  
 27 223, at vi (Aug. 2016),  
 28 <https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/fatty-acids->

1 [cardiovascular-disease\\_research.pdf](#) (last accessed Oct. 26, 2018), submitted  
2 herewith as Exhibit 11 (concluding that omega-3 supplements do not affect “major  
3 adverse [cardiovascular] events, all-cause death, sudden cardiac death, coronary  
4 revascularization, atrial fibrillation, or [blood pressure]” *in populations at risk for,*  
5 *or with cardiovascular disease*, or in “general healthy populations”); Asmaa S.  
6 Abdelhamid, et al., Omega-3 Fatty Acids for the Primary and Secondary  
7 Prevention of Cardiovascular Disease, COCHRANE DATABASE OF  
8 SYSTEMATIC REVIEWS 1, 3 (July 2018),  
9 <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003177.pub3/ful>,  
10 submitted herewith as Exhibit 12 (“There is evidence that taking omega-3 capsules  
11 does not reduce heart disease, stroke or death.”).

12 41. Moreover, there is currently no scientific consensus that omega-3  
13 dietary supplements are beneficial even in *diseased* patients. Another meta-  
14 analysis, published in the Journal of the American Medical Association (“JAMA”),  
15 in 2018, called into question the validity of guidelines recommending the use of  
16 omega-3 dietary supplements for the prevention of coronary heart disease (“CHD”)  
17 and major vascular events in people with CHD. *See* Theingi Aung, et al.,  
18 *Associations of Omega-3 Fatty Acid Supplement Use with Cardiovascular Disease*  
19 *Risks: Meta-analysis of 10 Trials Involving 77,917 Individuals*, 3 JAMA  
20 CARDIOLOGY 225, Jan. 31, 2018,  
21 <https://jamanetwork.com/journals/jamacardiology/fullarticle/2670752>, submitted  
22 herewith as Exhibit 13. After reviewing 10 studies involving 77,917 patients, the  
23 authors stated that “[t]his meta-analysis demonstrated that omega-3 fatty acids had  
24 no significant association with fatal or nonfatal coronary heart disease or any major  
25 vascular events. It provides no support for current recommendations for the use of  
26 such supplements in people with a history of [CHD].” *Id.* at 225.

27 42. In addition, on information and belief, Coromega has no reliable  
28 studies supporting the extrapolation of the REDUCE-IT results to Coromega’s



1 omega-3 “dietary supplements,” and thus the first two statements identified above  
2 are false and misleading for that reason as well.

3 43. The REDUCE-IT results show that Amarin’s Vascepa, a prescription  
4 drug of a particular composition and dosage, reduced major cardiovascular events  
5 in a very specific patient population—i.e., *statin-treated* adult patients with  
6 persistently high triglycerides, who also had either (1) a history of cardiovascular  
7 events, such as heart attacks, strokes, and angina, or (2) Type 2 diabetes and other  
8 risk factors like high blood pressure. *See generally* Deepak L. Bhatt et al.,  
9 *Rationale and Design of REDUCE-IT: Reduction of Cardiovascular Events with*  
10 *Icosapent Ethyl-Intervention Trial*, 40 CLINICAL CARDIOLOGY 138 (2017),  
11 <https://onlinelibrary.wiley.com/doi/epdf/10.1002/clc.22692>, submitted herewith as  
12 Exhibit 14.

13 44. These results cannot be extrapolated to Coromega’s omega-3 products  
14 —unproven, non-prescription products that are marketed as “dietary supplements”  
15 to the general population (i.e., a population, including children, that is not taking  
16 statins and is not at high risk for cardiovascular events)—particularly when those  
17 supplements have different omega-3 fatty acid compositions, different omega-3  
18 dosages, different dosage forms (e.g., capsule versus emulsified liquid), and added  
19 ingredients.

20 45. It is false and misleading for Coromega to suggest that clinical trial  
21 results involving a prescription drug can be extrapolated to dietary supplements at  
22 all because the regulatory regimes are so different. Before FDA approves a drug it  
23 verifies that the drug is safe and effective for its labeled uses. 21 U.S.C. §  
24 355(d)(1), (5). FDA also verifies, pre-market, that the drug is labeled properly and  
25 that it is manufactured in accordance with quality controls that ensure that each lot  
26 of the drug has the same “identity, strength, quality, and purity” as the lots of the  
27 drug that were tested in the clinical studies that formed the basis for the drug’s  
28 approval, *see* 21 U.S.C. § 355(d)(3), (7). In other words the quality controls for

1 drugs ensure that the clinical trial results for the drug may be properly extrapolated  
2 to subsequent lots of the *same drug*.

