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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

AMARIN PHARMA, INC. AND AMARIN PHARMACEUTICALS IRELAND, LTD.

Plaintiffs,

v.

COROMEGA HEALTH, INC.,

Defendant.

Case No. '18CV2481 BEN NLS

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

DEMAND FOR JURY TRIAL

Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland, Ltd. ("Amarin") bring this action against The Coromega Company, Inc. ("Coromega") and allege the following:

NATURE OF ACTION

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

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

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

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

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

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

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

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

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

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

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

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

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

11. Coromega's press release falsely and misleadingly stated, for example: "Thanks to results from Amarin's Reduce-It clinical study, we have great news on how omega-3s can positively affect those at risk for heart attack and stroke." *See Breaking News: High EPA Omega-3 Proving to Decrease Heart Attack Risk*, THE SQUEEZE (Oct. 3, 2018) (hereinafter "Coromega Press Release"), 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 misleadingly states that "[o]ur product Coromega Max has a powerful 2,400mg of Omega-3 fatty acids including both DHA and EPA. This proves to be an optimal amount for maximum health benefits for the heart, body and mind." *Id.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21. Amarin has suffered and is suffering from competitive injuries as a result of Coromega's unlawful activities. Amarin's drug, Vascepa, competes with Coromega's omega-3 line of products, which 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.

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

PARTIES

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

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

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

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

JURISDICTION

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

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

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

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.

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

34. Coromega's website advertises Omega-3 Squeeze for "anyone in the family," with a picture of a mother holding a child. *See Shop: Coromega Family*, COROMEGA, https://www.coromega.com/shop?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE (last visited Oct. 26, 2018), Exhibit 6, at 0084. The labeling for the product indicates that it is for adults and children over the age of 4. *See Shop: Coromega Original Squeeze*, COROMEGA, https://www.coromega.com/product-page/super-value-bag?gclid=EAIaIQobChMI0Je56aKL3gIVyYSzCh2KbQ9BEAAYASAAEgJYuvD_BwE (last visited Oct. 26, 2018), Exhibit 6, at 0093. Coromega Max Citrus Burst and Coromega Max Coconut Bliss have labeling indicating that the products are for adults and children over the age of 4 as well. *See Shop Coromega Max Citrus Burst*, COROMEGA, 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 Women's Health Omega-3 Fish Oil +D is not fully visible on the website, upon information and belief, the labeling indicates that the product may be taken by adults and children over the age of 4. The full labeling of Coromega Omega-3 Mango Squeeze and Coromega Omega-3 Kids are not fully visible on Coromega's website, but based on the websites of third party vendors, these products also have labels indicating that the products are suitable for adults and children over the age of 4. *See Coromega Big Squeeze Omega-3 Mango Nectar*, VITACOST, https://www.vitacost.com/coromega-big-squeeze-omega-3-mango-nectar-16-fl-oz?csrc=BPA&utm_campaign=Shopping_Campaign_RLSA&utm_medium=cpc&

utm_source=bing&mtp=iEH4v0hUdc%7cpcrid%7c13752925770&msclkid=472b583d4e491dc8c67403ecb407e61a&utm_term=1100505165491&utm_content=Vitamins%20%26%20Supplements&gclid=CKmguI2Mot4CFUWkgQodjGQL7w&gclsrc=ds (last visited Oct. 26, 2018); *Coromega Omega 3 Kids Tropical Orange*, VITACOST, https://www.vitacost.com/coromega-omega-3-kids?csrc=BPA-&utm_campaign=Shopping_Campaign_RLSA&utm_medium=cpc&utm_source=bing&mtp=DcVEMlUbdc%7cpcrid%7c13752925770&msclkid=80c9b8c63c2e188132fee31563f45cdf&utm_term=1100505165430&utm_content=Vitamins%20%26%20Supplements&gclid=CLjEh4vhpN4CFUfSDQod9IsJ9g&gclsrc=ds (last visited Oct. 26, 2018), Exhibit 6, at 0089, 0091.

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

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

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

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

i. Coromega's Unsubstantiated Cardiovascular Treatment and Prevention Claims Are False and Misleading.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PHARMACY (2015), submitted herewith as Exhibit 15; Rufus Turner, Carlene H. McLean, & Karen M. Silvers, *Are the Health Benefits of Fish Oils Limited by Products of Oxidation?*, 19 NUTRITION RESEARCH REVIEWS 53 (2006), 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 Exhibit 16; *Supplements and Safety*, PBS: FRONTLINE (Jan. 19, 2016) at 39:30, http://www.pbs.org/video/frontline-supplements-and-safety/ (last accessed Oct. 26, 2018) (discussing the difference between FDA-approved omega-3 drug products and fish oil dietary supplements, and related negative effects of oxidized lipids in fish oil).

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

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

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

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

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

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

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

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

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

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

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

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

59. In fact, to the contrary, FDA has stated that it considers "any label or labeling suggesting that 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 to be false and misleading under Section 403(a) of the Act" because scientific evidence regarding dose relationships are inconclusive. *Letter Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401)*, FDA.GOV (Sept. 8, 2004), http://wayback.archive-it.org/7993/20171114183727/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072932.htm, submitted herewith as Exhibit 20.

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

60. Coromega's false and misleading statements regarding the efficacy of its omega-3 dietary supplements is particularly concerning from a public health perspective in light of the fact that the company does not appear to disclose any information regarding the potential risks associated with the products. Indeed, the FDA-approved labeling for Vascepa as well as the FDA-approved labeling for Lovaza, a competing omega-3 drug, contain warnings and disclosures, as applicable, regarding the facts that (1) omega-3 products may prolong bleeding time (particularly in conjunction with drugs affecting coagulation), (2) omega-3 products may increase liver enzyme levels in people with poor liver function, and (3) omega-3 products that contain DHA may increase bad cholesterol and lead to more frequent recurrences of atrial fibrillation. *See Vascepa® Full Prescribing Information*, Exhibit 2; *Lovaza Full Prescribing Information*, https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Lovaza/pdf/LOVAZA-PI-PIL.pdf, submitted herewith as Exhibit 21.

ii. Coromega's Claims that Its Omega-3 Products Are Comparable or Superior to Amarin's Vascepa Prescription Drugs Are False and Misleading.

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

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

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

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

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

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

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

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

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

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

B. Coromega's Violation of the Sherman Law's Drug Approval Provisions

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

be used as substitutes. Examples of these claims include:

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

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

70. The claims listed above expressly or impliedly indicate that

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

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

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

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

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

C. Coromega's Activities Violate the Lanham Act's Prohibition on False or Misleading Descriptions or Representations of Fact

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

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

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

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

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

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

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

unproven drugs.

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

82. Coromega's false or misleading statements were made in interstate commerce.

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

D. Coromega's Activities Violate the False Advertising Provisions of the Sherman Law.

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

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

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

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

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

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of the Lanham Act

(15 U.S.C. § 1051, et seq.)

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

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

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

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

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

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

SECOND CLAIM FOR RELIEF

Violation of California's Unfair Competition Law (UCL)

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

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

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

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

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

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

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

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

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

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

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

PRAYER FOR RELIEF

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

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

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

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

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

5. Declaratory relief;

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

7. Prejudgment interest; and

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

REQUEST FOR JURY TRIAL

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

DATED: October 29, 2018

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