UNITED STATES INTERNATIONAL TRADE COMMISSION

In The Matter Of	)	
	)	
Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-esterified Triglyceride Form	)	**Investigation No. 337-TA-_____**
	)	
	)	
	)	
	)	

VERIFIED COMPLAINT UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

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Date: August 30, 2017

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I. INTRODUCTION

1. Amarin Pharma, Inc. ("Amarin Pharma") and Amarin Pharmaceuticals Ireland Ltd. ("Amarin Ireland") (collectively, "Amarin" or "Complainants") file this Complaint pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337"). Amarin manufactures and markets Vascepa® capsules, a drug approved by the Food and Drug Administration ("FDA") consisting of 1 gram of eicosapentaenoic acid (the omega-3 acid commonly known as "EPA") in a 1-gram capsule. The EPA in Vascepa® is in ethyl ester form and is synthetically produced. Amarin respectfully requests that the U.S. International Trade Commission (the "ITC" or "Commission") commence an investigation into the unlawful importation or sale in the United States of synthetically produced omega-3 products that are predominantly comprised of EPA in either ethyl ester ("EE") or re-esterified ("rTG") form and are falsely labeled, and/or promoted for use as, or in "dietary supplements" (the "Synthetically Produced Omega-3 Products" (as defined with more particularity in paragraph 8, below)). **Exhibits 1-12.** These products are cloaked as "dietary supplements" but are actually unapproved "new drugs" under the Federal Food, Drug and Cosmetic Act ("FDCA"). The false labeling or promotion of these products constitutes an unfair act and/or unfair method of competition under Section 337 because, among other things, these acts violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and the standards established by the FDCA.

2. A large majority of omega-3 products that are imported or sold in the United States are legally marketed "dietary supplements" comprised of common fish oil. *See* Global Organization for EPA and DHA Omega-3s ("GOED") Blog, June 5, 2014, (noting that, for example, "[e]thyl esters represented 12% of the US dietary supplement market in 2013"), **Exhibit 13**. Common fish oil typically includes a mixture of saturated and unsaturated fats,

including a variety of omega fatty acids in their natural triglyceride ("nTG") form. *See* R. Preston Mason and Samuel C.R. Sherratt, Omega-3 fatty acid fish oil dietary supplements contain saturated fats and oxidized lipids that may interfere with their intended biological benefits, Biochemical and Biophysical Research Communications (2016), **Exhibit 14**. Common fish oil is not synthetically produced. Amarin is not alleging that the import or sale in the United States of common fish oil, *i.e.*, for use in, or as "dietary supplements," violates Section 337, or other U.S. laws *per se*, and Amarin is not requesting an investigation into the import or sale of those natural products. Nor is Amarin requesting an investigation into synthetically produced omega-3 products in EE or rTG form that are not predominantly comprised of the omega-3 acid, EPA.

3. The Synthetically Produced Omega-3 Products are being sold in the United States as ingredients for finished products, and as finished products themselves. Certain of the Proposed Respondents are selling synthetically produced omega-3 oil, or encapsulated synthetically produced omega-3 oil, *for use in or as* finished products marketed as "dietary supplements"– namely:

- Royal DSM NV ("DSM NV"), **Exhibit 1**;
- DSM Marine Lipids Peru S.A.C. ("DSM-Peru"), **Exhibit 1**;
- DSM Nutritional Products LLC in the United States ("DSM-US"), **Exhibit 1**;
- DSM Nutritional Products Canada Inc., ("DSM-Canada"), **Exhibit 1**;
- Ultimate Biopharma Corp. ("Ultimate"), **Exhibit 2**;
- Marine Ingredients AS, **Exhibit 3**;
- Marine Ingredients LLC, **Exhibit 3**;

- Golden Omega S.A., **Exhibit 4**;
- Golden Omega USA LLC, **Exhibit 4**;
- Nordic Pharma Inc., **Exhibit 5**;
- Croda Europe Ltd., **Exhibit 6**;
- Croda, Inc., **Exhibit 6**; and
- Technologica de Alimentos S.A., **Exhibit 7**

(collectively the "Manufacturers").

4. The other Proposed Respondents are selling finished products containing synthetically produced omega-3 oil *as* "dietary supplements" directly to consumers – namely:

- The Nature's Bounty Co. ("Nature's Bounty"), **Exhibit 8**;
- Nordic Naturals, **Exhibit 9**;
- Pharmavite LLC, **Exhibit 10**;
- Innovix Pharma Inc. ("Innovix Pharma"), **Exhibit 11**; and
- J. R. Carlson Laboratories ("Carlson"), **Exhibit 12**

(collectively, the "Distributors").

5. The Synthetically Produced Omega-3 Products, like Vascepa®, are derived from common fish oil. Common fish oil includes omega-3 fatty acids in their natural triglyceride form ("nTG-OM3"), such as EPA (eicosapentaenoic acid) in its natural triglyceride form ("nTG-EPA") and docosahexaenoic acid ("DHA") in its natural triglyceride form ("nTG-DHA"). Although the Synthetically Produced Omega-3 Products are derived from common fish oil, they are not the same as common fish oil. As discussed in more detail in paragraphs 42-51, typically,

common fish oil is extracted from oily fish by using physical, not chemical processes, such that no chemical bonds are broken or created.

6. Depending upon the fish from which the oil was extracted and the environmental conditions in which the fish were raised, the ratio of nTG-EPA and nTG-DHA can differ. However, typically, 30% of common fish oil by weight is nTG omega-3 fatty acids, or nTG-OM3. The remaining 70% of the oil has other constituents, most predominantly, saturated fat, other omega-3 fatty acids, and omega-6 and omega-9 fatty acids. *See* Figure 1 (below).

Figure 1. Leading Common Fish Oil Supplement with 30% nTG-OM3*

See* R. Preston Mason and Samuel C.R. Sherratt, Omega-3 fatty acid fish oil dietary supplements contain saturated fats and oxidized lipids that may interfere with their intended biological benefits, Biochemical and Biophysical Research Communications (2016), 1-5. **Exhibit 14.

7. It is not possible to produce natural marine oil with a collective concentration of nTG-EPA and nTG-DHA that is greater than approximately 30% by weight of the oil. Oils with a higher collective concentration of EPA and DHA must be chemically synthesized, *i.e.*, synthetically produced. Many of the Synthetically Produced Omega-3 Products are chemically altered to deliver heightened levels of EPA and/or DHA – well beyond the levels that are found

in nature, *see, e.g.,* **Exhibits 8-I, 9-T, 9-V, 11-A, 12-D**. Some are also chemically altered to remove less valuable or unwanted components of common fish oil, such as saturated fat. *See* Figure 2 (below).

8. Common molecular forms and mixtures of Synthetically Produced Omega-3 Products include the following:

(i) purified EPA in its ethyl ester form ("E-EPA"),

(ii) purified EPA in its re-esterified form ("rTG-EPA"),

(iii) omega-3 mixtures in their ethyl ester form ("E-OM3"), and

(ii) omega-3 mixtures in their re-esterified form ("rTG-OM3").

Amarin believes that all of the Synthetically Produced Omega-3 Products identified in this complaint contain E-EPA, rTG-EPA, E-OM3 (where E-EPA is the predominant component), or rTG-OM3 (where rTG-EPA is the predominant component). **Exhibits 8-A – 12-M**[1]; *see also* Section VII.

9. To synthesize omega-3 fatty acid mixtures, or their EPA or DHA components, from their natural triglyceride form into their ethyl ester form, the natural triglyceride molecules undergo chemical reactions. First, the glycerol backbone of each triglyceride molecule in the common fish oil is removed. Second, the resulting free fatty acids are reacted with ethanol through a process known as esterification. This ethyl ester form allows for the substantial heightening of the level of the E-EPA and/or E-DHA in the synthetically produced oil. The

[1] Throughout this document, when a range of exhibits is given, it refers to all like subparts within the given range, unless otherwise noted.

manufacturer can choose which fatty acid levels to heighten, and either to manipulate the ratio of E-EPA to E-DHA or to purify the product into E-EPA or E-DHA.

10. The differences between the complex mixture of multiple constituents that comprise common fish oil products and the various pharmacologically designed and chemically synthesized products is illustrated by comparing Figure 1 (above) to Figure 2 (below).

Figure 2. Vascepa® (Purified E-EPA)*

*Vascepa® Full Prescribing Information, **Exhibit 15** (reflecting that FDA has labeled Vascepa® 1 gram capsules as containing 1 gram of E-EPA. The capsules also contain trace amounts of inactive ingredients including, tocopherol, an anti-oxidation agent designed to protect the fragile active ingredient).

11. Vascepa®, the product highlighted in Figure 2, is the only drug approved by the FDA that contains purified E-EPA. *See* List of FDA-Approved Icosapent Ethyl (E-EPA) Drugs in Orange Book, **Exhibit 16** (icosapent ethyl is an alternate name for eicosapentaenoic acid in ethyl ester form). Vascepa® is manufactured and marketed by Amarin. There are also branded and generic FDA-approved drugs that contain omega-3 mixtures in their ethyl ester form (E-OM3). *See* List of FDA-Approved Omega-3 Ethyl Ester Drugs in the Orange Book, **Exhibit 17**. FDA has approved these drugs for use as an adjunct to diet to reduce triglyceride levels in adult

patients with severe hypertriglyceridemia. *See, e.g.*, Vascepa® Full Prescribing Information, **Exhibit 15**; Lovaza® Full Prescribing Information, **Exhibit 18**. Severe hypertriglyceridemia (too much fat in the blood) is a disease that can lead to inflammation of the pancreas, which can cause life-threatening complications. *See* Pancreatitis, Patient Care & Health Information, Mayo Clinic (accessed August 4, 2017), **Exhibit 19**. Severe hypertriglyceridemia can also raise or indicate increased risk of heart disease. *See* High Cholesterol-Medicines To Help You, FDA Website (accessed August 4, 2017) (noting that "[t]riglycerides are another form of fat in your blood that can raise your risk for heart disease"), **Exhibit 20.**

12. Since the launch of these FDA-approved drugs, companies have been increasingly falsely labeling and promoting products that contain chemically heightened levels of EPA as "dietary supplements." *See* Jennifer Grebow, Ultra-High Concentrates and the Next Omega-3, Supply Side West Report, Nutritional Outlook, Oct. 14, 2015, **Exhibit 21** ("Omega-3 suppliers . . . are now taking omega-3 concentrates for dietary supplements into near-pharmaceutical territory . . . . "); *see also* Hank Schultz, EPA-only nutraceuticals ride pharma's coattails into marketplace, NUTRA Ingredients-usa.com, Oct. 21, 2013, **Exhibit 22**. This recent free-riding is not surprising, and it is likely that it has occurred ever since E-EPA first gained recognition in the marketplace as a "drug" in the mid-1980s, as discussed in paragraphs 80-83.

13. The ethyl ester components of the FDA-approved drugs (*i.e.*, E-OM3, E-EPA, and E-DHA) can also be *further* chemically altered into the re-esterified triglyceride (rTG) form using enzymes in a chemical process called glycerolysis. Food-grade enzymes separate the ethanol molecule from the fatty acid, creating a free fatty acid ("FFA") molecule and a free ethanol molecule. When glycerol is reintroduced to the solution, the enzymes then re-esterify the

fatty acids back onto a glycerol backbone, creating re-esterified triglyceride (rTG) oil. The molecular distinctions between omega-3 fatty acids in their natural triglyceride forms (*e.g.*, nTG-OM3 and nTG-EPA), in their ethyl ester forms (*e.g.*, E-OM3 and E-EPA), and in their re-esterified forms (*e.g.*, rTG-OM3 and rTG-EPA) are further explained in paragraphs 49-50, and in Figure 3, in Section IV.

14. The Proposed Respondents are falsely labeling and/or promoting Synthetically Produced Omega-3 Products for use in, or as "dietary supplements." **Exhibits 1-B – 7-B, 8-A-ii – 12-M-ii**. As explained in paragraphs 58-105, labeling and/or promoting these products as "dietary supplements" is false because E-OM3, E-EPA, rTG-OM3, and rTG-EPA do not meet the definition of "dietary supplement" in the FDCA, 21 U.S.C. § 321(ff), and these products are actually unapproved "new drugs" under the FDCA. This false labeling and/or promotion of the Synthetically Produced Omega-3 Products constitute unfair trade practices or unfair methods of competition in violation of Section 337 because they deceive or have the capacity to deceive a substantial segment of potential consumers, and that deception is material to purchasing decisions in violation of Section 43(a) of the Lanham Act. False labeling and/or promotion also misbrands the products under the standards set forth in Section 502 of the FDCA. 21 U.S.C. § 352.

15. Moreover, such false labeling and/or promotion is unfair to Amarin and other pharmaceutical companies that have invested the necessary resources to bring competing drug products to market, and it serves as a disincentive for drug companies to invest resources in drug development in the future. In particular, falsely labeling and/or promoting products as "dietary supplements" enables the Proposed Respondents to avoid the drug approval process and the

associated time and investment necessary to conduct clinical trials to show that their products are safe and effective for each intended use and to obtain FDA approval for each intended use. *See* 21 U.S.C. § 355. Disregarding the FDA drug approval process also enables the Proposed Respondents to avoid the following: (i) limiting the indications for their products to those that have been approved by FDA, *see id.* § 355(a)*;* (ii) applicable user fee costs associated with manufacturing drugs, *id.* § 379h; and (iii) applicable costs associated with complying with FDA's drug registration, *id.* § 360, listing, *id.*, and labeling and manufacturing requirements, *id.* §§ 502(f), 501(a)(2)(B). In addition, it allows the Distributors to avoid the need to sell their products pursuant to a prescription by a licensed healthcare professional, *see id.* § 353(b).

16. Amarin has a domestic industry. Amarin specializes in developing effective therapies, approved by FDA, to treat disease, with a focus on hypertriglyceridemia and cardiovascular disease. Amarin developed Vascepa®, a prescription drug that lists icosapent ethyl as the drug's active pharmaceutical ingredient ("API") – legally – by investing the necessary resources to conduct clinical trials to show that the drug is safe and effective. Amarin then obtained FDA approval for the drug. *See* List of FDA-Approved Icosapent Ethyl Drugs (E-EPA) in Orange Book, **Exhibit 16**. Icosapent ethyl, Vascepa®'s API, is the ethyl ester form of EPA, namely E-EPA. The FDA approved Vascepa® for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. *See* Vascepa® Full Prescribing Information, **Exhibit 15**. Amarin markets and sells Vascepa® in the United States as a prescription drug. Vascepa® is the only FDA-approved purified E-EPA mixture on the United States market. *See* List of FDA-Approved Icosapent Ethyl Drugs (E-EPA) in Orange Book, **Exhibit 16**. Vascepa® is a low-cost drug from a consumer perspective. According to Amarin's

records, on average, the monthly cost of Vascepa® is typically less than $200, and this cost is mostly covered by insurance plans. **Exhibit 23**. In addition, the majority of patients covered by insurance who obtain prescriptions for Vascepa® pay a monthly co-pay charge of $9.99 or less. **Confidential Exhibit 24.** In fact, a consumer with commercial insurance can pay as little as $9.00 for a 90-day supply prescription of Vascepa®. **Exhibit 25.** Finally, Amarin makes substantial investments in encapsulation, packaging, logistics, sales and marketing, along with substantial investments in labor conducting clinical trials in support of Vascepa®. **Exhibit 23**.

17. The Synthetically Produced Omega-3 Products compete with Vascepa® and injure Amarin because, like Vascepa®, they are chemically modified to deliver heightened levels of EPA. **Exhibits 9-O, 9-V, 9-T, 11-A, 12-D**. Indeed, all the Synthetically Produced Omega-3 products in ethyl ester form (*i.e.*, E-OM3 and E-EPA) actually contain E-EPA – Vascepa's active ingredient. Moreover, the Synthetically Produced Omega-3 Products are often marketed and used to treat the same diseases for which Vascepa® has been, and is being, developed. *See* **Tables 1 and 2.** The Proposed Respondents' importation and sale of Synthetically Produced Omega-3 Products has injured and/or threatened Amarin with substantial injury by (i) damaging the Vascepa® brand by exploiting Vascepa®'s status as an FDA-approved drug, (ii) causing lost sales and market share to Vascepa, and (iii) diminishing profitability and eroding prices. Amarin also has the capacity and/or inventory to supply the entire U.S. market demand for the Synthetically Produced Omega-3 Products (and similarly situated products), and Proposed Respondents' unfair acts prevent Amarin from making these sales, as discussed in paragraphs 225-229.

18. Finally, because false labeling and promotion enables purported "dietary supplement" products to evade the drug approval process, it also endangers the public health. Indeed, former-Attorney General Lynch observed the following with regard to "dietary supplements":

> What many Americans don't know is that dietary supplements are *not* subject to testing [by FDA] 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 of proven therapies they may need. But whether these supplements are deceptive or dangerous, the fact remains that too many companies are making profits by misleading – and in some cases harming – American consumers.

Former-Attorney General Lynch Discusses Department's Efforts to Protect Consumers From Unsafe Dietary Supplements, Department of Justice, Office of Public Affairs, March 8, 2016 (emphasis added), **Exhibit 26**. Then-Attorney General Lynch's remarks were in reference to the Department of Justice's ("DOJ's") "dietary supplement" enforcement sweep in November 2015, which it conducted with the FDA and other federal partners. *See* Justice Department and Federal Partners Announce Enforcement Actions of Dietary Supplement Cases, Nov. 18, 2015, **Exhibit 27**.

19. Although Section 337 and the Lanham Act are both designed to protect commercial interests against unfair methods of competition by authorizing private parties to sue competitors – they can also indirectly protect the public, particularly where FDA and other government entities have not acted, or have not acted to the full extent of their authority. Given

the government's limited resources, it simply cannot pursue all deceptively labeled and deceptively promoted products.