3 46. By contrast, FDA does not review dietary supplements before (or  
4 even after) they are marketed to the public. Thus, there can be no assurance that  
5 dietary supplements are safe and effective for their labeled and advertised uses.  
6 Moreover, FDA does not verify that a dietary supplement is labeled properly, or  
7 that it has the identity, strength, quality, or purity claimed before (or after) it is  
8 marketed. Further, dietary supplements are subject to less stringent manufacturing  
9 controls than drugs. *Compare* Cal. Health & Safety Code § 110105 (adopting 21  
10 C.F.R. pts. 210, 211 (drug good manufacturing practices)) *to* 21 C.F.R. pt. 111  
11 (dietary supplement good manufacturing practices). Thus, the identity, strength,  
12 quality and purity of a dietary supplement may not be accurately labeled and may  
13 vary from lot to lot.

14 47. Therefore, even if the labeling of a drug and a dietary supplement  
15 suggested that the products had identical formulations (which is not the case here),  
16 there would be no way of knowing—short of well-controlled and scientifically  
17 rigorous head-to-head testing—whether any given lot of a dietary supplement  
18 actually has the advertised identity, strength, quality, or purity, and thus whether  
19 that lot has the same safety and efficacy profile as the drug. And, in all likelihood,  
20 given the less stringent manufacturing and quality controls that apply to dietary  
21 supplements, it would not.

22 48. Manufacturing controls are particularly important for omega-3  
23 products because omega-3 fatty acids are highly prone to oxidation (spoilage  
24 typically evidenced by a fishy smell) that is believed to convert their antioxidant  
25 properties to pro-oxidant properties resulting in the potential for reduced efficacy,  
26 or even negative effects on health. *See, e.g.,* Preston Mason & Samuel C.R.  
27 Sherratt, *Analysis of Omega-3 Fatty Acid Dietary Supplements With Respect to*  
28 *Content: Are They Appropriate for Patients?* J. MANAGED CARE & SPECIALTY

1 PHARMACY (2015), submitted herewith as Exhibit 15; Rufus Turner, Carlene H.  
2 McLean, & Karen M. Silvers, *Are the Health Benefits of Fish Oils Limited by*  
3 *Products of Oxidation?*, 19 NUTRITION RESEARCH REVIEWS 53 (2006),  
4 [https://www.cambridge.org/core/journals/nutrition-research-reviews/article/are-](https://www.cambridge.org/core/journals/nutrition-research-reviews/article/are-the-health-benefits-of-fish-oils-limited-by-products-of-oxidation/BBEF89FBEB4252126BCBDFDCCC8D0FCE)  
5 [the-health-benefits-of-fish-oils-limited-by-products-of-](https://www.cambridge.org/core/journals/nutrition-research-reviews/article/are-the-health-benefits-of-fish-oils-limited-by-products-of-oxidation/BBEF89FBEB4252126BCBDFDCCC8D0FCE)  
6 [oxidation/BBEF89FBEB4252126BCBDFDCCC8D0FCE](https://www.cambridge.org/core/journals/nutrition-research-reviews/article/are-the-health-benefits-of-fish-oils-limited-by-products-of-oxidation/BBEF89FBEB4252126BCBDFDCCC8D0FCE), submitted herewith as  
7 Exhibit 16; *Supplements and Safety*, PBS: FRONTLINE (Jan. 19, 2016) at 39:30,  
8 <http://www.pbs.org/video/frontline-supplements-and-safety/> (last accessed Oct. 26,  
9 2018) (discussing the difference between FDA-approved omega-3 drug products  
10 and fish oil dietary supplements, and related negative effects of oxidized lipids in  
11 fish oil).

12 49. Moreover, the REDUCE-IT results cannot be extrapolated to  
13 Coromega's omega-3 dietary supplements because they have wholly and  
14 materially different fatty acid compositions, dosages, and dosage forms (i.e.,  
15 capsule versus liquid emulsion), as well as additional ingredients. As mentioned,  
16 Vascepa is purified EPA dosed at 4 grams per day in capsule form. The Coromega  
17 products, by contrast, contain combinations of EPA, DHA, and other omega-3 fatty  
18 acids; their dosages range from 650 mg per day to 2,400 mg (or 2.4 grams) per  
19 day; they are in liquid emulsion form; and they contain multiple other ingredients.  
20 *Compare, e.g., Coromega Original Squeeze*, Exhibit 6, 0093 with Vascepa® Full  
21 Prescribing Information, Exhibit 2.

22 50. Nor can the results of REDUCE-IT be extrapolated from the diseased  
23 population studied to healthy populations with Coromega's products, as Coromega  
24 wrongly claims, particularly because the diseased population in the REDUCE-IT  
25 trial was taking Vascepa with statins, another drug.