20. Indeed, FDA has primary responsibility for policing the "labeling" of "dietary supplements" and the "labeling" and "advertising" of unapproved "new drugs." *See* Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, 225-71-8003, Sept. 9, 1971, **Exhibit 28**; *see also* 21 U.S.C. § 321(m) (defining "labeling"); 21 C.F.R. § 202.1(l) (providing examples of "labeling" and "advertising"). Yet, according to a recent PBS "Frontline" documentary, produced in collaboration with *The New York Times*, FDA has only about 25 people in the division that oversees products positioned as "dietary supplements," and more than 85,000 of these products are sold each year. As reported in that program, "[FDA] target[s] companies they consider the most risky, but agree the problem remains much bigger than that." *See* Frontline: Supplements and Safety, PBS and *The New York Times*, **Exhibit 29**; *see also* Complainant's Brief On Jurisdiction, **Confidential Exhibit 30**.

II. COMPLAINANTS

21. Complainant Amarin Pharma is incorporated under the laws of Delaware with its primary office located at 1430 Route 206, Bedminster, NJ 07921. Amarin Pharma runs Amarin's United States operations, including sales, marketing, research and development, and regulatory affairs, among other things.

22. Complainant Amarin Ireland is organized under the laws of the Republic of Ireland with its principal offices at 2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2 Ireland. Amarin Ireland is a biopharmaceutical company specializing in developing effective, approved therapies to improve cardiovascular health. Amarin Ireland and Amarin Pharma are

both wholly owned subsidiaries of Amarin Corporation plc, a public limited liability company organized under the laws of England and Wales.

23. Amarin developed Vascepa®, a prescription drug that lists icosapent ethyl as the drug's API. Icosapent ethyl is another name for E-EPA. Amarin Ireland is the holder of NDA No. 202057 for Vascepa® (icosapent ethyl) Capsules, for oral use. The FDA approved Vascepa® for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Amarin markets and sells Vascepa® in the United States as a prescription drug.

III. PROPOSED RESPONDENTS

A. Manufacturers/Importers

24. Proposed Respondent Royal DSM NV ("DSM NV") is a manufacturer of Synthetically Produced Omega-3 Products. DSM NV's headquarters are located at Het Overloon 1 6411 TE, Heerleen, The Netherlands.

25. Proposed Respondent DSM Marine Lipids Peru S.A.C. ("DSM-Peru") is a manufacturer of Synthetically Produced Omega-3 Products. DSM-Peru's headquarters are located at Calle Principal S/N Caserio la Legua, Catacaos Piura, Peru.

26. Proposed Respondent DSM Nutritional Products LLC ("DSM-US") is a manufacturer of Synthetically Produced Omega-3 Products. DSM-US's headquarters are located at 45 Waterview Blvd., Parsippany, NJ 07054.

27. Proposed Respondent DSM Nutritional Products Canada, Inc. ("DSM-Canada") is a manufacturer of Synthetically Produced Omega-3 Products. DSM-Canada is located at 105 Neptune Crescent, Dartmouth, NS B2Y4T6.

28. Proposed Respondent Ultimate Biopharma (Zhongshan) Corporation ("Ultimate") is a Chinese foreign joint venture limited company that manufactures softgel capsules containing Synthetically Produced Omega-3 Products. Ultimate's headquarters are located at 10 Jiankang Road, National Health Technology Park, Zhongshan, Guandong, People's Republic of China.

29. Proposed Respondent Marine Ingredients AS is a manufacturer of Synthetically Produced Omega-3 Products. Marine Ingredients AS's headquarters are located at Strandgata 60, 6270 Brattvag, Norway.

30. Proposed Respondent Marine Ingredients LLC is a U.S. importer of Synthetically Produced Omega-3 Products. Its headquarters are located at 794 Sunrise Blvd., Mt. Bethel, Pennsylvania 18343.

31. Proposed Respondent Golden Omega S.A. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Avenida Apoquindo Ote. 5550, Piso 8, Las Condes, Santiago, Chile.

32. Proposed Respondent Golden Omega USA LLC is a U.S. importer of Synthetically Produced Omega-3 Products. Its headquarters are located at 65 Enterprise, Aliso Viejo, California, 92656.

33. Proposed Respondent Nordic Pharma, Inc. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Ropnesveien 71, 9107 Kvaløya, Norway.

34. Proposed Respondent Croda Europe Ltd. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Cowick Hall, Snaith Goole, East Yorkshire DN14 9AA, United Kingdom.

35. Proposed Respondent Croda Inc. is a U.S. importer of Synthetically Produced Omega-3 Products. Its headquarters are located at 300-A Columbus Circle, Edison, NJ 08837.

36. Proposed Respondent Tecnologica de Alimentos S.A. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Las Begonias 441, Of. 352, San Isidro, Lima 27, Peru.

B. Distributors

37. Proposed Respondent The Nature's Bounty Co. ("Nature's Bounty"), is a U.S. distributor of imported Synthetically Produced Omega-3 Products. In 2010, a Nature's Bounty subsidiary acquired Ultimate. **Exhibit 2-E-ii**. Nature's Bounty's headquarters are located at 2100 Smithtown Avenue, Ronkonkoma, New York 11779.

38. Proposed Respondent Nordic Naturals, Inc. is a U.S. distributor of imported Synthetically Produced Omega-3 Products. Nordic Naturals' headquarters are located at 111 Jennings Drive, Watsonville, California 95076.

39. Proposed Respondent Pharmavite LLC is a U.S. distributor of Nature Made-branded imported Synthetically Produced Omega-3 Products. Its headquarters are located at 8510 Balboa Blvd. # 100, Northridge, California 91325.

40. Proposed Respondent Innovix Pharma Inc. is a U.S. distributor of OmegaVia-branded imported Synthetically Produced Omega-3 Products. Its headquarters are located at 26500 Agoura Road, Suite 102790, Calabasas, CA 91302.

41. Proposed Respondent J.R. Carlson Laboratories, Inc. is a U.S. distributor of imported Synthetically Produced Omega-3 Products. Its headquarters are located at 600 W. University Dr., Arlington Heights, Illinois, 60004.

IV. THE PRODUCTS AT ISSUE

42. The Proposed Respondents' Synthetically Produced Omega-3 Products that are the subject of this investigation contain derivatives of naturally occurring omega-3 fatty acids. Omega-3 fatty acids are a category of polyunsaturated fatty acids that include EPA and DHA. Omega-3 fatty acids are marketed, legally and illegally, in the United States in a number of different mixtures and molecular forms. Common mixtures and molecular forms include the following: (i) common fish oil (*i.e.*, a natural omega-3 mixture ("nTG-OM3")), (ii) purified EPA mixtures in their ethyl ester form ("E-EPA"), (iii) purified EPA mixtures in their re-esterified form ("rTG-EPA"), (iv) omega-3 mixtures in their ethyl ester form ("E-OM3"), and (v) omega-3 mixtures in their re-esterified form ("rTG-OM3"). Although common fish oil contains omega-3 fatty acids in their natural triglyceride form (nTG-OM3) – E-EPA, rTG-EPA, E-OM3, and rTG-OM3 are synthetically produced through processes involving a number of chemical reactions.

43. Upon information and belief, all of the Synthetically Produced Omega-3 Products identified in this complaint contain E-EPA, rTG-EPA, E-OM3 (where the predominant component is E-EPA) or rTG-OM3 (where the predominant component is rTG-EPA). **Exhibits 8-A – 12-M**; *see also* Section VII.

44. Omega-3 fatty acids are found in fish and are most prevalent in oily fish, such as salmon, tuna, lake trout, mackerel, menhaden, sardines, anchovies, and herring. Oil in these fatty acids can be extracted by: (1) cooking and pressing the fish to separate the water and oil from the proteins and solids, (2) removing the water from the oil, and (3) polishing the oil (*i.e.*, deacifying, degumming, and washing the oil several times). When this oil is used for human consumption, it is also bleached and deodorized. At this point, the nTG-OM3 has been extracted

from the fish through physical processes only – no chemical bonds have been broken or created. The resulting oil is common fish oil in nTG form, and depending upon the fish from which the oil was derived and the environmental conditions in which the fish were raised, the ratio of nTG-EPA and nTG-DHA can differ. Before it is sold, however, common fish oil is generally blended and standardized to contain approximately 180 mg of nTG-EPA and 120 mg of nTG-DHA per gram (1000 mg) of oil. Though the ratio of EPA to DHA may vary slightly, this oil is often referred to as 18:12 fish oil. The numbers 18:12 represent the approximate ratio of nTG-EPA to nTG-DHA by weight: 18% of the oil, by weight, is nTG-EPA; and 12% of the oil, by weight, is nTG-DHA (therefore, 30% of the oil, by weight is nTG omega-3 fatty acids). The remaining 70% of the oil has other constituents, typically, most predominantly, saturated fat, other omega-3 fatty acids, and omega-6 and omega-9 fatty acids. *See* Figure 1 (in Section I, and repeated below).

45. It is not possible to produce natural marine oil with a collective concentration of nTG-EPA and nTG-DHA that is greater than approximately 30% by weight of the oil. Oils with a higher concentration of EPA and DHA than approximately 30% must be chemically synthesized. Synthetic oils with higher concentrations of EPA and/or DHA that are available today are commonly in either the ethyl ester form or the re-esterified triglyceride form.

46. The first step in the process of synthesizing common fish oil to yield higher concentrations of EPA and DHA involves a chemical reaction wherein the glycerol backbone of each triglyceride molecule in the fish oil is removed, resulting in "free fatty acids" ("FFA"), including FFA-EPA and FFA-DHA, and a "free glycerol" molecule. The FFA-EPA and FFA-DHA are then chemically reacted with ethanol through a process known as esterification.

Esterification changes the fatty acids into ethyl ester form, such that FFA-EPA becomes E-EPA, and FFA-DHA becomes E-DHA.

47. The resulting ethyl ester form allows for substantial heightening of the level of the E-EPA or other components. The fatty acid level can be heightened using a number of different physical procedures, the two most common of which are molecular distillation and supercritical fluid technology. These technologies allow the manufacturer to choose which fatty acid levels to heighten, and to either manipulate the ratio of E-EPA to E-DHA or to purify the product into substantially only E-EPA.

48. Synthetically produced ethyl ester fatty acids, such as E-EPA, can also be chemically converted to the re-esterified triglyceride form using enzymes in a chemical process called glycerolysis. Food-grade enzymes separate the ethanol molecule from the fatty acid, creating a FFA and a free ethanol molecule. When glycerol is reintroduced to the solution, the enzymes then re-esterify the fatty acids back onto a glycerol backbone, creating re-esterified triglyceride (rTG) oil.

49. Omega-3 mixtures in their ethyl ester form, regardless of whether they are characterized as E-OM3 mixtures or more purified E-EPA or E-DHA mixtures, are different from omega-3 mixtures in their natural triglyceride, or nTG, form in a number of ways. For example, the ratio of EPA to DHA in ethyl ester mixtures is often significantly different from the ratio in naturally occurring (nTG) mixtures. In addition, the EPA and DHA levels in the ethyl ester mixtures typically are much higher than they are in natural mixtures. Also, the E-EPA and E-DHA molecules are chemically altered from the nTG-EPA and nTG-DHA molecules and become chemically distinct as a result of such alteration. These types of differences are material

because they can affect the efficacy and safety of the ethyl ester mixture, compared to the nTG mixture (*e.g.*, concentration can lead to greater efficacy and, for example, higher levels of DHA have been associated with certain unwanted effects, particularly in diseased patients with severely high levels of triglycerides in the blood). The differences between the complex mixture of multiple constituents that comprise common fish oil products and the pharmacologically designed highly pure synthesized E-EPA product, Vascepa®, are illustrated in Figures 1 and 2. The differences between the E-OM3 and nTG-OM3 molecules, and their components, are illustrated in Figure 3.

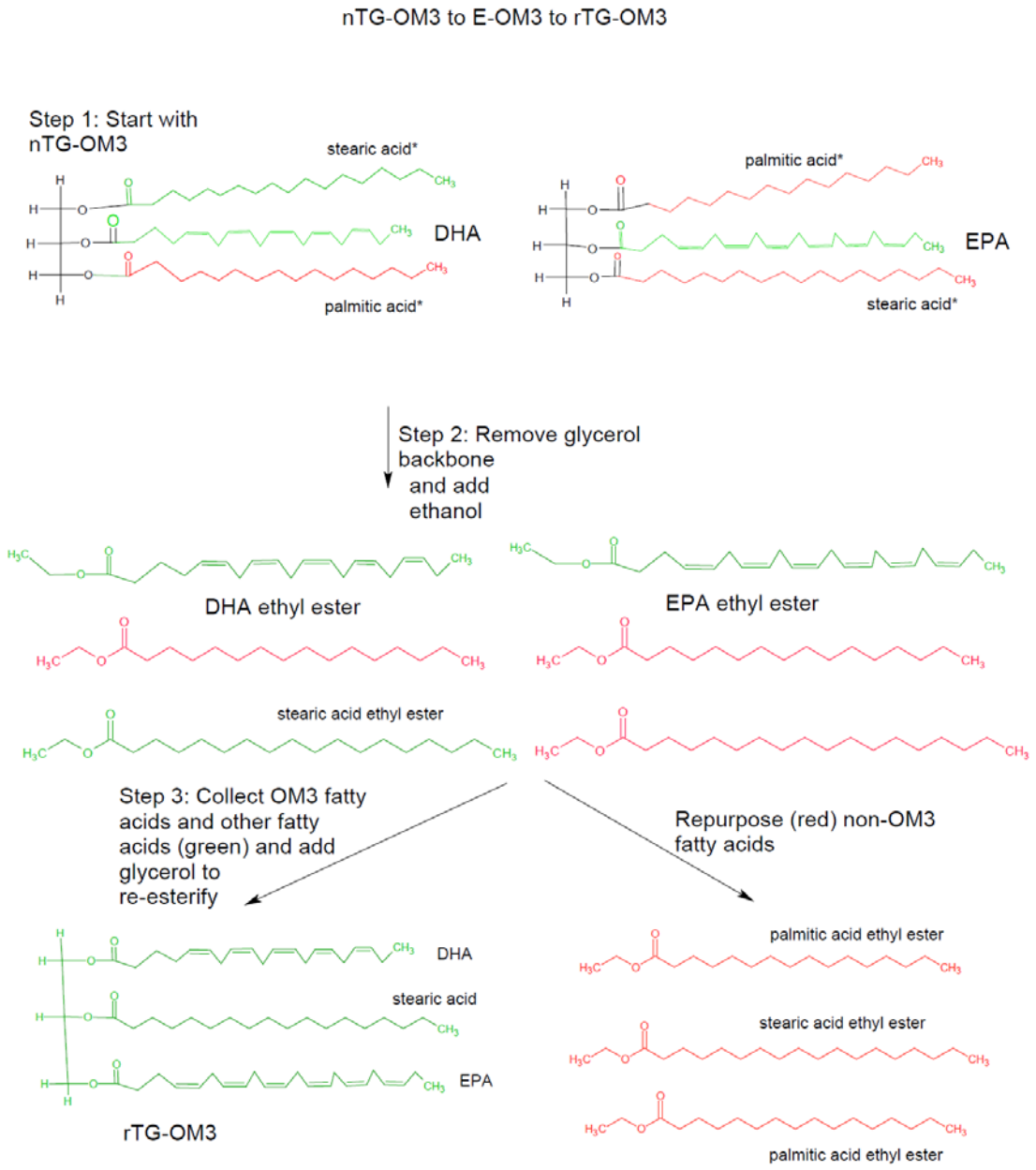
Figure 1. Leading Common Fish Oil Supplement with 30% nTG-OM3.*

See* R. Preston Mason and Samuel C.R. Sherratt, Omega-3 fatty acid fish oil dietary supplements contain saturated fats and oxidized lipids that may interfere with their intended biological benefits, Biochemical and Biophysical Research Communications (2016), 1-5. **Exhibit 14.

Figure 2. Vascepa® (E-EPA)*

*Vascepa®, Full Prescribing Information, **Exhibit 15** (reflecting that FDA has labeled Vascepa® 1 gram capsules as containing 1 gram of E-EPA. The capsules also contain trace amounts of inactive ingredients including, tocopherol, an anti-oxidation agent designed to protect the fragile active ingredient).

Figure 3. Conversion of nTG-OM3 to E-OM3 to rTG-OM3



Disclaimer - The triglyceride molecules shown in the scheme are merely representative of certain molecular species that would be expected to be present in both natural fish oil and rTG oil. They do not represent the only molecular species in these mixtures. These mixtures would contain a variety of fatty acid residues, inaddition to DHA, EPA, stearic and palmitic acid. The scheme is intended to represent, qualitatively, the type of chemical transformation that occurs in each step.

50. Omega-3 mixtures in their rTG form, regardless of whether they are characterized as rTG-OM3 mixtures or the more purified rTG-EPA or rTG-DHA mixtures, are also different from omega-3 mixtures in their natural triglyceride, or nTG, form in a number of ways. For example, the ratio of EPA to DHA in rTG-OM3 mixtures is often different from the ratio in naturally occurring (nTG) mixtures. In addition, the EPA and DHA levels in the rTG mixtures are typically much higher than they are in natural mixtures. This is because the re-esterification process adds, on average, one extra fatty acid to each triglyceride molecule. Further, nTG and rTG typically have different molecular structures. When the EPA, DHA, and other fatty acids, are re-attached to the glycerol molecule, during the chemical re-esterification process, they randomly attach to one of three different points on the glycerol molecule: SN-1, SN-2, or SN-3. Even though the pattern of attachment is random, based on statistical probability, more EPA, DHA, and other fatty acids attach to the SN-1 and SN-3 points than the SN-2 point. In nTG, however, the EPA and DHA are typically bound to the SN-2 position. Finally, during the re-esterification process, not all fatty acids, such as EPA and DHA, reattach to the glycerol molecule as triglycerides. Thus, large percentages of the oil, often approximately 40%, are in di-glyceride or mono-glyceride form. Notably, di-glycerides and mono-glycerides are not components of natural fish oil, nTG, at all. In nTG-OM3 mixtures (common fish oil), 100% of the oil is in triglyceride form. As described above, these types of differences are material because they can affect the efficacy and safety of the rTG mixture, compared to the nTG mixture (*e.g.,* concentration can lead to greater efficacy and, for example, higher levels of DHA have been associated with unwanted effects, particularly in some diseased patients with abnormally high levels of triglycerides in the blood). The differences between the rTG-EPA and nTG-EPA

molecules, as well as the differences between the rTG-DHA and nTG-DHA molecules are illustrated in Figure 3.