26 51. Additionally, it is false and misleading for Coromega to appropriate  
27 the results of the Vascepa study when marketing products designed specifically for  
28 children, as the REDUCE-IT study only studied the effects of EPA on adults.

1 Coromega aggressively markets both omega-3 supplements specifically intended  
2 for children and standard omega-3 supplements for use by whole families,  
3 including children. *See, e.g., Coromega Kids Omega-3 Squeeze*, Exhibit 6, at  
4 0090–91 ; *Shop: Coromega Family*, Exhibit 6, at 0084–91 (“Introducing Omega-3  
5 squeeze shots for anyone in the family . . . enjoy the countless health benefits.”).

6 52. Even Coromega’s claim that implies that 4 grams per day of EPA  
7 helps at risk patients reduce cardiovascular events is false and misleading. As  
8 explained above, the REDUCE-IT results cannot be extrapolated to all products  
9 dosed at 4 grams of EPA per day (assuming they exist) given the number of  
10 potential confounding factors that may be present in such products—e.g., whether  
11 the product is a drug or dietary supplement, whether the product contains other  
12 omega-3 fatty acids or other ingredients, or whether the product is taken with  
13 statins.

14 53. Upon information and belief, Coromega is aware that the REDUCE-  
15 IT results cannot be extrapolated to its products, and that as a result, its advertising  
16 is false and misleading.

17 54. The Federal Trade Commission (“FTC”), in its 2001 guide for  
18 advertising dietary supplements, specifically advised dietary supplement  
19 companies that “[c]laims that do not match the science, no matter how sound that  
20 science is, are likely to be unsubstantiated” and thereby false and misleading.  
21 DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, FEDERAL TRADE  
22 COMMISSION 16 (2001) [https://www.ftc.gov/system/files/documents/plain-](https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf)  
23 [language/bus09-dietary-supplements-advertising-guide-industry.pdf](https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf), submitted  
24 herewith as Exhibit 17. The FTC also specifically recognized that promotional  
25 claims for dietary supplements “do not match the science” when the research was  
26 conducted on a product that differs from the dietary supplement—with regard to  
27 the dosage, the formulation, additional ingredients, and the study population.  
28

1           55. FDA also has confirmed that formulation, serving size, route of  
2 administration, length of exposure, frequency in exposure, whether one product  
3 contains additional ingredients, study population, and regulated product type (e.g.,  
4 conventional food compared to a dietary supplement) all affect the accuracy of  
5 claims made comparing a studied ingredient with an advertiser's product. *See*  
6 *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under*  
7 *Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act*, U.S. FOOD &  
8 DRUG ADMIN. (Dec. 2008),  
9 [https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinform](https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm)  
10 [ation/dietarysupplements/ucm073200.htm](https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm), submitted herewith as Exhibit 18.

11           56. Using the results from a study involving a purified EPA product to  
12 support the safety and efficacy of a different omega-3 product (or indeed, a line of  
13 omega-3 products), as Coromega is doing, is false and misleading when the  
14 advertised products have different fatty acid compositions (EPA, DHA, and other  
15 fatty acid ratios), different dosages, different dosage forms, and different  
16 ingredients, as they do here. These differences are not small nor immaterial.  
17 Indeed, FDA treats drugs with different omega-3 fatty acid compositions as having  
18 wholly different active ingredients. *See* Dormer Letter, Exhibit 3.

19           57. Additionally, for the same reasons, it is false and misleading for  
20 Coromega to use the results of the JELIS trial to suggest that omega-3 products  
21 sold in lower doses than Vascepa are effective in reducing the risk of  
22 cardiovascular events in the general population. The JELIS trial involved a 1.8  
23 mg/day purified EPA product that is not available in the United States, and the  
24 product was studied in a Japanese population receiving statin therapy that was at  
25 high risk for cardiovascular events. The JELIS trial results cannot be extrapolated  
26 to Coromega's omega-3 products because the product used in the JELIS study is  
27 materially different from Coromega's products in that, among other things, it  
28 contained purified EPA whereas Coromega's products contain a mix of omega-3

1 fatty acids; the product in JELIS contained a different dosage of omega-3 than  
2 Coromega’s products; the product in JELIS was in a different dosage form than  
3 Coromega (i.e., capsule versus liquid emulsion); the product in JELIS did not  
4 contain additional active ingredients, such as pasteurized egg yolk and stevia leaf  
5 extract, which are found in Coromega’s products; and the population studied in  
6 JELIS was a statin-treated Japanese population (which typically has a higher  
7 baseline blood level of EPA, due to higher consumption of fish, than populations in  
8 the U.S.) at high risk for cardiovascular events. *See* Mitsuhiro Yokoyama et al.,  
9 *Effects of Eicosapentaenoic Acid on Major Coronary Events in*  
10 *Hypercholesterolaemic Patients (JELIS): A Randomized Open-label Blinded*  
11 *Endpoint Analysis*, 369 LANCET 1090 (2007), submitted as Exhibit 19.