51. Upon information and belief, all of the Proposed Respondents' Synthetically Produced Omega-3 Products contain E-EPA, rTG-EPA, E-OM3, or rTG-OM3. **Exhibits 1 – 12**. Upon information and belief, all of these products are synthesized (*i.e.*, chemically altered) using the same basic chemical processes described above, and as such, they are distinct from common fish oil, *i.e.*, nTG-OM3.

V. JURISDICTION

52. The Commission had jurisdiction over this investigation for the reasons set forth in Complainant's Brief On Jurisdiction. **Exhibit 30**.

VI. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENTS

A. Proposed Respondents' Importation And Sale Of The Synthetically Produced Omega-3 Products Violate The Lanham Act

53. The Proposed Respondents' importation and sale of the Synthetically Produced Omega-3 Products, and their false or misleading representations about those products, constitute unfair acts or unfair methods of competition under Section 337, and violate Section 43(a) of the federal Lanham Act, 15 U.S.C. § 1125(a), and the federal common law of unfair competition.

54. Section 43(a) of the Lanham Act provides that:

> [a]ny person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which – . . . (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a).

55. The elements of a false advertising/promotion claim under the Lanham Act are (i) a false or misleading statement of fact is being made by the defendant about a product; (ii) the statement is deceiving or has the capacity to deceive a substantial segment of potential consumers; (iii) the deception is material, in that it is likely to influence a purchasing decision; (iv) the defendant is causing the false statement to enter interstate commerce; and (v) the complainant has been or is likely to be injured as a result of the statement. *See Hewlett-Packard Co. v. NU-Kote Int'l, Inc.*, 155 F.3d 571 (Fed. Cir. 1998) (*citing Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997)); *see also Marcinkowska v. IMG Worldwide, Inc.*, 342 F. App'x 632, 636 (Fed. Cir. 2009) (*citing Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 272 (4th Cir.2002)).

56. When a complainant can show that a statement is "literally false," or false on its face, however, the consumer deception is presumed, such that proving the third element is not necessary. *See Clock Spring, L.P. v. Wrapmaster, Inc.*, 560 F.3d 1329, n. 10 (Fed. Cir. 2009). A statement may be "literally false" due to a material omission, among other reasons. *See, e.g.*, *Pfizer Inc. v. Miles Inc.*, 868 F.Supp. 437 (D. Ct. 1994) (holding that an omission that is likely to deter physicians from using an FDA approved drug is material and makes the advertisement's statement "a literal falsity").

57. In addition, parties other than those making false statements can be contributorily liable for Lanham Act violations. *See, e.g., Duty Free Ams., Inc. v. Estee Lauder Co.*, 797 F.3d 1248, 1273 (11th Cir. 2015); *Merck Eprova AG v. Gnosis S.p.A.*, 901 F. Supp. 436, 456 (S.D.N.Y. 2012) (finding company liable to Merck for contributory false advertising). The

elements of a contributory false advertising/promotion claim include showing that (1) a third party directly engaged in false advertising/promotion that injured the plaintiff and (2) the respondent at issue contributed to that conduct by knowingly inducing or causing the conduct, or by materially participating in it. *See Duty Free Ams.*, 797 F.3d at 1277.

1. Proposed respondents are making false statements about the Synthetically Produced Omega-3 Products by labeling and/or promoting them as "dietary supplements" when they are actually unapproved "new drugs"

58. The Distributors of the Synthetically Produced Omega-3 Products are unlawfully importing or selling their products with labeling, advertising and/or other promotional materials ("Promotional Materials") that are literally false. Among other things, the labeling for all of the Distributors' Synthetically Produced Omega-3 Products falsely asserts that the products are "dietary supplements," or it falsely implies that they are "dietary supplements" by using some modification of that term (*e.g.,* "Omega-3 Supplement"). **Exhibits 8-A-ii – 12-M-ii**. Indeed, the term "dietary supplement" or a modification of that term using the name of the ingredient in the product is required to appear on "dietary supplement" labeling by law. 21 U.S.C. §§ 321(ff)(2)(C), 343(s)(2)(B).

59. In addition, all of the Manufacturers (except Ultimate) are unlawfully importing or selling their products with Promotional Materials that are literally false because they assert that the products are for use in, or as "dietary supplements." **Exhibits 1-B – 7-B**.

60. Labeling and/or promoting Synthetically Produced Omega-3 Products for use in, or as "dietary supplements" is literally false because these products (i) cannot meet the definition of "dietary supplement" in Section 201(ff) of the FDCA, 21 U.S.C. § 321(ff) and (ii) are being

referred to as "dietary supplements" to hide the fact that they are actually unapproved "new drugs."

a. The Synthetically Produced Omega-3 Products cannot meet the definition of "dietary supplement" in the FDCA

61. None of the Synthetically Produced Omega-3 Products meets the definition of "dietary supplement" in the FDCA because none of the products bears or contains a "dietary ingredient." 21 U.S.C. § 321(ff)(1). Moreover, although the failure to bear or contain a "dietary ingredient" is sufficient to preclude a product from being a "dietary supplement," the Synthetically Produced Omega-3 Products that emphasize E-EPA in their manufacture or marketing are also excluded from the definition of "dietary supplement" by the definition's "exclusionary clause." *See id.* § 321(ff)(3)(B).

i. The Synthetically Produced Omega-3 Products do not meet the definition of "dietary supplement" because they do not bear or contain a "dietary ingredient"

62. The definition of "dietary supplement" in the FDCA applies only to products that, among other things, bear or contain one or more of the following "dietary ingredients": "(A) a vitamin, (B) a mineral, (C) an herb or other botanical, (D) an amino acid, (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." 21 U.S.C. § 321(ff)(1). Products marketed with ingredients that do not fall within the categories of "dietary ingredients" listed in Section 201(ff)(1) of the FDCA, 21 U.S.C. § 321(ff)(1), cannot be marketed as, or for use in, "dietary supplements." *See id.*

63. The Synthetically Produced Omega-3 Products are not "dietary supplements" because E-EPA, rTG-EPA, E-OM3, and rTG-OM3 do not fall into any of the categories of

"dietary ingredients" under the Section 201(ff)(1) of the FDCA. As an initial matter, E-EPA, rTG-EPA, E-OM3, E-EPA, and rTG-OM3 are not vitamins, minerals, herbs, or other botanicals, and therefore, they do not fall under subsections 201(ff)(1)(A)-(D). Moreover, they do not fall under subsections 201(ff)(1)(E) or (F) either.

a) The Synthetically Produced Omega-3 Products do not fall under subsection 201(ff)(1)(E) of the "dietary ingredient" definition

64. Unlike nTG-OM3 and nTG-EPA, which naturally occur in fish oil, E-EPA, rTG-EPA, E-OM3, and rTG-OM3 do not fall under subsection (E). They are not "dietary substance[s] for use by man to supplement the diet by increasing the total dietary intake." 21 U.S.C. § 321(ff)(1)(E). According to FDA, when the chemical structure of a dietary ingredient is altered, for example, by the "addition of new chemical groups as in *esterification*," it:

> creates a new substance that is different from the original dietary ingredient. The new dietary ingredient is not considered to be a dietary ingredient merely because it has been altered from a substance that is a dietary ingredient, and therefore, is in some way related to the dietary ingredient.

Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry (Draft), August 2016 (NDI Guidance), at 41 (emphasis added), **Exhibit 31**. This is a well-settled FDA policy that previously has been articulated in Federal Register notices and implemented in rejections of new dietary ingredient notifications. *See, e.g.*, 81 Fed. Reg. 61700, 61702 (Sept. 7, 2016), **Exhibit 32**, (noting that vinpocetine "is a synthetic compound, derived from vincamine, an alkaloid found in the *Vinca minor* plant" because it undergoes transesterification and/or dehydration of vincamine in ethanol); FDA Letter to AIBMR Life

Sciences, Inc., dated March 19, 2014, **Exhibit 33** (finding that synthetic fish oil fatty acid esters were "not constituents of a dietary substance for use by man under Section 201(ff)(1)(F)").

65. FDA refers to these chemically altered ingredients – these new substances – as "synthetic" or "synthetically produced" ingredients, and it uses those terms interchangeably to refer to ingredients that are synthesized from natural starting materials as well as unnatural starting materials. *See, e.g.*, NDI Guidance, at 37-41, **Exhibit 31**; *see also* 81 Fed. Reg. at 61702, **Exhibit 32**; FDA Warning Letter to Quincy Bioscience Manufacturing Inc., dated Oct. 16, 2012, **Exhibit 34** (concluding that synthetic apoaequorin manufactured from "rapidly dividing host cells," which are natural materials, is not a "dietary ingredient"); FDA Letter to Syntech (SSPF) International, dated December 6, 2004, **Exhibit 35** (finding that betaphrine, an ingredient chemically synthesized from substances that are themselves "dietary ingredients," is not a "dietary ingredient" under any subsection in Section 201(ff)(1)(A)-(F) of the Act).

66. Because E-EPA, rTG-EPA, E-OM3, and rTG-OM3 are each chemically altered, or synthesized from common fish oil, they are synthetically produced, or synthetic. As such, they cannot fall under subsection 201(ff)(1)(E), unless they themselves are commonly used in conventional food.

67. For more than 15 years, FDA has consistently found that synthetic substances do not fall under subsection 201(ff)(1)(E), or subsections 201(ff)(1)(C) and (F) of the "dietary ingredient" definition for that matter, unless the synthetic substance itself is commonly used in conventional food. And when purported "dietary supplements" have contained a synthetic ingredient that is not common in conventional foods, FDA has taken action. For example, the agency has

(i) brought enforcement actions on this basis, *see, e.g.*, 69 Fed. Reg. 6787, 6793 (Feb. 11, 2004), **Exhibit 36** (citing *United States v. 1009 Cases* * * * No. 2:01CV-820C (D. Utah filed October 22, 2001));

(ii) denied citizen petitions on this basis, *see, e.g.*, Letter from FDA to Ullman, Shapiro, & Ullman LLP, Docket No. FDA-2009-P-0298, dated Feb. 23, 2011, **Exhibit 37** (citizen petition response stating that synthetic homotaurine may not be marketed as a "dietary supplement" because it is not a "dietary ingredient");

(iii) advised other federal agencies on this basis, *see, e.g.*, Letter from Dennis E. Baker, Associate Commissioner of Regulatory Affairs, FDA, to Laura M. Nagel, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, June 21, 2001 (Nagel Letter), **Exhibit 38** (concluding that synthetic ephedrine alkaloids are not "dietary ingredients");

(iv) announced in the Federal Register that certain ingredients cannot be sold as "dietary supplements" on this basis, 69 Fed. Reg. 6793, **Exhibit 36** (acknowledging that synthetic ephedrine hydrochloride "and other synthetic sources of ephedrine cannot be dietary ingredients because they are not constituents or extracts of a botanical, nor do they qualify as any other type of dietary ingredient");

(v) issued warning letters on this basis, *see, e.g.*, FDA Warning Letter to ATS Labs, LLC, dated February 3, 2016, **Exhibit 39** (finding that 1,3-dimethylbutylamine ("DMBA") is not a "dietary ingredient" because it is synthetic and to the best of FDA's knowledge it is not used in conventional foods); FDA Warning Letter to DBM Nutrition, dated Nov. 30, 2015, **Exhibit 40** (finding that picamilon, "a unique chemical entity synthesized from the

dietary ingredients niacin and aminobutyric acid" does not fall within any of the "dietary ingredients" categories in the statute, and therefore, is not a "dietary ingredient"); FDA Warning Letter to Quincy Bioscience Manufacturing Inc., dated Oct. 16, 2012, **Exhibit 34** (finding that synthetic apoaequorin is not a "dietary ingredient"); FDA Warning Letter to Supplementstogo.com LLC, dated March 8, 2006, **Exhibit 41** (finding that methasterone, a synthetic steroid, is not a "dietary ingredient"); and

(vi) rejected new dietary ingredient notifications on this basis, *see, e.g.*, FDA Letter to Syntech (SSPF) International, dated December 6, 2004, **Exhibit 35** (finding that betaphrine, a chemically synthesized substance is not a "dietary ingredient"). In addition, FDA recently reiterated this position in 2016 draft guidance on "new dietary ingredients." *See* NDI Guidance at 38, **Exhibit 31**.

68. The FDA's long-standing position is based on a plain language interpretation of the definition of "dietary supplement" in the text in subsection 201(ff)(1)(E) – namely, "a dietary substance for use by man to supplement the diet by increasing the total dietary intake." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**. According to FDA, *Webster's II New Riverside University Dictionary*, provides that the term "dietary" means "of or relating to the diet" and "diet" means "an organism's usual food and drink." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**. Reading those definitions in conjunction with the phrase, "for use by man," FDA construes the term "dietary substance" to mean "a substance commonly used as human food or drink." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**. FDA also maintains that the last phrase in subsection (E), "to supplement the diet by increasing the total dietary intake," provides further evidence that Congress intended the term "dietary

substance" to refer to "foods and food components that humans eat as part of their usual diet" because "[o]ne cannot increase the 'total dietary intake' of something that is not part of the human diet in the first place." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**.

69. Upon information and belief, E-EPA, rTG-EPA, E-OM3, and rTG-OM3 are not common in conventional food in the United States. Each is synthetically produced.

b) The Synthetically Produced Omega-3 Products do not fall under subsection 201(ff)(1)(F) of the "dietary ingredient" definition

70. Similarly, E-EPA, rTG-EPA, E-OM3, and rTG-OM3 do not fall under subsection 201(ff)(1)(F) because each is a synthetically produced substance, and upon information and belief, none of the ingredients is a concentrate, constituent, extract, or combination of a "dietary substance" that falls under subsection 201(ff)(1)(E), or subsections 201(ff)(1)(A)-(D) for that matter. Notably, in 2014, FDA specifically rejected a new dietary ingredient notification for a product dubbed "synthetic fish oil fatty acid esters"– in part, because the proponent of the ingredient had not submitted evidence sufficient for FDA to determine whether it met the definition of "dietary ingredient." *See* FDA Letter to AIBMR Life Sciences, Inc., dated March 19, 2014, **Exhibit 33**. In reaching this conclusion, FDA stated that the synthetic fish oil fatty acid esters at issue were "not constituents of a dietary substance for use by man under Section 201(ff)(1)(F)." *Id.* This approach by FDA is consistent with its conclusion that "[o]ne cannot increase the 'total dietary intake' of something that is not part of the human diet in the first place." NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**.

ii. Certain Synthetically Produced Omega-3 Products are excluded from the definition of "dietary supplement" under the exclusionary clause contained in subsection 321(ff)(3)(B) of the FDCA

71. Subsection 201(ff)(3)(B) of the FDCA (*i.e.,* the exclusionary clause) also excludes from the definition of "dietary supplement" any "article" that is approved as a "new drug" or authorized for study as a "new drug" (where substantial clinical investigations have been instituted), that was not before such approval or authorization legally marketed as a "dietary supplement" or as a food. 21 U.S.C. § 321(ff)(3)(B). As explained below in paragraphs 80-83, E-EPA first gained recognition in the market place by being studied as a drug in the mid-1980s, and upon information and belief it was not legally marketed as a "dietary supplement" or a food prior to that time. Thus, as explained below, E-EPA products, as well as products containing E-OM3 that emphasize E-EPA in the way that they are manufactured or promoted, are excluded from the definition of "dietary supplement" under subsection 201(ff)(3)(B) of the FDCA.

72. The relevant "article" for the purposes of the exclusionary clause is dictated by the circumstances surrounding the manufacture and marketing of the purported "dietary supplements" at issue. *See Pharmanex v. Shalala ("Pharmanex III")*, 2001 WL 741419 (D. Utah 2001), *2, *4-*5 (upholding FDA's administrative determination); FDA Administrative Determination on Cholestin, dated May 20, 1998, at 10, **Exhibit 42**. In the seminal case on the exclusionary clause, Pharmanex, Inc. ("Pharmanex") marketed a product that contained red yeast rice as a "dietary supplement." *See* FDA Administrative Determination on Cholestin, dated May 20, 1998, at 1, **Exhibit 42**. FDA, however, determined that Cholestin was not a "dietary supplement," but rather an unapproved "new drug" under the FDCA. *See id.* FDA reasoned that Cholestin did not meet the definition of "dietary supplement" because Cholestin contained

lovastatin, an active ingredient in an FDA-approved drug. *See id.* at 7, 10. As such, products containing lovastatin were excluded from the definition of "dietary supplement" by the exclusionary clause. *See id.* According to FDA, lovastatin was the relevant "article" for the purposes of the exclusionary clause, as opposed to the finished Cholestin product, because of the "particular circumstances surrounding the Cholestin product, which indicate[d] that Pharmanex, in marketing and manufacturing Cholestin, [was] marketing and manufacturing lovastatin, not the traditional food product red yeast rice." *Id.* at 10.

73. Notably, the Tenth Circuit upheld FDA's determination that an "article" for the purposes of the exclusionary clause can be either a finished drug product or a component of a drug product. *See Pharmanex v. Shalala ("Pharmanex II")*, 211 F.3d 1151 (10th Cir. 2000); FDA Administrative Determination on Cholestin, dated May 20, 1998, **Exhibit 42**. This interpretation ensures that substances that have gained recognition in the marketplace as drugs cannot be marketed as, or incorporated into, "dietary supplements." *See* FDA Administrative Determination on Cholestin, dated May 20, 1998, at 6, **Exhibit 42**.

74. The exclusionary clause encourages and protects investment in drug development and the resulting innovation. The Tenth Circuit and FDA have observed, respectively, that permitting "manufacturers to market dietary supplements with components identical to the active ingredients in prescription drugs" would undermine the FDCA's incentive structures for drug development, *see Pharmanex II*, 211 F.3d at 1159, and it would "serve as a disincentive to the often significant investment needed to gain FDA approval of new drugs." *See* FDA Administrative Determination on Cholestin, dated May 20, 1998, at 4-5, **Exhibit 42**. Protecting drug innovation is such a critical underpinning of the FDCA that Congress later enacted a

separate exclusionary clause to prohibit substances that have gained recognition in the marketplace by being studied as, or approved as drugs, from being incorporated into conventional food as well, unless those substances were first marketed in a food. *See* 21 U.S.C. § 331(ll)).

75. In this case, consistent with the FDA's decision in *Pharmanex* and the underlying principle of the exclusionary clause, E-EPA is the relevant "article" when the purported "dietary supplements" at issue (i) contain E-EPA and (ii) emphasize E-EPA in the way that they are manufactured or promoted. In those instances, it is clear that the Proposed Respondents are importing or selling E-EPA, not common fish oil, or nTG-EPA. To adequately protect investment in drug development and the resulting innovation, E-EPA, which gained recognition in the marketplace as a "new drug", as explained in paragraphs 80-83, cannot be marketed as, or incorporated into, "dietary supplements."

76. The affected products are identified in **Exhibits 1-A – 4-A, 6-A – 7-A, 8-A – 8-C, 8-E – 8-F, 8-H – 8-N, 10-A – 10-G, 12-C – 12-F, 12-J – 12-K**. By pharmacological design, E-EPA is the most predominant component in these purified E-EPA products and E-OM3 mixtures. *Id.* Upon information and belief, these products are manufactured by following the same basic steps that drug companies follow, as summarized in paragraphs 42-51 of the complaint. In addition, as demonstrated in the attached charts, these products are typically promoted not just for their EPA content – but for their *chemically concentrated EPA content* – which would not be possible but for the ethyl ester form. **Tables 3 and 4**. The chemical cleaving of the glycerol backbone from the nTG-OM3 and the reaction with the ethanol to form E-EPA or E-OM3

enables EPA to be substantially heightened to a level beyond that which exists in nature. EPA in its natural triglyceride form cannot be heightened to the same level.

77. Moreover, the esterification of EPA – *i.e.*, the ethyl ester form – allows these products to be concentrated and differentiates these products from common fish oil or other natural sources of EPA. A consumer would have to consume a likely intolerable amount of common fish oil or common krill oil in an effort to even get the same dosage of E-EPA in Vascepa®, a highly pure form of E-EPA. For example, a 300 mg capsule of MegaRed® Omega-3 Krill Oil contains approximately 50 mg of natural EPA in each capsule, *see* MegaRed Website, **Exhibit 43**, whereas a 1 gram capsule of Vascepa® contains 1000 mg of E-EPA. *See* Vascepa® Full Prescribing Information. **Exhibit 15**. Given that the FDA-approved dose of Vascepa® to reduce triglyceride levels in adult patients with severe hypertriglyceridemia is 4000 mg per day (*e.g.*, two, 1 gram capsules twice a day), consumers would have to take approximately 80 capsules of MegaRed® Omega-3 Krill Oil daily to get a similar dose of EPA from that product as they would get from four, 1 gram capsules of Vascepa®.

78. For this reason, companies often tout their chemically manipulated products containing E-EPA as being comparable to drugs that contain E-EPA (*e.g.*, "Most fish oils are not the same as Lovaza. But some Are! A few over-the counter pharmaceutical grade fish oils [sic] are just as potent, pure and effective at reducing triglycerides as Lovaza," *see* OmegaVia Website, **Exhibit 44**; *see also* OmegaVia Website 2, **Exhibit 45** (making implicit comparisons of OmegaVia's so-called "pharmaceutical grade fish oil" products to both Vascepa® and Lovaza® (another FDA-approved drug product)).

79. The Synthetically Produced Omega-3 Products that contain E-EPA, and emphasize that component in the manufacture and/or promotion of the product, are excluded from the definition of "dietary supplement" under subsection 201(ff)(3)(B) of the FDCA, 21 U.S.C. § 321(ff)(3)(B), because the relevant "article" – E-EPA – gained recognition in the marketplace by being studied as a "drug," as explained below. And upon information and belief, Synthetically Produced Omega-3 Products that incorporate E-EPA are not saved from exclusion from the "dietary supplement" definition by the "prior market clause" because E-EPA was never legally marketed as food or as a "dietary supplement."

80. E-EPA first gained recognition in the marketplace as a drug when it was clinically studied as a drug in the United States in the mid-1980s, if not earlier. Studies on E-EPA, in E-OM3 mixtures, began to proliferate after the Biomedical Test Materials Program ("BTM Program") was created in 1986. *See* Sylvia B. Galloway, Ph.D., Biomedical Test Materials Program: Drug Master Files for Biomedical Test Materials, Produced From Refined Menhaden Oil, and Their Placebos, United States Department of Commerce, October 1989 (1989 BTM Report), **Exhibit 46**, at 1-1, 2-1, 2-2. The BTM Program was created by the National Oceanographic and Atmospheric Administration ("NOAA") and the National Institutes of Health ("NIH")/Alcohol, Drug Abuse, and Mental Health Administration ("ADAMHA"), and it provided standardized test materials to help researchers better identify the role of different forms of omega-3 fatty acids on health and disease. *See id.* at 1-1. The standardized test materials included an E-OM3 mixture that contained E-EPA as its principal component. *See id.* at 2-3. Specifically, the E-OM3 mixture contained approximately 80% omega-3 fatty acid ethyl esters, 44% E-EPA and 24% E-DHA, and 10-12% other omega-3 fatty acid ethyl esters, as well as other

components. *See id.* Notably, the test materials, by chemically converting the EPA to ethyl ester form, increased the level of EPA in the mixture by approximately 26%. Typically, common fish oil contains 18% EPA. The availability of the test materials was announced on a number of occasions in the NIH Guide for Grants and Contracts, starting on May 29, 1987; requests from researchers were received by June 1987; and the BTM Program began shipping materials by September 1987. *See id.* at 2-1. Notably, in a February 1988 announcement, the program was explicit that "[i]n accordance with federal regulations, an [investigational new drug ("IND")] number will be required for the use of these materials in human studies." NIH Guide for Grants and Contracts, Vol. 17, No. 5, Feb. 12, 1988, **Exhibit 47** at 1; *see also* 1989 BTM Report, **Exhibit 46**, at 2-1. In 1989, the BTM Program also made purified mixtures of E-EPA and E-DHA available for study. *See* P.H. Fair, Biomedical Test Materials Program: Distribution Management Manual, Department of Commerce, Dec. 1989 (1989 BTM Distribution Manual), **Exhibit 48**. The E-EPA mixture contained >95% ethyl esters (of the ethyl esters, EPA was 97%, other omega-3 fatty acids were < 1% and omega-6 fatty acids were < 1%). *See id.* at 5.

81. Upon information and belief, no "dietary supplement" or food containing E-EPA was legally marketed prior to these studies. In the late 1980s, FDA was skeptical that any omega-3 products, even those containing common fish oil (*i.e.*, nTG-OM3), were marketed legally. Many, if not all, of the omega-3 products at the time, were marketed with promotional claims that rendered them unapproved new drugs. In 1988, FDA sent more than 50 letters to manufacturers and distributors of omega-3 products citing them for that illegal practice. *See, e.g.*, FDA Letter to Barth Vitamin Corp., dated April 1988 (and related letters), **Exhibit 49**. For example, an FDA letter to American Health Products stated that the promotional material

distributed with a product, known as SuperEPA (i) suggested that the product may be useful in "the prevention or treatment of cancer, arthritis, atherosclerosis, heart disease, platelet aggregation, immune system effects, and the lowering of blood levels of cholesterol and triglycerides" and (ii) rendered the product an unapproved "new drug" under the FDCA. *See* FDA Letter to American Health Products, dated May 18, 1988, **Exhibit 50**.

82. In addition, in the late 1980s and in the 1990s (at least before the Dietary Supplement Health and Education Act of 1994, P.L. 103-417, amended the FDCA), no omega-3 supplements had been authorized for use by FDA as food ingredients, and agency statements reveal that the agency considered them to be unsafe "food additives." *See* 21 U.S.C. §§ 321(s), 342(a)(2)(C). A "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food" that is not (i) generally recognized as safe ("GRAS") or (ii) used in food prior to January 1, 1958, and shown to be safe through scientific procedures or common use. 21 U.S.C. § 321(s). Substances falling within the definition of "food additive" are deemed "unsafe" as a matter of law and marketing them is illegal when FDA has not approved them through regulation. 21 U.S.C. §§ 348(a)(2), 342(a)(1)(C)(i). In 1990, FDA sent a letter to a trade association stating that:

> We have continued concerns about any food use of omega-3 polyunsaturated fatty acids. We are unaware of any history of use of these substances as food ingredients prior to 1958, and FDA has not listed omega-3 polyunsaturated fatty acids as approved food additives or as being generally recognized as safe [GRAS]. Thus, addition of these substances to foods may render those foods adulterated under 21 U.S.C. 342(a)(2)(C).

See FDA Letter to R. William Soller, dated June 20, 1990, **Exhibit 51**. Further, when FDA affirmed natural menhaden oil to be GRAS in 1997, the agency noted that it declined to make the same determination in 1989 because the oil contained high levels of the omega-3 fatty acids, EPA and DHA, which were known to have physiologic effects, such as effects on blood clotting. 62 Fed. Reg. 30751, 30752 (June 5, 1997), **Exhibit 52**. In other words, in 1989, FDA did not believe that nTG-OM3 in menhaden oil, or its components nTG-EPA or nTG-DHA, were GRAS, and as such, nTG-OM3, nTG-EPA, and nTG-DHA could not have avoided the designation of "food additive" at that time. If nTG-OM3, nTG-EPA, and nTG-DHA in menhaden oil could not have avoided the designation of "food additive" until 1997, there is no basis to support the lawful marketing of E-OM3 and E-EPA as GRAS ingredients prior to that time.

83. Accordingly, for purported "dietary supplements" containing E-EPA to be saved from exclusion from the "dietary supplement" definition, a product must be identified that contained E-EPA that (i) was marketed before the proliferation of E-EPA clinical studies in the mid-1980s, (ii) was not an unapproved new drug, based on the manner in which it was promoted, (iii) did not contain an unsafe "food additive," and (iv) was not otherwise illegally marketed. Upon information and belief, no such "unicorn" exists.

b. Synthetically Produced Omega-3 Products are actually unapproved "new drugs" under the FDCA

84. Section 201(g)(1) of the FDCA defines the term "drug" as (A) "articles" recognized in the official United States Pharmacopeia ("USP") or official National Formulary ("NF") (which have now been combined into one publication, the "USP/NF"); (B) "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or

other animals;" (C) "articles (other than food) intended to affect the structure or any function of the body of man or other animals;" and/or (D) "articles intended for use as a component of any articles specified in clause (A), (B), or (C)." 21 U.S.C. § 321(g)(1)(A)-(D); *see also* 21 C.F.R. § 101.93(f) (further describing "structure/function" claims under subsection (C)), (g) (further describing "disease" claims under subsection (B)).

85. Products that meet the definition of "dietary supplement," however, are subject to a safe harbor – they may be promoted with claims indicating that they are intended to affect the structure or function of the body without invoking drug status. 21 U.S.C. § 321(g)(1). But, because the Synthetically Produced Omega-3 Products are not "dietary supplements," they are not subject to that safe harbor. Thus, the Synthetically Produced Omega-3 Products are "drugs" if they meet any of the four prongs of the "drug" definition contained in Section 201(g)(1)(A)-(D) of the FDCA – including if they are intended to affect the structure or function of the body. *See* 21 U.S.C. § 321(g)(1)(A)-(D).

86. FDA need not deem products to be "drugs," for them to be "drugs." Products are "drugs" if they meet any of the four prongs of the definition of "drug" in the FDCA. 21 U.S.C. § 321(g)(1). Drug sponsors often take steps toward drug approval before any FDA involvement at all. Typically, basic scientists collect data from animal studies. If the data look promising, the drug company develops a prototype drug, and it seeks permission from FDA to begin clinical testing in humans by way of an IND application. *See id.* § 355(i). Once the clinical trials are conducted, the sponsor may submit an NDA, and if FDA believes that the drug is safe and effective, that the proposed labeling is appropriate, and that manufacturing methods assure that the drug's identity, strength, quality, and purity, then the agency will approve the drug. *See id.* §

355(d). At that point, the drug may be legally marketed. In other words, it is incumbent upon the sponsor of a "drug" to recognize that a product is a "drug" pursuant to the definition in the FDCA, and to comply with FDA's regulatory requirements for "drugs" accordingly. *See generally*, Susan Thaul, How FDA Approves Drugs and Regulates Their Safety and Effectiveness, Congressional Research Service, June 25, 2012, **Exhibit 53**.

87. Sponsors of products that meet the definition of "drug," that fail to comply with FDA's *drug approval process* are engaging in a prohibited act. The FDCA expressly prohibits the introduction or delivery for introduction of an *unapproved "new drug"* into interstate commerce. 21 U.S.C. §§ 355(a), 331(d); *see also* 21 U.S.C. §§ 352(f), 331(a)-(c). And, as a practical matter, all unapproved "drugs" are also unapproved "new drugs." Products that meet the definition of "drug" are "new drugs" under Section 201(p) of the FDCA if they are not generally recognized by qualified experts as safe and effective for their intended uses. 21 U.S.C. § 321(p). To be so "generally recognized," the Supreme Court has found that, among other things, there must be a consensus of expert opinion that a drug is safe and effective based on "substantial evidence," as that term is defined in Section 505(d) of the FDCA. *See Weinberger v. Hynson, Wescott & Dunning Inc.*, 412 U.S. 609, 632 (1973) (citing 21 U.S.C. 355(d)). Notably, the *Hynson* decision effectively incorporates FDA's "new drug" approval standard for efficacy into the "new drug" definition. *See id.* Since 1975, FDA has opposed virtually every attempt to deem a "new drug" as generally recognized by qualified experts as safe for the uses mentioned in the labeling by any mechanism other than FDA approval. *See* David G. Adams, *et al.*, Food and Drug Law and Regulation (3d. 2015), at p. 298, **Exhibit 54**. In other words,

practically speaking, to avoid designation as a "new drug," a product that meets the definition of "drug," must be approved by FDA.

88. Some sponsors of products that are "drugs," pursuant to the "drug" definition, may attempt to illegally evade the drug approval requirements by hiding the identity of these products with false labels, such as "dietary supplement," or even "medical food" – because products that actually meet those definitions are exempt from certain "drug" requirements, including premarket review. *See id.* §§ 321(g), (ff), 360ee(b)(3). But if the products do not actually meet the definitions of those terms in the statute, and they meet the definition of the term "drug," then they are unapproved "new drugs." Because "dietary supplements" and "medical foods" are not subject to premarket review, FDA would not review the labeling of those products before the products are marketed or have the occasion to consider whether the products are actually unapproved "new drugs." And, once the products are on the market, FDA still may not be aware of the statements made in the labeling or have the occasion to consider whether the products are actually unapproved "new drugs." Accordingly, the sponsors' false statements may go undetected.

89. When FDA detects such false labeling and has the requisite resources to pursue the violation, it may send a warning letter to the violator. For example, in late May and early June of this year, FDA sent three separate warning letters to different companies that cited them for selling products containing synthetic steroids as "dietary supplements" when in fact (1) the products did not meet the definition of "dietary supplement," and (2) the products were actually unapproved "new drugs." *See* FDA Warning Letter to Flex Fitness Products and Big Dan's Fitness, dated May 25, 2017, **Exhibit 55**; FDA Warning Letter to Hardcore Formulations, dated

June 5, 2017, **Exhibit 56**; FDA Warning Letter to AndroPharm LLC, dated June 5, 2017, **Exhibit 57**.

90. FDA has taken similar actions against unapproved "new drugs" falsely labeled as "medical foods." For example, FDA took action in May 2017 against Enzymotec Ltd. (and one of its suppliers) for falsely positioning three *omega-3 fatty acid products* – Vayarol®, Varyarin®, and Vayacog® – as "medical foods," when they were actually unapproved "new drugs." *See* BRIEF-Enzymotec Ltd- FDA issued import alert that included vayarol, vayarin and vayacog products, Reuters.com, May 10, 2017, **Exhibit 58**; Import Alert 66-41, Detention Without Physical Examination of Unapproved New Drugs Promoted in the U.S., dated June 19, 2017, **Exhibit 59**; Enzymotec Ltd., SEC Form 6-K, dated May 2017, **Exhibit 60**; FDA Warning Letter to Rainbow Gold Products, Inc. dated May 4, 2017, **Exhibit 61** (citing Vayarin® as an unapproved "new drug").