12 58. Finally, upon information and belief, the fifth Coromega statement  
13 identified above—“Break out your spy glass and look at the serving size to make  
14 sure you don’t need to take 10 pills, wasting piles of money in the process, just to  
15 get the recommended dosage stated by the FDA, recommending 3000mg as of  
16 2017. For many brands, 3000mg is about 3-4 pills. Coromega MAX squeezes are  
17 2400mg per serving!”—is literally false. *The Quality of Your Fish Oil Matters*,  
18 Exhibit 9. To Amarin’s knowledge, the FDA has made no such recommendation.

19 59. In fact, to the contrary, FDA has stated that it considers “any label or  
20 labeling suggesting that suggesting a level of omega-3 fatty acids to be useful in  
21 achieving a reduction in the risk of CHD for the general healthy population to be  
22 false and misleading under Section 403(a) of the Act” because scientific evidence  
23 regarding dose relationships are inconclusive. *Letter Responding to Health Claim*  
24 *Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and*  
25 *Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401)*, FDA.GOV  
26 (Sept. 8, 2004), [http://wayback.archive-](http://wayback.archive-it.org/7993/20171114183727/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072932.htm)  
27 [it.org/7993/20171114183727/https://www.fda.gov/Food/IngredientsPackagingLab](http://wayback.archive-it.org/7993/20171114183727/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072932.htm)  
28 [eling/LabelingNutrition/ucm072932.htm](http://wayback.archive-it.org/7993/20171114183727/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072932.htm), submitted herewith as Exhibit 20.

1 Amarin is not aware of any scientific evidence establishing a dose relationship  
2 between omega-3 dietary supplements and any other health benefit either.

3 60. Coromega’s false and misleading statements regarding the efficacy of  
4 its omega-3 dietary supplements is particularly concerning from a public health  
5 perspective in light of the fact that the company does not appear to disclose any  
6 information regarding the potential risks associated with the products. Indeed, the  
7 FDA-approved labeling for Vascepa as well as the FDA-approved labeling for  
8 Lovaza, a competing omega-3 drug, contain warnings and disclosures, as  
9 applicable, regarding the facts that (1) omega-3 products may prolong bleeding  
10 time (particularly in conjunction with drugs affecting coagulation), (2) omega-3  
11 products may increase liver enzyme levels in people with poor liver function, and  
12 (3) omega-3 products that contain DHA may increase bad cholesterol and lead to  
13 more frequent recurrences of atrial fibrillation. *See Vascepa® Full Prescribing*  
14 *Information*, Exhibit 2; *Lovaza Full Prescribing Information*,

15 [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Lovaza/pdf/LOVAZA-PI-PIL.pdf](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Lovaza/pdf/LOVAZA-PI-PIL.pdf), submitted herewith as Exhibit

16 21.

17  
18 ***ii. Coromega’s Claims that Its Omega-3 Products Are Comparable or***  
19 ***Superior to Amarin’s Vascepa Prescription Drugs Are False and***  
20 ***Misleading.***

21 61. Coromega also makes a number of claims that falsely express or  
22 imply that Coromega’s Omega-3 products are comparable to or superior to  
23 Amarin’s prescription Vascepa product and/or other omega-3 products. These  
24 include:

- 25 - “Thanks to results from Amarin’s Reduce-It clinical study, we have great  
26 news on how omega-3s can positively affect those at risk for heart attack and  
27 stroke.” *See Error! Hyperlink reference not valid.* Coromega Press Release,  
28 Exhibit 4, at 0071.

- 1 - “25% risk reduction in at-risk patients for cardiac events with 4 grams of  
2 EPA per day. Dose matters!” *Id.*
- 3 - “Clinically proven to be 3X more effective than standard fish oil pills and  
4 gummies.” COROMEGA, <https://www.coromega.com/> (last visited Oct. 26,  
5 2018), submitted herewith as Exhibit 22.
- 6 - “Our product Coromega Max has a powerful 2,400mg of Omega-3 fatty  
7 acids including both DHA and EPA. This proves to be an optimal amount  
8 for maximum health benefits for the heart, body and mind.” Coromega  
9 Press Release, Exhibit 4.

10 62. The first, second, and last claims are false and misleading because  
11 they convey that Coromega’s line of omega-3 products, such as its high-  
12 concentrate Coromega Max product, are comparable or superior to Amarin’s  
13 Vascepa, when they are not.

14 63. On information and belief, Coromega has no reliable studies  
15 supporting the extrapolation of the REDUCE-IT results to Coromega’s omega-3  
16 “dietary supplements.” As explained above, the results of REDUCE-IT cannot be  
17 extrapolated from the tested Vascepa prescription product to Coromega’s omega-3  
18 products, or to omega-3 dietary supplements generally because of numerous  
19 confounding factors.

20 64. For the same reasons, the first, second, and last claims cited above, or  
21 any similar claims suggesting that Coromega’s omega-3 “dietary supplements” are  
22 somehow comparable or superior to Vascepa, or any prescription drug with a  
23 materially different omega-3 fatty acid composition and dosage (among other  
24 things), are false and misleading.

25 65. In addition, the third claim cited above – stating that Coromega’s  
26 emulsified oil supplements are “[c]linically proven to be 3X more effective than  
27 standard fish oil pills and gummies” falsely and misleadingly expresses that  
28 Coromega’s emulsified oil packets have been “clinically proven” to be more



1 effective than other fish oil dietary supplements. That claim (especially when read  
2 with the other claims cited above), upon information and belief, misleads  
3 consumers to believe that Coromega’s products are more effective than all omega-  
4 3 pills, including omega-3 prescription drugs like Vascepa (even though omega-3  
5 prescription drugs are not standard fish oil pills). The study Coromega relies on to  
6 support this statement is scientifically unreliable, as only ten individuals were  
7 tested, only a single dose was provided, and effects were only observed for 48  
8 hours. *See* Susan K. Raatz et. al, *Enhanced Absorption of Omega-3 Fatty Acids*  
9 *From Emulsified Compared With Encapsulated Fish Oil*, 109 J. AM. DIET ASSOC.  
10 1076 (abstract) (2009) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2701654/>.  
11 Submitted herewith as Exhibit 23.

12 66. On information and belief, Coromega has no reliable scientific  
13 evidence to support its contention that its products are comparable or superior to  
14 Vascepa in reducing cardiovascular risk, “for heart, body, and mind,” or indeed  
15 regarding any other health effect. Nor, on information and belief, does Coromega  
16 have evidence to support its claims that it is clinically proven to be more effective  
17 than other omega-3 *dietary supplements* on the market.

18 67. Significantly, Coromega’s false and misleading statements that its  
19 “dietary supplements” are comparable to, or superior than, Vascepa are particularly  
20 concerning from a public health perspective in light of the fact that the company  
21 does not disclose any information regarding the potential risks associated with  
22 Coromega’s omega-3 dietary supplements products, which when taken at doses  
23 similar to Vascepa may have similar risks.

24 **B. Coromega’s Violation of the Sherman Law’s Drug Approval Provisions**

25 68. Coromega is making a number of disease claims—claims that express  
26 or imply that its omega-3 dietary supplements treat or prevent cardiovascular  
27 disease, and claims that express or imply that its omega-3 dietary supplements are  
28 comparable to prescription drugs that treat or prevent disease, such that they may

1 be used as substitutes. Examples of these claims include:

- 2 - “Thanks to results from Amarin’s Reduce-It clinical study, we have great  
3 news on how omega-3s can positively affect those at risk for heart attack and  
4 stroke.” Coromega Press Release, Exhibit 4, at 0071.
- 5 - ““25% risk reduction in at-risk patients for cardiac events with 4 grams of  
6 EPA per day. Dose matters!”” *Id.*
- 7 - “Both acids lower triglyceride issues, reduce inflammation, and have blood-  
8 thinning effects—all of which, in turn, can reduce the risk of future heart  
9 disease.” *Id.*, at 0072.

10 69. As discussed, the Sherman Law defines “drug” to include any product  
11 that is “used or intended for use in the diagnosis, cure, mitigation, treatment, or  
12 prevention of disease.” Cal. Health & Safety Code § 109925. FDA’s definition of  
13 “drug” is almost identical to the Sherman Law’s definition: under both statutes,  
14 disease claims render purported dietary supplements “drugs,” subject to all of the  
15 rigorous requirements that accompany that designation. *Compare* 21 U.S.C. §  
16 321(g) *to* Cal. Health & Safety Code § 109925. The federal agency’s regulations  
17 at 21 C.F.R. § 101.93(g) provide examples of the types of claims that constitute  
18 “disease” claims that subject purported dietary supplements to the drug approval  
19 processes. 21 C.F.R. § 101.93(g). These claims include those that explicitly, or  
20 implicitly, indicate that the purported dietary supplement, among other things: (1)  
21 has an effect on “a specific disease or class of diseases,” 21 C.F.R. §  
22 101.93(g)(2)(i); (2) has an effect on “the characteristic signs or symptoms of a  
23 specific disease or class of diseases,” *id.* § 101.93(g)(2)(ii); or (3) “[i]s a substitute  
24 for a product that is a therapy for a disease,” *id.* § 101.93(g)(2)(vi). In addition, the  
25 Sherman Law expressly incorporates “[a]ll regulations relating to . . . new drug  
26 applications . . . adopted pursuant to Section 505” of the Federal Food, Drug and  
27 Cosmetic Act (“FDCA”). Cal. Health & Safety Code 110110(a).