91. The Synthetically Produced Omega-3 Products come in several molecular forms (*e.g.*, E-EPA, rTG-EPA, E-OM3, and rTG-OM3) and, typically, in two different physical forms (*i.e.,* in liquid form, as an oil for use in or as a "dietary supplement," or in an encapsulated form, for use as a "dietary supplement"). Each Synthetically Produced Omega-3 Product is a "drug" because it triggers one or more elements of the "drug" definition, and the elements in the "drug" definition triggered by each product depend on the molecular and physical form of the product.

i. All of the Synthetically Produced Omega-3 Products meet the definition of "drug" in the FDCA

a) Encapsulated E-OM3

92. The encapsulated E-OM3 products subject to this complaint are "drugs" because they meet at least one of the four prongs of the "drug" definition. *See id.* With regard to the first

prong, subsection 201(g)(1)(A) of the FDCA, "Omega-3-Acid Ethyl Ester Capsules" are named in the drug USP/NF, *see* USP/NF (USP40-NF35), Vol. 2 (2017), at 5430-5433. **Exhibit 62**. Notably, to be "recognized" in the USP, products need only meet the definition of a product named in the USP; they need not comply with compendial identity standards. *See* 21 U.S.C. §§ 351(b), 352(e)(3)(B); *see also* USP/NF (USP40-NF35), at xiii, § 2.30. **Exhibit 63**. (Recognized products that do not meet the compendial identity standards are "drugs" that are adulterated, misbranded or both. *See* 21 U.S.C. §§ 351(b), 352(e)(3)(B)). According to the USP, "Omega-3-Acid Ethyl Ester Capsules" are capsules that include E-EPA and E-DHA as well as five other omega-3 fatty acids in ethyl ester form (*e.g.*, alpha-linolenic acid in ethyl ester form). *See* USP/NF (USP40-NF35), Vol. 2 (2017), **Exhibit 62**, at 5430-5433. Upon information and belief, all of the encapsulated E-OM3 products identified in this complaint (and attachments hereto) meet that definition. Accordingly, they are all "recognized" in the USP, and therefore, are "drugs."

93. With regard to the second and third prongs of the "drug" definition, subsections 201(g)(1)(B) and 201(g)(1)(C) of the FDCA, all of the Proposed Respondents' E-OM3 capsules named in this complaint (except those sold by Ultimate) are clearly intended to affect disease and/or the structure/function of the body. Under FDA's regulations, evidence that a product is intended to be used as "drug" includes advertising, labeling, or "other oral or written statements" by the entities that are legally responsible for the labeling of the drug, as well as the circumstances surrounding the distribution of the product. 21 C.F.R. § 201.128. As set forth in Section VII below, the Promotional Materials associated with each of these products (except those sold by Ultimate) indicate that the products are intended to affect disease and/or the

structure function of the body. Moreover, upon information and belief, the circumstances of sale corroborate that intent.

94. With regard to the fourth prong of the "drug" definition, subsection 201(g)(1)(D) of the FDCA, upon information and belief, the encapsulated E-OM3 products sold by Ultimate are intended for use as a component of a "drug."

b) E-OM3 in Oil Form

95. The E-OM3 products in oil form are "drugs" because they meet at least one of the four prongs of the "drug" definition. With regard to the first prong, subsection 201(g)(1)(A) of the FDCA, "Omega-3-Acid Ethyl Esters" (in oil form) are named in the drug USP/NF, *see* USP/NF (USP40-NF35), Vol. 2 (2017), at 5428-5430, **Exhibit 64**. According to the USP/NF, "Omega-3 Acid Ethyl Esters" are mixtures of ethyl esters, principally E-EPA and E-DHA, that may also contain one of five other omega-3 fatty acids. *See id.* Upon information and belief, all E-OM3 sold by the Proposed Respondents in oil form meet this definition. Therefore, they are recognized in the USP/NF, and as such are "drugs."

96. With regard to the second and third prongs of the "drug" definition, subsections 201(g)(1)(B) and 201(g)(1)(C) of the FDCA, all of the Proposed Respondents' E-OM3 oil named in this complaint (except that sold by Ultimate) is clearly intended to affect disease and/or the structure/function of the body. As set forth in Section VII below, the Promotional Materials associated with each of these products (except those sold by Ultimate) indicate that the products are intended to affect disease and/or the structure function of the body. Moreover, upon information and belief, the circumstances of sale corroborate that intent.

97. With regard to the fourth prong of the "drug" definition, subsection 201(g)(1)(D) of the FDCA, upon information and belief, the E-OM3 oil sold by Ultimate is intended for use as a component of a "drug."

c) E-EPA, rTG-EPA, and rTG-OM3, as well as other forms of E-OM3

98. E-EPA, rTG-EPA, and rTG-OM3, as well as other forms of E-OM3, are "drugs" because they meet one or more of the prongs of the definition of "drug" in the FDCA. With regard to the second and third prong, namely subsections 201(g)(1)(B) and 201(g)(1)(C), most of these products are intended to affect disease and/or the structure/function of the body. As set forth in Section VII below, the Promotional Materials associated with each of these products (except those sold by Ultimate and Nordic Pharma) indicate that the products are intended to affect disease and/or the structure function of the body. Moreover, upon information and belief, the circumstances of sale corroborate that intent.

99. With regard to the fourth prong, subsection 201(g)(1)(D) of the FDCA, upon information and belief, when these substances are sold by Ultimate and Nordic Pharma, they are intended for use as a component of a "drug."

ii. All of the Synthetically Produced Omega-3 Products are unapproved "new drugs"

100. All of the Synthetically Produced Omega-3 Products are also "new drugs" under Section 201(p) of the FDCA because they are not generally recognized by qualified experts as safe and effective for their intended uses. 21 U.S.C. § 321(p).

101. As mentioned above, as a practical matter, for a drug to be generally recognized by qualified experts as safe and effective for its intended uses, it has to be FDA-approved. None

of the Synthetically Produced Omega-3 Products is an FDA-approved drug. *See* List of FDA-Approved Icosapent Ethyl Drugs (E-EPA) in Orange Book, **Exhibit 16** (listing none of the Synthetically Produced Omega-3 Products); List of FDA-Approved Omega-3 Ethyl Ester Drugs in the Orange Book, **Exhibit 17** (same). Thus, they are all "new drugs" – and indeed, *unapproved* "new drugs."

2. The other elements for false advertising and contributory false advertising under the Lanham Act are met

102. The Promotional Materials associated with all of the Synthetically Produced Omega-3 Products (except for those sold by Ultimate) indicate that the products are for use in, or as "dietary supplements," **Exhibits 1-B – 7-B, 8-A-ii – 12-M-ii**. As explained above, falsely labeling or promoting these products as "dietary supplements" is literally false for two reasons: (1) the products do not meet the definition of "dietary supplement" in 21 U.S.C. § 321(ff), and (2) calling the products "dietary supplements" hides the material fact that the products are actually unapproved "new drugs."

103. Because these statements are literally false, they have the capacity to deceive a substantial segment of potential consumers, and this deception is presumed to be material to consumer purchasing decisions. Indeed, the express use of a false moniker and the failure to disclose the unapproved "new drug" status of the products is undoubtedly material. If consumers knew that the products were illegally marketed unapproved "new drugs" and that, as such, it was unclear whether the products were safe and effective, it would influence the consumers' purchasing decisions.

104. All of the Proposed Respondents (except Ultimate) are causing the literally false statements to enter interstate commerce, **Exhibit 1-B – 7-B and 8-A-ii – 12-M-ii**. Finally, the

false statements of the Proposed Respondents (except Ultimate) about their products have injured, or are likely to injure, Amarin, as discussed in paragraphs 217-238.

105. Further, upon information and belief, as set forth in Section VII, Ultimate and Nordic Pharma Inc. are contributorily liable under the Lanham Act for knowingly inducing or causing the entities distributing their products, respectively, Nature's Bounty and Nordic Naturals, to falsely advertise their products as "dietary supplements," or for materially participating in that illegal conduct.

B. Proposed Respondents' Importation And Sale Of The Synthetically Produced Omega-3 Products Violate Section 337 Based On The Standards Set Forth In The FDCA

106. The importation and sale of the Proposed Respondents' Synthetically Produced Omega-3 Products constitute unfair acts or unfair methods of competition under Section 337 based upon the standards set forth in the FDCA. As discussed in paragraphs 61-83, none of Proposed Respondents' Synthetically Produced Omega-3 Products meets the definition of "dietary supplement" in the FDCA, 21 U.S.C. § 321(ff). In addition, as discussed in paragraphs 84-101, all of the products are actually unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a); *see also* 21 U.S.C. § 352(f). The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" violates the standards set forth in Section 505(a) of the FDCA, *id.* § 355(a); *see also* 21 U.S.C. §§ 352(f), 331(a)-(c).

107. As explained in paragraphs 86-87, products that meet the definition of "drug" in the FDCA, *id.* § 321(g), must follow the requirements in the FDCA and its implementing regulations that apply to "drugs," regardless of whether FDA has acknowledged that the products are "drugs." As explained below, none of the Synthetically Produced Omega-3 Products follows

a number of these requirements, and as such, they are misbranded drugs in violation of the standards set forth in Section 502 of the FDCA, *id.* § 352, and adulterated drugs, in violation of Section 501 of the FDCA, *id.* § 351.

108. Section 502(a) of the FDCA prohibits "labeling" that is "false or misleading in any particular." *Id.* § 352(a); *see also* 21 U.S.C. § 321(m) (defining the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article"). In addition, Section 502(n) of the FDCA similarly prohibits promotional material other than labeling from being false or misleading. 21 U.S.C. § 352(n); 21 C.F.R.§ 202.1(e)(6). The labeling for all of the Distributors' Synthetically Produced Omega-3 Products is false, at minimum, because it falsely asserts that the products are "dietary supplements," or it falsely implies that they are "dietary supplements" by using some modification of that term. **Exhibits 8-A-ii – 12-M-ii**. Similarly, the Promotional Materials associated with the Manufacturer's products (except for Ultimate's products) are false because they provide that the products at issue are for use in, or as "dietary supplements." **Exhibits 1-B – 7-B**.

109. Further, Section 502(f) of the FDCA provides that drugs are misbranded if their labeling fails to bear "adequate directions for use." 21 U.S.C. § 352(f). "Adequate directions for use" means "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. According to FDA,

> Prescription drugs can only be used safely at the direction, and under the supervision, of a licensed practitioner. Therefore, it is impossible to write "adequate directions for use" for prescription drugs. FDA-approved drugs which bear their FDA-approved labeling are exempt from the requirement that they bear adequate

> directions for use by a layperson. But otherwise, all prescription drugs by definition lack adequate directions for use by a layperson.

See, e.g., FDA Warning Letter to Flex Fitness Products and Big Dan's Fitness, dated May 25, 2017, **Exhibit 55** (citing 21 U.S.C. §§ 352(f)(1), 353(b)(2)). All of the Distributors' Synthetically Produced Omega-3 Products are "prescription drugs" as defined by the FDCA, 21 U.S.C. § 353(b)(1)(A), because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary for their use. *See id.* Indeed, all products containing synthetically produced omega-3 that have been approved by FDA are prescription drugs. *See* List of FDA-Approved Icosapent Ethyl (E-EPA) Drugs in Orange Book, **Exhibit 16**; List of FDA-Approved Omega-3 Ethyl Ester Drugs in the Orange Book, **Exhibit 17**. As explained in paragraphs 84-101, all of the Distributors' Synthetically Produced Omega-3 Products are intended for "drug" uses (*i.e.*, to affect the structure/function of the body and/or to affect disease), **Exhibits 8-A-iii – 12-M-iii, 8-A-iv – 12-M-iv**; **Table 1**. Those uses have not been approved by FDA, and therefore, the labeling for the products at issue does not, and cannot, contain adequate directions for those uses. Accordingly, those products are misbranded in violation of Section 502(f).

110. Further, upon information and belief, all of the Synthetically Produced Omega-3 Products are misbranded drugs under Section 502(o) of the FDCA because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or the products at issue were not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j). *Id.* § 352(o).

111. In addition, upon information and belief, all of the Synthetically Produced Omega-3 Products are adulterated for failure to comply with current good manufacturing

practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

112. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

113. Finally, the FDCA prohibits unapproved "new drugs," and adulterated and misbranded "drugs," from entering the United States under Section 801(a) of the FDCA, 21 U.S.C. § 381(a), when the "drugs" have been manufactured, prepared, propagated, compounded, or processed in a foreign establishment that is not registered in accordance with Section 510(i) of the FDCA. Upon information and belief all of the products sold by the Manufacturers were manufactured, prepared, propagated, compounded, or processed in such a foreign establishment. Section 801(a) requires FDA to (1) sample any drugs that have been manufactured in an unregistered establishment, and (2) examine samples to determine whether any appear to be misbranded, adulterated, or unapproved new drugs. *See Cook v. FDA*, 733 F.3d 1, 10 (D.C. Cir. 2013). If FDA finds an apparent FDCA violation (*e.g.,* that a product is an unapproved, misbranded, and adulterated "new drug"), it must refuse the drug admission to the United States. *See id.*

VII. INSTANCES OF UNFAIR IMPORTATION AND SALE

A. Manufacturers

DSM

114. Proposed Respondent Royal DSM NV ("DSM NV") and its corporate affiliates, DSM Marine Lipids Peru S.A.C. ("DSM-Peru"), DSM Nutritional Products Canada Inc., ("DSM-Canada") and "DSM Nutritional Products LLC" in the United States ("DSM-US") manufacture, import, and/or sell Synthetically Produced Omega-3 Products. Royal DSM NV acquired a fish oil concentration facility in Nova Scotia, Canada in 2012, to "strengthen its position in the North American dietary supplement market." Koninklijke DSM NV to Acquire Ocean Nutrition Canada to Expand Its Nutritional Lipids Growth Platform Conference Call – Final, May 18, 2012 FDA (Fair Disclosure) Wire, **Exhibit 65**. Upon information and belief, this facility is now DSM-Canada. At the time of acquisition, the facility manufactured fish oil concentrates of up to 70% EPA/DHA levels, and those supplements were sold in "Walmart, GNC, and Sam's Club." *Id.* Since that time, DSM has begun to use 3C technology, a new concentrating technology, to make "[u]ltra-pure, high potency EPA and DHA up to 85%," and it continues to manufacture those oils at the Nova Scotia facility. *See* The Modern Movement Forward In Omega-3, DSM Brochure, **Exhibit 66**; Meg-3, Business Opportunities, Accessed Aug. 8, 2017 ("DSM's flagship fish oil production facility is located in Mulgrave, Nova Scotia. In 2015, DSM invested $40 million to expand the facility, which refines and concentrates Omega-3 fish oil"), **Exhibit 67.** In April 2017, World Fishing & Aquaculture announced that DSM's Meg-3 ingredients "processed in DSM's facilities in Peru and Canada (DSM Marine Lipids Peru SAC and DSM Nutritional Products Canada Ltd [sic])," received a Friend of the Sea

seal of approval, and the article noted that Meg-3 is a "leading global brand containing omega-3 EPA and DHA. The ingredients are used in dietary supplement, pharmaceutical and food & beverage applications worldwide." World Fishing & Aquaculture, April 20, 2017, **Exhibit 68**. DSM also advertises Meg-3 as conforming to the quality and purity standards established for dietary supplements by the U.S. FDA. Meg-3, Business Opportunities, **Exhibit 67**. The Meg-3 product line sold by DSM includes E-OM3 concentrates and concentrates in the triglyceride form (upon information and belief, these concentrates are rTG-OM3 and rTG-EPA). *See* DSM in Food, Beverages & Dietary Supplements, **Exhibit 1-A-i**. Upon information and belief, DSM-Peru and DSM-Canada are manufacturing Meg-3 products that are Synthetically Produced Omega-3 Products, including E-OM3 oil and rTG-OM3 oil comprised predominantly of E-EPA or rTG-EPA.

115. Complainants have obtained data from Datamyne, Inc.[2] showing that DSM-Peru shipped to the United States, to DSM-US, "240 drums containing 45.60 MT of omega3T1000 [and] Meg-3 refined fish oil." **Exhibits 1-F-i.** Upon information and belief, DSM-Peru is supplying DSM-US with E-OM3 oil and/or rTG-OM3 oil comprised predominantly of E-EPA or rTG-EPA. In addition, DSM-Peru imported 191 MT of purified fish oil into the United States in bond for immediate export to consignee DSM-Canada. **Exhibit 1-F-i.** Based on the commercial relationships described above, DSM-Canada's concentrated production facility in Nova Scotia, and DSM-Canada's "focus on the North American Market" described in paragraph 114 above, and upon information and belief, DSM-Canada is supplying those products to DSM-US.

[2] Datamyne, Inc. obtains trade data gathered from U.S. Customs and Border Protection's Automated Manifest System, customs declarations, and import-export Customs statistics. U.S. shipment data are updated daily upon receipt from U.S. Customs and Border Protection.

116. DSM violates Section 337 of the Tariff Act, because it violates the standards established in the FDCA. Specifically, the E-OM3 sold by DSM cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-70, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. As further explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF, **Exhibit 64**. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by DSM. For example, DSM makes the following structure/function claims: "Omega-3 fatty acids play a critical role in supporting human health across different stages. DHA . . . provides important brain and eye benefits, while DHA and EPA . . . together promote cardiovascular health." **Exhibit 1-C-i**; **Table 2**. In addition, DSM makes the following disease claims:

> The omega-3s EPA and DHA have been the focus of cardiovascular research for several decades. Numerous observational and randomized clinical trials have shown EPA/DHA intake reduces cardiovascular risk via reduction in blood triglycerides (TGs), resting heart rate, blood pressure and inflammation and improved vascular function. The strongest evidence for EPA/DHA is for reduction of coronary heart disease (CHD) death and sudden cardiac death (SCD), with the latter being attributed to the antiarrhythmic effects of omega-3s.