28 70. The claims listed above expressly or impliedly indicate that

1 Coromega’s omega-3 dietary supplements treat or prevent cardiovascular disease  
2 and/or can be used as a substitute for Vascepa, a prescription drug that treats and  
3 prevents disease. Thus, these claims are “disease” claims that render Coromega’s  
4 omega-3 dietary supplements unapproved drugs.

5 71. The last claim listed above additionally implies that Coromega’s  
6 omega-3 products treat inflammation, lower triglycerides, and have blood thinning  
7 effects. Notably, anti-inflammatory claims, like cardiovascular disease claims, are  
8 “disease” claims, as are triglyceride lowering claims. *See, e.g.*, FDA Warning  
9 Letter to Y.S. Health Corp., FDA.GOV (Aug. 29, 2013),  
10 [https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm36783](https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm367832.htm)  
11 [2.htm](https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm367832.htm), submitted herewith as Exhibit 24 (citing the claim “[i]t supports . . . the  
12 body’s natural anti-inflammatory response” as a “disease” claim that triggers  
13 unapproved drug status); *Letter from FDA to Dr. Dunbar*, FDA.GOV (Nov. 10,  
14 2016), submitted herewith as Exhibit 25 (“The intended use of a product  
15 determines whether the product fits within the drug definition. Based on the  
16 materials you provided, the second phase of your study is designed to evaluate  
17 (among other endpoints) the comparative ability of these two oils to lower  
18 triglycerides after meals. Because elevated postprandial triglyceride levels are  
19 associated with cardiovascular disease, these oils are considered to be drugs for the  
20 purpose of the study”).

21 72. In addition, the last claim’s reference to “blood-thinning effects” is  
22 also a disease claim because it implies that omega-3 prevents blood clots, a  
23 characteristic cause of heart attacks and strokes and artery and vein blockages. *See*  
24 *Blood Thinners*, MEDLINE PLUS, U.S. NATIONAL LIBRARY OF MEDICINE,  
25 <https://medlineplus.gov/bloodthinners.html> (last visited Oct. 26, 2018), submitted  
26 herewith as Exhibit 26. Blood thinners are well known types of prescription drugs,  
27 and the last claim identified above impliedly suggests that omega-3 may be a  
28 substitute for these therapies.

1 73. As discussed, California’s Sherman Law provides that “[n]o person  
2 shall sell, deliver, or give away any new drug” that has not been approved by FDA  
3 or by the State of California. Cal. Health & Safety Code § 111550(a)–(b).

4 74. Coromega is violating California’s Sherman Law because, despite  
5 advertising and marketing its omega-3 products with “disease” claims rendering  
6 those products “drugs,” upon information and belief, it has not obtained the  
7 approval of either the State of California or FDA to introduce any of the drugs that  
8 it is manufacturing, marketing, and/or selling, such as Coromega Max, into  
9 commerce. *See id.* § 111550(a)–(b).

10 **C. Coromega’s Activities Violate the Lanham Act’s Prohibition on False or**  
11 **Misleading Descriptions or Representations of Fact**

12 75. The Lanham Act protects those engaged in commerce from unfair  
13 competition by the use of false or misleading descriptions of fact, or false or  
14 misleading representations of fact, in commercial advertising or promotion. 15  
15 U.S.C. § 1125(a)(1).

16 76. The Lanham Act creates a cause of action against “[a]ny person who,  
17 on or in connection with any goods or services . . . uses in commerce any . . . false  
18 or misleading description of fact, or false or misleading representation of fact,  
19 which . . . is likely to cause confusion, or to cause mistake, or to deceive as to the  
20 . . . approval of his or her goods, services, or commercial activities by another  
21 person, or . . . in commercial advertising or promotion, misrepresents the nature,  
22 characteristics [or] qualities . . . of his or her . . . goods, service, or commercial  
23 activities.” 15 U.S.C. § 1125(a).

24 77. Coromega is violating the Lanham Act because its advertising and  
25 promotion for its omega-3 dietary supplements is materially misleading to  
26 consumers. Coromega “misrepresents the nature, characteristics [or] qualities” of  
27 its omega-3 dietary supplements and deceives consumers into believing that  
28 Coromega’s omega-3 products are effective at treating or preventing

1 cardiovascular disease, that they are comparable to pharmaceutical drugs like  
2 Vascepa when that is not the case, and that there is some FDA-sanctioned  
3 recommended dose for omega-3 dietary supplements when there is not.

4       78. Coromega's false and misleading advertising and promotion is  
5 material and reasonably relied on by consumers. On information and belief, these  
6 representations have caused, and are likely to continue to cause, consumers to  
7 purchase Coromega's omega-3 products instead of consulting with their physicians  
8 and purchasing Amarin's pharmaceutical drug, Vascepa, when medically  
9 necessary. Coromega's omega-3 products can be purchased at pharmacies, big box  
10 stores, and over the Internet, without restriction. By contrast, Vascepa can only be  
11 distributed pursuant to a prescription. Thus, as a result of Coromega's misleading  
12 advertising, which states that its products are equally or more effective at treating  
13 cardiovascular disease, consumers have purchased Coromega's omega-3 products  
14 rather than seeking appropriate medical care, which may include Vascepa, to treat  
15 their cardiovascular symptoms.

16       79. On information and belief, but for Coromega's false and misleading  
17 statements, sales of Vascepa would displace a significant percentage of  
18 Coromega's sales of its omega-3 products in the direct-to-consumer channel of  
19 distribution because consumers would seek prescriptions for Vascepa and other  
20 FDA-approved triglyceride-lowering drugs. And in the absence of Coromega's  
21 actions, sales of Vascepa or other FDA-approved prescription triglyceride-  
22 lowering drugs would likely displace all of Coromega's sales of its omega-3  
23 products in the physician prescription channel of distribution.

24       80. If consumers knew the truth about Coromega's dietary supplements,  
25 they would not purchase Coromega's products and would consult with their  
26 physicians to determine whether they have a medical condition or disease that  
27 would benefit from an FDA-approved therapy, rather than taking serious health  
28 matters into their own hands with purported dietary supplements that are actually

1 unproven drugs.

2 81. Although the FDA and the State of California both have authority to  
3 bring similar cases against Coromega, *see, e.g.*, 21 U.S.C. §§ 355, 331; Cal. Health  
4 & Safety Code § 11840, that authority does not preclude Amarin’s action.

5 82. Coromega’s false or misleading statements were made in interstate  
6 commerce.

7 83. Amarin has suffered and will continue to suffer irreparable harm and  
8 actual damages as a result of Coromega’s unfair competition and false advertising,  
9 including but not limited to reputational harm in that Amarin’s product is being  
10 unfairly associated in the marketplace with unapproved drugs marketed with  
11 unproven statements and the cost of corrective advertising to address this unfair  
12 association.

13 **D. Coromega’s Activities Violate the False Advertising Provisions of the**  
14 **Sherman Law.**

15 84. The Sherman Law makes it unlawful for anyone to “disseminate any  
16 false advertisement [about] any . . . drug,” and “[a]n advertisement is false if it is  
17 false or misleading in any particular.” Cal. Health & Safety Code § 110390. “In  
18 determining whether the labeling or advertisement of a . . . drug . . . is misleading,  
19 all representations made or suggested by statement, word, design, device, sound, or  
20 any combination of these, shall be taken into account.” *Id.* § 110290. “The extent  
21 that the labeling or advertising fails to reveal facts concerning” the drug “shall also  
22 be considered.” *Id.*

23 85. Coromega is violating the Sherman Law because the advertising and  
24 promotional materials for its unapproved drugs, which are manufactured and  
25 marketed under the guise of being dietary supplements (e.g., its line of omega-3  
26 dietary supplements), are misleading to California consumers.

27 86. Coromega makes false and misleading statements in its promotional  
28 materials to consumers that lead consumers into believing that Coromega’s omega-

1 3 products are effective at treating or preventing cardiovascular disease and are  
2 comparable to pharmaceutical drugs like Vascepa—when that is not the case.

3 87. Coromega also makes false and misleading statements in its  
4 promotional materials and that there is some FDA-sanctioned recommended dose  
5 for omega-3 dietary supplements, when that is not the case.

6 **CLAIMS FOR RELIEF**

7 **FIRST CLAIM FOR RELIEF**

8 Violation of the Lanham Act

9 (15 U.S.C. § 1051, et seq.)

10 88. Amarin realleges and incorporates by reference each and every  
11 allegation set forth above as if fully stated herein.

12 89. Coromega’s practices, as described in this Complaint, constitute  
13 unfair competition and false advertising in violation of the Lanham Act, 15 U.S.C.  
14 § 1125(a).

15 90. Coromega has violated the Lanham Act by using “false or misleading  
16 descriptions of fact” and “false or misleading representations of fact” in its  
17 commercial advertising or promotion that “misrepresent[] the nature,  
18 characteristics, [or] qualities” of its products, as set forth above. These include (by  
19 way of example only) its promotion of its omega-3 dietary supplements as  
20 effective at treating or preventing cardiovascular disease, its promotion of its  
21 products as comparable to Amarin’s prescription drug product, Vascepa, and its  
22 statements about an FDA-sanctioned dose of omega-3 in dietary supplements.