Exhibit 1-D-i; **Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

117. Similarly, the rTG-OM3 oil sold by DSM cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in

paragraphs 61-83. As further explained in paragraphs 98-99, it is a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the structure/function and disease claims identified in paragraph 116, above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

118. In addition, DSM's E-OM3 and rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose, and they are actually unapproved "new drugs," in violation of Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 1-B-i – 1-B-iii**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

119. DSM also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

120. In addition, DSM violates Section 337 of the Tariff Act, based upon violations of the Lanham Act. Specifically, DSM is falsely stating that its E-OM3 oil and its rTG-OM3 oil

can be used in "dietary supplements" when these products are actually unapproved "new drugs," **Exhibits 1-B-i – 1-B-iii**; these literally false statements have the capacity to deceive customers and are likely to influence purchasing decisions; DSM caused these false statements to enter interstate commerce; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Ultimate BioPharma

121. Proposed Respondent Ultimate Biopharma (Zhongshan) Corporation ("Ultimate") is a Chinese company that manufactures softgel capsules containing E-OM3 and OM3 in triglyceride form, **Exhibit 2-A**. Upon information and belief, some, if not all, of the OM3 in triglyceride form is rTG-OM3 comprised predominantly of rTG-EPA.

122. **Exhibit 2-F** contains 30 Datamyne documents showing 29 shipments of fish oil (labeled, 2100 Fish Oil, 2340 Fish Oil, 2099 Fish Oil, 2370 Fish Oil, and 2333 Fish Oil), and one shipment of 2340 Fish Oil Softgels, from Ultimate to Nature's Bounty between September 15, 2016 – February 11, 2017. Upon information and belief, Ultimate is shipping E-OM3 comprised predominantly of E-EPA and rTG-OM3 comprised predominantly of rTG-EPA in oil and softgel form to Nature's Bounty.

123. As discussed in paragraphs 163-173 below, Proposed Respondent Nature's Bounty is a U.S. importer and distributor of Synthetically Produced Omega-3 Products under brand names Nature's Bounty®, Puritan's Pride®, and Solgar®, **Exhibit 2-E-i**. Nature's Bounty was the consignee on the import shipments described in paragraph 122 above. **Exhibit 2-F**. Ultimate is a subsidiary or affiliate of Nature's Bounty. **Exhibit 2-E-ii**.

124. Ultimate violates Section 337 of the Tariff Act, because it violates the standards set forth in the FDCA. Specifically, the E-OM3 oil and capsules sold by Ultimate cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. As further explained in paragraphs 92 and 95, both the E-OM3 oil and capsules are "drugs" because, upon information and belief, they are drugs recognized in the USP/NF. **Exhibits 62 and 64**. Ultimate's E-OM3 capsules and oil are also drugs because, upon information and belief, as explained in paragraphs 94 and 97, they are intended for use in, or as, a final product that is a "drug" (*e.g.*, Nature's Bounty purported "dietary supplements," which are actually unapproved "new drugs"). **Exhibits 8-A-ii – 8-N-ii**; **Table 4**. As explained in paragraphs 100-101, these products are also unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

125. Similarly, the rTG-OM3 oil and capsules sold by Ultimate cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather, Ultimate's rTG-OM3 oil and capsules are drugs because, upon information and belief, the rTG oil and capsules are intended for use in (or as) a final product that is a "drug" (*e.g.*, Nature's Bounty purported "dietary supplements," which are actually unapproved "new drugs"). **Exhibits 8-A-ii – 8-N-ii**; **Table 4**. As explained in paragraphs 100-101, these products are also unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

126. In addition, upon information and belief, Ultimate's E-OM3 oil and capsules are (1) as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* §

352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (2) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, as required by Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

127. Ultimate also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

128. In addition, Ultimate violates Section 337 of the Tariff Act, predicated upon violations of the provisions of the Lanham Act. Specifically, Ultimate is liable for contributory false advertising because Nature's Bounty is engaged in false advertising, as explained in paragraphs 163-173, and upon information and belief, Ultimate knowingly induced or caused that false advertising or otherwise materially participated in it.

Marine Ingredients

129. Marine Ingredients is a KD Pharma Group Company. **Exhibit 69**. Proposed Respondent Marine Ingredients AS is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that Marine Ingredients AS, in Norway, shipped to Marine Ingredients LLC, in the United States: 17.06 metric tons of oil, including "Omevital 400200 EE Mix" and "Omevital 3322 EE," around July

23, 2017; in two separate shipments, 17.06 metric tons of oil (in each shipment), including "Omevital 400200 EE Mix," "Omevital 3322 EE," "4510 TG Ultra," and "Omevital 3322 TG," around July 17, 2017; 17.06 metric tons of oil, including "Omevital 4510 TG Ultra" and "Omevital 3322EE" in June 2017; and 22 Drums of "Omevital 3322 EE," in December 2016, **Exhibit 3-F-i**. Omevital 3322EE and Omevital 400200 EE are E-OM3, **Exhibit 3-F-i**, and upon information and belief, Omevital 4510 TG Ultra is rTG-OM3. *See id.* Thus, E-OM3 oils comprised predominantly of E-EPA and rTG-OM3 oils comprised predominantly of rTG-EPA are being imported into the United States from Marine Ingredients AS to Marine Ingredients LLC.

130. Proposed Respondent Marine Ingredients LLC is a U.S. importer of Synthetically Produced Omega-3 Products. Marine Ingredients LLC was the consignee on the import shipment described in paragraph 129 above. **Exhibit 3-F-i**. Marine Ingredients LLC markets its Synthetically Produced Omega-3 Products under the brand "Omevital." **Exhibit 3-A-i**. These products include E-OM3 oil comprised predominantly of E-EPA, and upon information and belief, they include rTG-OM3 oil comprised predominantly rTG-EPA as well. *See id.* Marine Ingredients LLC acquired BASF's concentrated fish oil production facility in 2014, which produces "Omevital" brand Synthetically Produced Omega-3 Products, and it merged with KD Pharma in 2016. **Exhibit 3-E-i**. Marine Ingredients AS is a subsidiary of Marine Ingredients LLC. **Exhibit 3-E-ii**.

131. Marine Ingredients violates Section 337 of the Tariff Act, because it violates certain standards in the FDCA. Specifically, the E-OM3 oil sold by Marine Ingredients cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21

U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF, **Exhibit 64**. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Marine Ingredients. Marine Ingredients' structure/function claims include the following:

> Together EPA & DHA play a critical role in our cell development, growth, and maintenance . . . [they] are necessary for several important body functions, such as •Essential building blocks for our brain, eyes, and nerves . . . • Building cell membrane [sic] in our brain . . . • Maintenance of normal brain function . . . . More than 20,000 clinical studies showing positive health benefits have been conducted on Omega-3 EPA & DHA.

Exhibit 3-C-ii; Table 2. In addition, Marine Ingredients' disease claims include:

> More than 20,000 clinical studies showing positive health benefits have been conducted on Omega-3 EPA & DHA. Many of these studies indicate that these vital nutrients may be of importance by themselves or in combination with other drugs for the management of the following disorders: • Cardiovascular Disease, • Inflammation and Rheumatoid Arthritis, • Developmental Disorders, • Psychiatric Disorders, •Cognitive Aging, • Coronary Heart Disease, • Lupus, • Cancer.

Exhibit 3-D-ii, **Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

132. Similarly, the rTG-OM3 oil sold by Marine Ingredients cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the

same structure/function and disease claims cited above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

133. In addition, Marine Ingredients' E-OM3 oil and rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose and they are actually unapproved "new drugs," in violation of the standards set forth in Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 3-B-i – 3-B-iv**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 110, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, as required by Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

134. Marine Ingredients also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

135. In addition, Marine Ingredients violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Marine Ingredients is falsely stating that its E-OM3 oil and rTG-OM3 oil can be used in "dietary supplements" when these products are actually unapproved "new drugs" **Exhibits 3-B-i – 3-B-iv**. These literally false statements have the

capacity to deceive consumers and are likely to influence purchasing decisions; Marine Ingredients caused these false statements to enter interstate commerce; and as discussed in paragraphs 216-237, Amarin is likely to be injured as a result.

Golden Omega

136. Proposed Respondent Golden Omega S.A. is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that Golden Omega S.A. shipped to the United States 6.84 metric tons of "Fish Oil Omega-3 Concentrate Ethyl Ester (EE3322)," 6.84 metric tons of Fish Oil Omega-3 Concentrate Ethyl Ester (EE4020)," and 1.52 metric tons of "Fish Oil Omega-3 Concentrate Triglyceride (TG3624)" in October 2016. **Exhibit 4-F-i**. Proposed Respondent Golden Omega USA LLC is a U.S. importer of Synthetically Produced Omega-3 Products. In particular, it was the consignee on the import shipments described above. **Exhibit 4-F-i**. Golden Omega S.A. and Golden Omega USA LLC are affiliated entities. **Exhibit 4-E**.

137. Golden Omega identifies "EE3322" as a "balanced EPA+DHA EE concentrate" **Exhibit 4-A-iii**, "TG3624 as a balanced EPA+DHA TG concentrate," **Exhibit 4-A-iii**, and "EE4020" as a "high EPA EE concentrate" **Exhibit 4-A-iv**. The "EE," or E-OM3, products are Synthetically Produced Omega-3 Products, and upon information and belief the concentrated TG product is rTG-OM3.

138. Golden Omega violates Section 337 of the Tariff Act, because it violates certain standards of the FDCA. Specifically, the E-OM3 oil sold by Golden Omega cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary

supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF, **Exhibit 64**. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Golden Omega. For example, Golden Omega's structure/function claims include:

> Omega 3s and specifically EPA and DHA, are involved in the structure and function of cells in your body – from your head to your toes. There are more than 30,000 published studies on EPA and DHA Omega 3s, focused on the positive impact that the high consumption of Omega 3s has for the health of the heart, brain, and eye.

Exhibit 4-C-i; **Table 2.** In addition, disease claims include the following: "High EPA Omega-3 concentrates are commonly used in products to support . . . anti-inflammatory health." **Exhibit 4-D**; **Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

139. Similarly, rTG-OM3 oil sold by Golden Omega cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the same structure/function and disease claims cited in the paragraph above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

140. In addition, Golden Omega's E-OM3 oil and its rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose,

and they are actually unapproved "new drugs," in violation of Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 4-B-i – 4-B-iv**; (2) upon information and belief, as explained in paragraph 1109, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, as required by Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

141. Golden Omega also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

142. In addition, Golden Omega violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Golden Omega is falsely stating that its E-OM3 oil and its rTG-OM3 oil can be used in "dietary supplements" when these products are actually unapproved "new drugs" **Exhibits 4-B-i – 4-B-iv**; these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Golden Omega caused these false statements to enter interstate commerce; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Nordic Pharma

143. Proposed Respondent Nordic Pharma, Inc. ("Nordic Pharma") is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc., that show that Nordic Pharma imported into the United States: "Fish Oil, TG90 2050" on or about July 30, 2017; "Fish Oil TG90 3525" also on or about July 30, 2017; "Fish Oil TG90 3525" on or about May 19, 2017; "Fish Oil TG90 3525" and "Fish Oil TG 2050" on or about May 7, 2017; and "Fish Oil TG90 4020 80 drums" and "Fish Oil TG90 3525 37 Drums" in December 2016. **Exhibit 5-F**. Nordic Pharma is "exclusively dedicated to manufacturing Nordic Naturals omega oils" and the company is "privately owned by Nordic Naturals." **Exhibit 5-E**. Nordic Naturals, as explained in paragraphs 174-181, sells a large number of concentrated omega-3 products in triglyceride form. Upon information and belief, the products sold by Nordic Naturals and the products referenced in Datamyne, Inc. are rTG-OM3 oil comprised predominantly of rTG-EPA.

144. Nordic Pharma violates Section 337 of the Tariff Act, because it violates certain standards of the FDCA. The rTG-OM3 oil sold by Nordic Pharma cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather Nordic Pharma's rTG-OM3 oil is a drug because, as explained in paragraph 99, upon information and belief, the rTG-OM3 oil is intended for use in a final product that is a "drug" (*e.g.*, the purported "dietary supplements" sold by Nordic Naturals that are actually unapproved "new drugs"). **Exhibits 9-A-ii – 9-UU-ii**. As explained in paragraphs 100-101, these products are also unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

145. In addition, Nordic Pharma's rTG-OM3 oil is (1) falsely promoted for use in "dietary supplements" when it cannot legally be used for that purpose and it is actually an unapproved "new drug," in violation of the standards set forth in Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 9-A-ii – 9-UU-ii**; (2) upon information and belief, as explained in paragraph 110 a misbranded drug under Section 502(o) of the FDCA, *id.* § 352(o), because it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, an adulterated drug because it was not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

146. Nordic Pharma also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

147. In addition, Nordic Pharma violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Nordic Pharma is liable for contributory false advertising because Nordic Naturals is engaged in false advertising, as explained in paragraphs 174-181, and upon information and belief, Nordic Pharma knowingly induced or caused that false advertising or otherwise materially participated in it.

Croda

148. Proposed Respondent Croda Europe Ltd. is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that Croda Europe Ltd. shipped to the United States: 13.6 metric tons of oil, including TG 3322, in March 2017; 17.29 metric tons of "Crodamol/Incromega" in January 2017; 16.08 metric tons of Incromega E3322-LQ in August 2016; and 16.07 metric tons of oil including Incromega E3322-LQ in May 2016. **Exhibit 6-F.**

149. Proposed Respondent Croda Inc. is a U.S. importer of Synthetically Produced Omega-3 Products. In particular, it was the consignee on the import shipment described in paragraph 148 above. **Exhibit 6-F**. Croda Europe Ltd. and Croda Inc. are affiliated entities, namely "[r]elated undertakings" of Croda International Plc. **Exhibit 6-E-i**.

150. Croda's Promotional Materials identify "Incromega" as the name for a number of fish oils, including fish oil concentrates that are produced using PureMax™ technology. **Exhibit 6-A-i**. Incromega products include a number of E-OM3 products and concentrated OM3 products in triglyceride form. **Exhibit 6-A-ii**. Upon information and belief, these E-OM3 products and concentrated OM3 products in triglyceride form are among the Incromega products imported into the United States.

151. Croda violates Section 337 of the Tariff Act, because it violates certain standards in the FDCA. Specifically, the E-OM3 oil sold by Croda cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained

in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF. **Exhibit 64**. It is also a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Croda. For example, structure/function claims include "Croda's Incromega™ range offers many possibilities for consumer health trends having clear benefits in numerous condition specific areas such as heart health, joint health, cognitive function, and eye health." **Exhibit 6-C-i**; **Table 2**. In addition, disease claims include "EPA can be beneficial for • Depression, • Inflammatory and autoimmune conditions," "Studies reveal that essential Omega 3 fats help reduce the brain inflammation associated with cognitive decline, which can harm brain cells," "Accumulating evidence suggests that diets that include Omega 3 fatty acids, specifically . . . [EPA and DHA] also protect against the development of dementia and Alzheimer's." **Exhibits 6-D-i and 6-D-iii; Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the` FDCA. *Id.* §§ 321(g), (p), 355(a).

152. Similarly, the rTG-OM3 oil sold by Croda cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather, it is a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the same promotional claims cited above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

153. In addition, Croda's E-OM3 oil and its rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose and they are actually unapproved "new drugs," in violation of the standards set forth in Section 502(n) of the

FDCA, *id.* § 352(n), **Exhibits 6-B-i – 6-B-iv**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).).

154. Croda also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

155. In addition, Croda violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, Croda is falsely stating that its E-OM3 oil and its rTG-OM3 oil can be used in "dietary supplements," **Exhibits 6-B-i – 6-B-iv**, when these products are actually unapproved "new drugs"; these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Croda caused these false statements to enter interstate commerce; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

TASA

156. Proposed Respondent Tecnologica de Alimentos S.A. ("TASA") is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that TASA shipped to the United States 16.61 metric tons of oil, including "Concentrate Omega 3 EE 33/22" on or about July 17, 2017; 32.37 metric tons of oil, including "Omega 3 Fish Oil EE 33-22," on or about July 6, 2017; 17.10 metric tons of oil, including "Omega 3 Fish Oil EE 33-22" on or about June 7, 2017; 16.23 metric tons of oil, including "Fish Oil EE 33-22" on or about May 15, 2017; and 80 drums of "Peruvian Refined Anchovy Omega 3 Fish Oil EE 33-22" in March 2017. **Exhibits 7-F-i**.

157. According to Promotional Materials on TASA's website, TASA "offer[s] . . . Omega-3 concentrates according to the needs of our customers with different concentration levels of EE and TG." **Exhibits 7-A-i**. "EE" stands for "ethyl esters," or E-OM3, **Exhibit 7-A-i**, and, upon information and belief "TG" stands for rTG-OM3. *See id.*

158. TASA violates Section 337 of the Tariff Act, because it violates certain standards in the FDCA. Specifically, the E-OM3 oil sold by TASA cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF. **Exhibit 64**. It is also a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by TASA. For example, TASA's structure/function claims

include the following: "HIGH Omega levels are related to speed improvements IN TEENS . . . . The study indicates that the 1% increase in the Omega-3 Index I related to an increase of 1.23 in the substitution test (LDST)." **Exhibit 7-C**; **Table 2**. In addition, TASA's disease claims include:

> Low Omega-3 consumption CONTRIBUTES to increased death rate . . . . The risk-of-morbidity study (GBD 2013), which quantifies threats to the health of the population and opportunities for prevention, concludes that low levels of omega-3 intake may increase the risk of disease . . .

Exhibit 7-D-i; **Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

159. Similarly, rTG-OM3 oil sold by TASA cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather, it is a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the same structure/function and disease promotional claims made by TASA cited above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

160. In addition, TASA's E-OM3 oil and its rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements," by TASA, when they cannot legally be used for that purpose and they are actually unapproved "new drugs," in violation of the standards set forth in Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 7-B-i – 7-B-ii**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included

in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 110, adulterated drugs because they were nor manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).).