23 91. Coromega has violated the Lanham Act by making false and  
24 misleading statements about its products, by: (1) making unsupported and false or  
25 misleading claims about product efficacy, both comparatively and absolutely; (2)  
26 making unsupported disease treatment claims; and (3) presenting its products  
27 under the false guise of “dietary supplements” while illegally promoting the  
28 products with drug treatment claims.

1 92. Amarin has suffered irreparable reputational harm, injury in fact, and  
2 actual damages resulting from Coromega’s false and misleading advertising and  
3 promotion and unfair competitive practices, including but not limited to the cost of  
4 corrective advertising needed to counter Coromega’s false and misleading  
5 advertising.

6 93. Amarin seeks disgorgement of Coromega’s profits and injunctive  
7 relief requiring Coromega to cease its false and misleading advertising and  
8 promotion and unfair competitive practices.

9 **SECOND CLAIM FOR RELIEF**

10 Violation of California’s Unfair Competition Law (UCL)

11 (Cal. Bus. & Prof. Code §17200, et. seq.)

12 94. Amarin realleges and incorporates by reference each and every  
13 allegation set forth above as if fully stated herein.

14 95. Coromega’s practices, as described in this complaint, constitute  
15 unlawful and/or unfair business practices in violation of California’s UCL, Cal.  
16 Bus. & Prof. Code, § 17200, *et seq.*

17 96. Coromega’s omega-3 products, marketed as “dietary supplements,”  
18 are “drugs” under California and federal law, namely Health & Safety Code  
19 sections 109925(b) –(c), 110110, and 21 U.S.C. § 321(g)(1) and 21 C.F.R. §  
20 310.527(a), because they are intended to cure, mitigate, treat, or prevent disease  
21 and are promoted by Coromega for these purposes and used by consumers in  
22 California for these purposes.

23 97. Coromega’s products are “new drugs” under California law, namely  
24 Health & Safety Code section 109980 , and 21 U.S.C. § 321(p)(1) and 21 C.F.R. §  
25 310.527(a), as incorporated by Health & Safety Code section 110110, because they  
26 are not generally recognized by qualified experts as safe and effective for their  
27 intended uses.

28



1 98. Coromega’s products have not been approved by FDA or by the  
2 California Department of Health Services as required by 21 U.S.C. § 355 *et seq.*,  
3 and Health & Safety Code sections 111550(a)–(b).

4 99. Coromega has violated the UCL by unlawfully marketing, selling, and  
5 distributing its products in violation of the California Sherman Law.

6 100. Coromega has also violated the UCL by unlawfully marketing and  
7 distributing its products in violation of the Sherman Law’s false advertising  
8 provisions.

9 101. Coromega’s practices as alleged in this Complaint constitute unfair  
10 business practices in violation of the UCL because they are substantially injurious  
11 to consumers and any utility of such practices is outweighed by the harm to  
12 consumers. Coromega’s practices violate California’s legislative policy of  
13 protecting patients and consumers by prohibiting the marketing, sale, and  
14 distribution of Coromega’s omega-3 products as drugs when such products have  
15 not been approved by FDA or the California Department of Health Services.  
16 Coromega’s practices have caused and are causing substantial injuries to Amarin  
17 and the public. Those injuries are not outweighed by any benefits.

18 102. Amarin has suffered irreparable reputational harm, injury in fact, and  
19 actual damages because of Coromega’s unlawful and unfair business practices.

20 103. Amarin seeks declaratory and injunctive relief requiring Coromega to  
21 cease the unlawful actions and misconduct alleged.

22 **PRAYER FOR RELIEF**

23 WHEREFORE, Amarin respectfully requests that this Court enter judgment  
24 in its favor as follows:

25 1. A permanent injunction prohibiting Coromega from continuing the  
26 unlawful and unfair practices alleged in this Complaint.

27 2. A judgment that Coromega violated the Lanham Act, 15 U.S.C. §  
28 1051, *et seq.*;

1           3.     A judgment that Coromega violated California Business and  
2 Professions Code section 17200, et seq.;

3           4.     Damages, corrective advertising costs, profits and other monetary  
4 relief according to proof;

5           5.     Declaratory relief;

6           6.     Attorneys' fees and costs incurred in this action;

7           7.     Prejudgment interest; and

8           8.     Any further relief the Court may deem just and proper.

9                           **REQUEST FOR JURY TRIAL**

10           Amarin demands a trial by jury on all claims and issues so triable.

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DATED: October 29, 2018

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