161. TASA also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

162. In addition, TASA violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, TASA is falsely stating that its E-OM3 oil and its rTG-OM3 oil can be used in "dietary supplements," **Exhibits 7-B-i – 7-B-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; TASA caused these false statements to enter interstate commerce; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

B. Distributor Respondents

Nature's Bounty

163. Proposed Respondent The Nature's Bounty Company ("Nature's Bounty") is a U.S. importer and distributor of Synthetically Produced Omega-3 Products under brand names Nature's Bounty®, Puritan's Pride®, Solgar®, and Sundown Naturals®. Nature's Bounty was the

consignee on the import shipments from its affiliate, Ultimate, described in paragraph 122 above. **Exhibit 2-F**.

164. Nature's Bounty sells the following E-OM3 products comprised predominantly of E-EPA in the United States under the brand name Nature's Bounty: Fish Oil 1400 mg (E-OM3), **Exhibit 8-A**, and Mini-Fish Oil 1290 mg (E-OM3), **Exhibit 8-B**. The Promotional Materials accompanying Mini-Fish Oil 1290 mg state that Nature's Bounty sources its fish oil "directly from Peru." **Exhibit 8-B-vi-b**. Although the Fish Oil 1400 mg product does not contain country of origin markings visible on the Nature's Bounty website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70.** In addition, at least one unit of Nature's Bounty Fish Oil 1400 mg has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Fish Oil 1400 mg product containing concentrated fish oil is imported.

165. The following Nature's Bounty E-OM3 products comprised predominantly of E-EPA and rTG-OM3 products comprised predominantly of rTG-EPA are offered for sale in the United States under the brand name Puritan's Pride®: Double Strength Omega-3 Fish Oil 1200 mg (E-OM3), **Exhibit 8-C**; Omega-3 Fish Oil 645 mg Mini Gels (upon information and belief, rTG-OM3), **Exhibit 8-D**; Krill Oil + High Omega-3 Concentrate 1085 mg (E-OM3), **Exhibit 8-E**; Lutigold™ Nutra-Vision with Lutein, Zeaxanthin & Omega-3 (E-OM3), **Exhibit 8-F**; One Per Day Omega-3 Fish Oil 1360 mg (upon information and belief, rTG-OM3), **Exhibit 8-G**; Specific Care™ Vision (E-OM3), **Exhibit 8-H**; Triple Strength Omega-3 Fish Oil 1360 mg (E-OM3), **Exhibit 8-I**; Ubiquinol 100 mg & Omega Fish Oil 400 mg (E-OM3), **Exhibit 8-J**. Upon information and belief, the Puritan's Pride® Synthetically Produced Omega-3 Products are

imported into the United States. Although the Puritan's Pride® Synthetically Produced Omega-3 Products do not contain country of origin markings visible on the Puritan's Pride® website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70**. In addition, at least one unit of Puritan's Pride® Omega-3 Fish Oil 645 mg Mini Gels has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Puritan's Pride® Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

166. The following Nature's Bounty E-OM3 Products comprised predominantly of E-EPA are sold in the United States under the brand name Solgar®: Triple Strength Omega 3 950 MG (E-OM3), **Exhibit 8-K**; Double-Strength Omega-3 700 MG (E-OM3), **Exhibit 8-L**; and EFA 1300 MG Omega 3-6-9 (E-OM3), **Exhibit 8-M**. Upon information and belief, the Solgar® Synthetically Produced Omega-3 Products are imported into the United States. Although the Solgar® Synthetically Produced Omega-3 Products do not contain country of origin markings visible on the Solgar® website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70**. In addition, at least one unit each of Solgar's Triple Strength Omega 3 950 MG and Double-Strength Omega-3 700 MG has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Solgar® Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

167. The following Nature's Bounty E-OM3 Product comprised predominantly of E-EPA is sold in the United States under the brand name Sundown Naturals®: Odorless Fish Oil 1290mg/900mg (E-OM3), **Exhibit 8-N**. The Promotional Materials accompanying the Sundown Naturals® Odorless Fish Oil 1290mg/900mg product state that Sundown Naturals®' "fish oil is

sourced in Peru." **Exhibit 8-N-vi-b**. In addition, at least one unit of Sundown Naturals® Fish Oil Omega 3-1290 MG has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Sundown Naturals® Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

168. Nature's Bounty violates Section 337 of the Tariff Act, because it violates standards established in the FDCA. Specifically, the E-OM3 capsules sold by Nature's Bounty cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 92, the capsules are "drugs" because, upon information and belief, they are recognized in the USP/NF. **Exhibit 62**. The capsules are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Nature's Bounty (**Table 1** (listing structure/function claims and disease claims for all of Distributors' products)).

169. Similarly, the rTG-OM3 capsules sold by Nature's Bounty cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. The capsules are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Nature's Bounty for those products (**Table 1** (listing structure/function claims and disease claims for all of Distributors' products)).

170. For example, Nature's Bounty's website provides the following structure/function claim, which applies to all of the Nature's Bounty brand products: "Nature's Bounty® Fish Oil contains Omega-3 fatty acids including EPA and DHA which help support and maintain the health of your cardiovascular and circulatory system." **Exhibits 8-A-iii-b, 8-B-iii-b**. The Puritan's Pride® website contains many structure/function claims, including "Omega-3 fatty acids are important for heart health," "Omega-3 fatty acids are important for the body's immune system," and "Omega-3's can support bone health." **Exhibits 8-C-iii-b – 8-J-iii-b**. The same website also contains disease claims, including "Omega 3 fatty acids are important for heart health . . . Cardiovascular disease is the number one cause of death in the United States [implied claim for the prevention or treatment of cardiovascular disease and for the prevention of death]," and "In a study of women over 65 with osteoporosis, those who took EPA and GLA supplements saw a reduced rate of bone loss. In fact, many of the women experienced an increase in bone density [implied prevention/treatment of osteoporosis claim]." **Exhibits 8-C-iv-b, 8-D-iv – 8-I-iv, 8-J-iv-b**. Further, a Solgar brochure for all of its essential fatty acid products contains structure/function claims, such as "EPA and DHA leapfrog several metabolic steps, so they quickly yield health benefits.* EPA forms the hormone-like prostaglandin 3 series of compounds, which have circulatory and other heart-healthy benefits." **Exhibits -K-iii-b - 8-M-iii-b**. In addition, Sundown Naturals®' Odorless Fish Oil 1290mg/900mg is marketed with a number of structure/function claims, including "Sundown Naturals® Odor-less Fish Oil 1290 mg supplies omegas that are important for your heart health.* Omega-3s are 'good fats' that support cardiovascular health, and cellular/joint/skin health.*" **Exhibit 8-N-iii**. Other structure/function and disease claims for these products are listed in **Table 2**.

171. In addition, Nature's Bounty's E-OM3 and rTG-OM3 products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibits 8-A-ii – 8-N-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

172. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

173. Nature's Bounty also violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, Nature's Bounty is falsely stating on the product labels for all of its E-OM3 and rTG-OM3 products that they are "dietary supplements," **Exhibits 8-A-ii – 8-N-ii**, when these products are actually unapproved "new drugs;" these literally false

statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Nature's Bounty caused these false statements to enter interstate commerce, **Exhibits 8-A-ii – 8-N-ii**; and as discussed in paragraphs 216-237, Amarin is likely to be injured as a result.

Nordic Naturals

174. Proposed Respondent Nordic Naturals is a U.S. distributor of Synthetically Produced Omega-3 Products. As described in paragraph 143 above, Complainants have obtained data from Datamyne, Inc. that show that Respondent Nordic Pharma imported "Fish Oil TG90 4020 80 drums" and "Fish Oil TG90 3525 37 Drums into the United States in December 2016. **Exhibit 5-F.** Nordic Pharma is "exclusively dedicated to manufacturing Nordic Naturals omega oils" and is "privately owned by Nordic Naturals." **Exhibit 5-E**. Nordic Naturals' Promotional Materials state that 100% of Nordic Naturals fish oil is manufactured in Norway" and its "soft gel products are bottled and encapsulated at [its] plant in Southern California." **Exhibit 71.**

175. Nordic Naturals distributes the following Synthetically Produced Omega-3 Products for direct sale to consumers or health care professionals: Ultimate Omega-D3, **Exhibit 9-A**; Ultimate Omega Xtra (Soft Gel), **Exhibit 9-B**; Ultimate Omega Xtra (Liquid), **Exhibit 9-C**; Ultimate Omega Liquid 2840 mg, **Exhibit 9-D**; Ultimate Omega Junior, **Exhibit 9-E**; Ultimate Omega in Fish Gelatin 1280 mg, **Exhibit 9-F**; Ultimate Omega D3 Sport (Professional Product), **Exhibit 9-G**; Ultimate Omega D3 Sport (Liquid) (Professional Product, **Exhibit 9-H**; Ultimate Omega 1280 mg, **Exhibit 9-I**; Ultimate Omega 2X, **Exhibit 9-J**; Ultimate Omega 2X with Vitamin D3, **Exhibit 9-K**; Ultimate Omega 2X Mini, **Exhibit 9-L**; Ultimate Omega 2X Mini with Vitamin D3, **Exhibit 9-M**; Ultimate Omega + CoQ10, **Exhibit 9-N**; ProEPA, **Exhibit 9-O**;

Complete Omega + D3 Junior, **Exhibit 9-P**; Complete Omega Junior, **Exhibit 9-Q**; Complete Omega XTRA, **Exhibit 9-R**; Daily Omega Kids, **Exhibit 9-S**; EPA Xtra, **Exhibit 9-T**; Omega ONE, **Exhibit 9-U**; EPA, **Exhibit 9-V**; Omega LDL, **Exhibit 9-W**; Omega Joint XTRA, **Exhibit 9-X**; Omega Curcumin, **Exhibit 9-Y**; Omega Blood Sugar, **Exhibit 9-Z**; ProOmega 2000 (Professional Product), **Exhibit 9-AA**; ProOmega (Professional Product), **Exhibit 9-BB**; ProOmega in Fish Gelatin (Professional Product), **Exhibit 9-CC**; Pro-Omega Liquid (Professional Product), **Exhibit 9-DD**; ProOmega-D (Professional Product), **Exhibit 9-EE**; ProOmega-D Xtra (Professional Product), **Exhibit 9-FF**; ProOmega-D Xtra Liquid (Professional Product), **Exhibit 9-GG**; ProOmega 2000-D (Professional Product), **Exhibit 9-HH**; Nordic Omega-3 Gummy Fish (Professional Product), **Exhibit 9-II**; Omega Boost Junior (Professional Product), **Exhibit 9-JJ**; Omega-3 Fishies (Professional Product), **Exhibit 9-KK**; Nordic Omega-3 Gummy Worms (Professional Product), **Exhibit 9-LL**; Nordic Omega-3 Gummies (Professional Product), **Exhibit 9-MM**; ProOmega 2000 Jr. (Professional Product), **Exhibit 9-NN**; ProOmega Junior (Professional Product), **Exhibit 9-OO**; ProOmega 3-6-9 (Professional Product), **Exhibit 9-PP**; ProOmega CRP (Professional Product), **Exhibit 9-QQ**; ProOmega Blood Sugar (Professional Product), **Exhibit 9-RR**; ProOmega LDL (Professional Product), **Exhibit 9-SS**; ProOmega Joint Xtra (Professional Product), **Exhibit 9-TT**; ProOmega CoQ10 (Professional Product), **Exhibit 9-UU**. In addition, at least one unit each of Nordic Naturals Complete Omega XTRA and Nordic Naturals ProOmega Blood Sugar has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Nordic Naturals Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

176. Notably, many of these products (*i.e.*, those designated as "Professional Product") are marketed directly to health care professionals (*see, e.g.*, **Exhibits 9-AA-i-a, 9-UU-i-a**). But, at least as a general matter, the purported "Professional Products" also are available to the general public on Amazon.com, *see, e.g.*, **Exhibits, 9-O-vi, 9-II-vi-a, 9-AA-vi-a, 9-GG-vi-a**.

177. The Nordic Naturals website states that "all Nordic Naturals formulas are produced in true triglyceride form," **Exhibit 72**. Upon information and belief, given that all of the products listed above contain EPA in concentrations above, or in ratios different from, common fish oil, *see id.*, all of these products contain rTG-OM3.

178. Nordic Naturals violates Section 337 of the Tariff Act, because it violates the standards established in the FDCA. Specifically, the products containing rTG-OM3 sold by Nordic Naturals cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. These products are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Nordic Naturals for those products. For example, the Nordic Naturals website contains structure/function claims that apply to all of the products, such as "Extensive research has documented the health benefits of EPA and DHA, which include not only a healthy heart, but brain and cognitive function, joint mobility, eye health, pregnancy and lactation, healthy skin and hair, and a normally functioning immune response." **Exhibits 9-A-iii, 9-B-iii-b – 9-DD-iii-b, 9-EE-iii, 9-FF-iii-b – 9-HH-iii-b, 9-II-iii, 9-JJ-iii-b - 9-KK-iii-b, 9-LL-iii – 9-MM-iii, 9-NN-iii-b - 9-QQ-iii-b, 9-RR-iii, 9-SS-iii-b - 9-UU-iii-b.** Similarly, the website contains disease claims that apply to all of the products such as "Protects against age-related oxidative damage," "Can

help alleviate [eye] dryness and redness," "May help slow the progression of age-related memory loss," "Supports internal repair systems that operate in response to physical stress," "Omega-3 consumption may reduce the risk of allergies in children," and "Omega-3 consumption may reduce the risk of colds in infants." **Exhibits 9-A-iv – 9-U-iv, 9-V-iv-b - 9-W-iv, 9-X-iv-b - 9-Y-iv-b, 9-Z-iv - 9-QQ-iv, 9-RR-iv-b, 9-SS-iv, 9-TT-iv-b – 9-UU-iv-b**. Other structure/function and disease claims for these products are listed in **Table 1**.

179. In addition, the Nordic Naturals rTG-OM3 products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibit 9-A-ii – 9-UU-ii**; (2) misbranded as a matter of law, in violation of Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

180. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or

misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

181. Nordic Naturals also violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, Nordic Naturals is falsely stating on the product labels for all of its products that they are "dietary supplements," **Exhibits 9-A-ii – 9-UU-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Nordic Naturals caused these false statements to enter interstate commerce, **Exhibits 9-A-ii – 9-UU-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Pharmavite LLC/Nature Made

182. Proposed Respondent Pharmavite LLC is a U.S. distributor of Nature Made-branded imported Synthetically Produced Omega-3 Products. In particular, Pharmavite sells at least the following Synthetically Produced Omega-3 Products in the United States under the Nature Made brand: Fish-Oil One Per Day Burpless (E-OM3), **Exhibit 10-A**; Fish Oil One Per Day (E-OM3), **Exhibit 10-B**; Fish Oil Pearls (E-OM3), **Exhibit 10-C**; Full Strength Mini Omega-3 (E-OM3), **Exhibit 10-D**; Omega-3 with Xtra Absorb (E-OM3), **Exhibit 10-E**; Triple Omega (E-OM3), **Exhibit 10-F**; and Ultra Omega-3 (E-OM3), **Exhibit 10-G**.

183. According to the applicable country of origin markings on the Nature Made Synthetically Produced Omega-3 Products, Norway is the country of origin of the fish oil used in Full Strength Mini Omega-3 product, **Exhibit 10-D-vi-b**, and the Omega-3 with Xtra Absorb product, **Exhibit 10-E-vi-b**. Colombia is the country of origin of the fish oil used in the Fish Oil Pearls product, **Exhibit 10-C-vi-b**. Canada is the country of origin of the fish oil used in the

Fish Oil One Per Day, Burpless product, **Exhibit 10-A-vi-b** and the Fish Oil One Per Day product, **Exhibit 10-B-vi-b**. The Triple Omega product also is imported into the United States. Although the Triple Omega product does not contain country of origin markings visible on the Nature Made website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70**. In addition, at least one unit of Nature Made Fish Oil Pearls has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Nature Made Synthetically Produced Omega-3 Products are imported.

184. Pharmavite violates Section 337 of the Tariff Act, because it violates the standards established in the FDCA. Specifically, the E-OM3 capsules sold by Pharmavite cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83.. In addition, as explained in paragraph 92, the capsules are "drugs" because, upon information and belief, they are recognized in the USP/NF. **Exhibit 62.** The capsules are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the structure/function and disease promotional claims made by Pharmavite. *See* **Table 1** (listing structure/function claims and disease claims for all of Distributors' products).

185. For example, structure/function claims on Pharmavite's website for Nature Made's fish oil products include the following: "A regular intake of EPA and DHA can play a positive role in your health. When made available to the body, EPA and DHA are incorporated into cell membranes (such as heart cells) and help support flexible cell membranes," and "EPA

and DHA . . . help support a healthy heart." **Exhibits 10-A-iii-b – 10-G-iii-b**; **Table 1**. Pharmavite's website for all of Nature Made's fish oil products also includes, for example, the disease claim, "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease." **Exhibits 10-A-iv-b – 10-G-iv-b**; **Table 1**. Notably, FDA has exercised enforcement discretion over this claim when it is used to promote dietary supplements and conventional foods. **Exhibit 73**. As explained in paragraph 184, however, Pharmavite's E-OM3 products are not "dietary supplements," and clearly, they are not conventional foods. Accordingly, they are not subject to FDA's enforcement discretion policy for this claim. Other structure/function and disease claims for these products are listed in **Table 1**.

186. In addition, Pharmavite's E-OM3 products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibits 10-A-ii – 10-G-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices

for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

187. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

188. Pharmavite violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Pharmavite is falsely stating on the product labels for all of its E-OM3 products that they are "dietary supplements," **Exhibits 10-A-ii – 10-G-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Pharmavite caused these false statements to enter interstate commerce, **Exhibits 10-A-ii – 10-G-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Innovix Pharma Inc./OmegaVia

189. Proposed Respondent Innovix Pharma Inc. ("Innovix Pharma") is a U.S. distributor of OmegaVia-branded imported Synthetically Produced Omega-3 Products. In particular, Innovix Pharma sells at least the following Synthetically Produced Omega-3 Products in the United States: OmegaVia EPA 500 (rTG-EPA), **Exhibit 11-A**, and OmegaVia Fish Oil (rTG-OM3), **Exhibit 11-B**. Both of these products contain omega-3 in the rTG form. **Exhibits 11-A-i and 11-B-i.**

190. According to the OmegaVia Promotional Materials, the concentrated fish oil used in the OmegaVia Synthetically Produced Omega-3 Products is sourced from Peru, Chile and the

United States, and is concentrated in Europe before being imported into the United States for encapsulation. **Exhibits 11-A-vi – 11-B-vi**. The labels for OmegaVia EPA 500 and for OmegaVia Fish Oil state that the "source" of the fish oil is Peru and Chile, and the product is "[c]oncentrated and purified in Europe." *See id.* In addition, at least one unit of OmegaVia's EPA 500 has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the OmegaVia Synthetically Produced Omega-3 Products are imported.

191. Innovix Pharma violates Section 337 of the Tariff Act, because it violates certain standards established in the FDCA. Specifically, the rTG-OM3 and rTG-EPA products sold by Innovix Pharma cannot meet the definition of "dietary supplement" because rTG-OM3 and rTG-EPA are not "dietary ingredients," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. These products are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Innovix Pharma for those products. For example, the Innovix Pharma website contains structure/function claims that apply to all of the products, such as: "Comfort your joints," "Keep Your Mind Sharp," and "maintaining mood health." **Exhibits 11-A-iii-c and 11-B-iii-c**. Similarly, the website contains disease claims that apply to all of the products such as: "Reduces enzymes that destroy cartilage," "reduces joint discomfort," "Moderate growth of atherosclerosis plaque," "EPA has been found to be as effective as prescription anti-depressants," "Manage age-related brain decline," "bring your triglyceride levels down naturally," "moderate blood pressure," "reducing redness and scaling," "That's 20% More Omega-3 Than Prescription Lovaza" (comparison claims to drugs are disease claims, 21 C.F.R. § 101.93(g)((vi)), "Clinically effective dose for triglycerides," "Pharmaceutical Grade,"

"EPA is more effective than DHA at lowering triglycerides," "improve mood and depression," "powerful anti-inflammatory for soothing arthritis." **Exhibits 11-A-iv-b – 11-A-iv-c, 11-B-iv-b – 11-B-iv-c**. Other structure/function and disease claims for these products are listed in **Table 1**.

192. In addition, Innovix Pharma's rTG-OM3 and rTG-EPA products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibit 11-A-ii – 11-B-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

193. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

194. Innovix Pharma also violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Innovix Pharma is falsely stating on the product labels for all of its rTG-OM3 and rTG-EPA products that they are "dietary supplements," **Exhibits 11-A-ii – 11-B-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Innovix Pharma caused these false statements to enter interstate commerce, **Exhibits 11-A-ii – 11-B-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Carlson

195. Proposed Respondent J.R. Carlson Laboratories, Inc. ("Carlson") is a U.S. distributor of imported Synthetically Produced Omega-3 Products. In particular, Carlson sells at least the following Synthetically Produced Omega-3 Products in the United States: Women's Omega Multi (upon information and belief, rTG-OM3), **Exhibit 12-A**; Very Finest Fish Oil Liquid (upon information and belief, rTG-OM3), **Exhibit 12-B**; Super Omega-3 Gems (E-OM3), **Exhibit 12-C**; Elite EPA Gems (E-EPA), **Exhibit 12-D**; Elite Omega-3 Gems (E-OM3), **Exhibit 12-E**; Fish Oil Q 100 mg (E-OM3), **Exhibit 12-F**; Inflammation Balance (upon information and belief, rTG-OM3), **Exhibit 12-G**; Maximum Omega 2000 (upon information and belief, rTG-OM3), **Exhibit 12-H**; MCT & Omega-3 (upon information and belief, rTG-OM3), **Exhibit 12-I**; Men's Omega Multi (E-OM3), **Exhibit 12-J**; Super Omega-3 Gems, Fish Gelatin (E-OM3), **Exhibit 12-K**; Omega 3-6-9 (upon information and belief, rTG-OM3), **Exhibit 12-L**; Super 2 Daily (upon information and belief, rTG-OM3), **Exhibit 12-M**. Notably, Carlson's omega-3 product brochure expressly states that its omega-3 products are comprised of (1) non-concentrated 100% natural triglycerides, (2) concentrated ethyl esters, (3) concentrated re-

esterified triglycerides (rTG), and (4) a mixture of both the natural triglyceride form and the more potent ethyl ester form. **Exhibits 12-A-i-c, 12-B-i-c, 12-G-i-c, 12-H-i-c, 12-I-i-c, 12-L-i-c, 12-M-i-c**.

196. According to the Carlson Promotional Materials, the concentrated fish oil used in the Carlson Omega-3 Products is sourced from Norway. **Exhibits 12-A-vi – 12-M-vi**. In addition, at least one unit each of Carlson's Elite EPA Gems and Elite Omega-3 Gems has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Carlson Synthetically Produced Omega-3 Products are imported.

197. Carlson violates Section 337 of the Tariff Act, because it violates certain standards established by the FDCA. Specifically, the E-OM3 capsules and oils sold by Carlson cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraphs 92 and 95, the E-OM3 capsules and the oil are "drugs" because, upon information and belief, they are recognized in the USP/NF. **Exhibits 62 and 64**. The E-OM3 products are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Carlson. *See* **Table 1** (listing structure/function claims and disease claims for all of Distributors' products).

198. Similarly, the rTG-OM3 products sold by Carlson cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. The products are also "drugs" because they are intended to affect

the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function promotional claims made by Carlson for those products. *See* **Table 1** (listing structure/function claims and disease claims for all of Distributors' products).

199. For example, a Carlson brochure accessible from Carlson's website provides the following structure/function claims, which apply to all of the Carlson Synthetically Produced Omega-3 Products: "EPA and DHA are required by our bodies and aid in our well-being by promoting and supporting:* Cardiovascular health . . . Brain and nerve health . . . Vision heath . . . Immune system health . . . Joint health . . . Skin health." **Exhibits 12-A-iii-c – 12-B-iii-c, 12-C-iii-b, 12-D-iii-c – 12-M-iii-c**. Other structure/function claims for these products are listed in **Table 1**.

200. In addition, Carlson's products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibits 12-A-ii – 12-M-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices

for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

201. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

202. Carlson also violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Carlson is falsely stating on the product labels for all of its Synthetically Produced Omega-3 Products that they are "dietary supplements," **Exhibits 12-A-ii – 12-M-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Carlson caused these false statements to enter interstate commerce, **Exhibits 12-A-ii – 12-M-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

VIII. CLASSIFICATION OF THE RESPONDENTS' PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE

203. The Proposed Respondents' products are imported under the following HTS classifications: HTS Nos. 0306.19.0030; 1504.20.6040; 1517.90.2080; 1605.40.1090; 2106.90.99; 106.90.9998; 2916.19.5000; 3003.90.0000; 3004.90.9120; 3504.00.5000; 3824.90.4020; and 3824.90.4090.

IX. RELATED LITIGATION

204. Complainants are not aware of any related litigation.

X. DOMESTIC INDUSTRY

205. Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Two of Amarin Corporation's wholly owned subsidiaries are Complainants in this action: Amarin Pharma and Amarin Ireland. Amarin Pharma is a Delaware corporation and is located in Bedminster, New Jersey. Amarin Ireland is organized under the laws of the Republic of Ireland and is headquartered in Dublin, Ireland. Amarin has made significant expenditures in the United States. The details of these expenditures are set forth below and in the Confidential Declaration of Michael W. Kalb, Senior Vice President and Chief Financial Officer of Amarin Pharma, attached as **Confidential Exhibit 23**.

206. Amarin Pharma has full time employees and leases property located at 1430 Route 206, Bedminster, New Jersey. Amarin's administrative, commercial, research and development, supply chain, and regulatory activities, among other business services, take place in its Bedminster, NJ location. The details of Amarin's U.S.-based employment and physical facilities at its Bedminster, NJ location are contained in **Confidential Exhibit 23, at ¶ 4.**

207. Amarin has entered into agreements with three commercial API encapsulators for the encapsulation of Vascepa®. These companies have qualified and validated their manufacturing processes and are capable of manufacturing Vascepa® in each case consistent with the stringent requirements applicable to manufacturing of drugs sold in the United States. The details of Amarin's U.S.-based encapsulation expenditures in 2016 and the first and second quarters of 2017 are contained in **Confidential Exhibit 23, at ¶ 5.**

208. Amarin also has entered into packaging arrangements with two commercial API packagers for the packaging of Vascepa®. These companies have qualified and validated their manufacturing processes and are capable of packaging Vascepa® in each case consistent with the stringent requirements applicable to manufacturing of drugs sold in the United States. The details of Amarin's U.S.-based portion of these packaging expenditures in 2016 and the first and second quarters of 2017 are contained in **Confidential Exhibit 23, at ¶ 6**.

209. Amarin also has entered into a Logistics Service Agreement with a U.S.-based company. This agreement provides for inbound receipt of product, warehousing, order acceptance, order fulfillment and shipment of orders, among other services. The details of the U.S.-based portion of Amarin's logistics expenditures in 2016 and the first quarter 2017 are contained in **Confidential Exhibit 23, at ¶ 7.**

210. Amarin markets Vascepa® in the United States through its direct sales force of approximately 150 sales professionals, including sales representatives and their managers. Amarin also employs various marketing and medical affairs personnel to support Amarin's commercialization of Vascepa®. In addition to Vascepa® promotion by Amarin sales representatives, Amarin has a co-promotion agreement with Kowa Pharmaceuticals America, Inc. ("Kowa") that provides for no fewer than 250 sales representatives to promote Vascepa® in the United States. Total sales and marketing expenses for Vascepa, including the Kowa co-promotion fee, are contained in **Confidential Exhibit 23, at ¶ 8**.

211. To comply with the stringent regulatory requirements for the sale of a drug in the United States, Amarin undertook substantial risk and has made substantial investments in labor dedicated to research and develop Vascepa® to its current state. Amarin's program for

developing Vascepa has lasted over a decade, and the details of the total U.S.-based labor expenses dedicated to research and development during 2016 and the first and second quarters of 2017 are contained in **Confidential Exhibit 23 at ¶¶ 9-11.**

212. Significantly, the Vascepa® development programs include three key human clinical trials entitled MARINE, ANCHOR, and REDUCE-IT. Each clinical trial was undertaken under a special protocol assessment ("SPA") agreement with FDA involving years of costly regulatory interactions and SPA amendments. Such agreements reflect FDA's concurrence on the vigorous testing the company had to successfully complete even to be considered for FDA approval of Vascepa®.

213. The MARINE clinical trial demonstrated that Vascepa® was safe and effective for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TGs ≥500 mg/dL) hypertriglyceridemia, commonly known as very triglyceride levels, and it supported FDA's July 26, 2012 approval of the drug for that indication.

214. Likewise, the ANCHOR clinical trial demonstrated that the product was safe and effective for use as an adjunct to diet to reduce triglyceride levels in adult patients with persistent high (TGs 200-499 mg/dL) triglyceride levels in addition to statin therapy.

215. The REDUCE-IT cardiovascular outcomes trial is an 8,175-patient clinical trial evaluating whether treatment with Vascepa® will reduce major cardiovascular events in patients who, despite stabilized statin therapy, have elevated triglyceride levels and other cardiovascular risk factors. The results of this important trial could help healthcare professionals save millions of lives and lead to improved medical care for tens of millions of patients. If successful, the REDUCE-IT study has the potential to significantly change the treatment paradigm for

cardiovascular risk reduction, the leading cause of death in the United States. In a 2014 letter to Amarin, John Jenkins, M.D., then FDA's Director, Office of New Drugs, Center for Drug Evaluation and Research (now retired) stated that completed REDUCE-IT study "data would be of significant public health value." Dr. Jenkins went on to state, "I strongly urge Amarin to complete the trial and I know [FDA's clinical data review division for cardiovascular-focused drugs], is ready and willing to work with Amarin to address any issues that may arise as you work to that end." *See* FDA Letter to Amarin Pharma, dated September 11, 2014. **Exhibit 74.**

216. Amarin manages the REDUCE-IT study through a Contract Research Organization with the exception of costs for clinical trials management and costs for internal management. Amarin expects to report results from the REDUCE IT study in the second or third quarter of 2018. Amarin's total historical and expected costs of conducting the REDUCE-IT study are more than $200 million, most of it in the United States, and are set forth in **Confidential Exhibit 23 at ¶¶ 9-11.** Amarin's total R&D expenses since 2007, including expenses for all three studies, are contained in **Confidential Exhibit 23 at ¶¶ 9-11.**

XI. SUBSTANTIAL INJURY

217. The Proposed Respondents have engaged in unfair acts and unfair methods of competition, the threat or effect of which is to substantially injure Amarin's domestic industry in manufacturing, selling, and distributing its Vascepa® capsules. The importation and sale of Proposed Respondents' Synthetic Omega-3 Products by means of their unfair acts and unfair methods of competition have injured Amarin's domestic industry or threatened it with injury by (i) damaging the Vascepa® brand by exploiting Vascepa®'s status as an FDA-approved drug, (ii)

causing lost sales and market share to Vascepa®, and (iii) diminishing Amarin's profitability and Vascepa®'s eroding prices.

A. Damage To The Vascepa® Brand

218. Amarin has spent considerable time, money, effort, and resources developing the Vascepa® brand. As described in paragraphs 205-216 above, it developed Vascepa® in compliance with the FDCA and obtained FDA approval of its drug. It conducted the successful ANCHOR and MARINE trials, and is conducting REDUCE-IT trial as part of its development of Vascepa®. To expand marketing claims for its drug by demonstrating its effect on cardiovascular risk reduction, Amarin has invested and expects to invest more than $200 million since 2011 on its REDUCE-IT study alone. **Confidential Exhibit 23 at ¶¶ 9-11.** Through this substantial pharmacological development risk, effort and investment, Amarin has built and is continuing to build a successful, branded FDA-approved pharmaceutical product that helps patients who have been diagnosed with persistent high or very high triglyceride levels.

219. By contrast, Proposed Respondents market their Synthetic Omega-3 Products as non-prescription "dietary supplements," which exploits the Vascepa® brand and creates non-prescription competition and product substitution by the Synthetically Produced Omega-3 Products marketed illegally as "dietary supplements." These products are largely untested and much less stringently regulated, despite the fact that they are accompanied by claims by the Proposed Respondents that such products reduce triglyceride levels. By labeling and promoting Synthetically Produced Omega-3 Products as "dietary supplements" when, in fact, they are unapproved "new drugs," Proposed Respondents are diluting the Vascepa® brand and its status and notoriety as an FDA-approved drug and profiting from Amarin's substantial efforts and

investments – all without using their own resources, investing their own time or money, or exerting similar efforts of their own.

220. For example, a 2015 article on the NutraceuticalsWorld website entitled *Omega-3s: Turning the Tide & Watching the Current*, explained how Omega-3 manufacturers exploit the presence of Vascepa® and other prescription drugs in the market at the expense of Amarin and the Vascepa® brand. The article explains that "[t]he presence in the market of prescriptions forms of omega-3 esters such as Lovaza, Vascepa and Epanova gives an extra level of confidence even in the absence of [a Reference Daily Intake] or unqualified health claim." **Exhibit 75.**

221. In another article entitled *Lovaza: A Wolf in Sheep's Clothing*, a Nordic Naturals sales manager was quoted as saying that the presence of FDA-approved pharmaceuticals in the market is "very positive" because "it validates the use of omega 3s in a clinical application." **Exhibit 76.** Another market participant agreed, noting that if pharmaceutical companies "want[] to spend millions of dollars advertising the health benefits of fish oil on TV, it can do nothing but benefit all of us. I'm in." **Exhibit 76.**

222. The Proposed Respondents' conflation of Amarin's FDA-approved Vascepa® product with their Synthetically Produced Omega-3 Products has caused confusion in the marketplace about the distinction between "drugs" and "dietary supplements" to the detriment of the Vascepa® brand. A survey conducted by Fairleigh Dickenson University's Public Mind Poll entitled, "*What's In Your Supplements? Even The Experts Are Stumped*," reported that "[a]mong those physicians and pharmacists who had recommended a non-prescription omega-3 product to patients, more than four in five (85%) believed incorrectly that they had recommended an FDA-

approved OTC product . . . ." **Exhibit 77.** Notably, there are no legally marketed OTC drugs containing omega-3 fatty acids.

223. Companies like Proposed Respondent Innovix Pharma intentionally add to the confusion by promoting their products with claims that make direct comparisons to FDA-approved drugs (*e.g.*, "Most fish oils are not the same as Lovaza. But some Are! A few over-the counter pharmaceutical grade fish oils [sic] are just as potent, pure and effective at reducing triglycerides as Lovaza," *see* OmegaVia Website, **Exhibit 44**; *see also* OmegaVia Website 2, **Exhibit 45** (making implicit comparisons of OmegaVia's so-called "pharmaceutical grade fish oil" products to both Vascepa® and Lovaza®)).

224. These and other statements made by the Proposed Respondents in conjunction with the importation and sale of the Synthetically Produced Omega-3 Products have damaged or diluted the Vascepa® brand causing injury and threatened injury to Amarin.

B. Lost Sales And Market Share

225. Amarin has lost sales and market share as a result of Proposed Respondents' unfair acts and unfair methods of competition in multiple channels of distribution. The Synthetically Produced Omega-3 Products can be purchased off the shelf at retail establishments, such as grocery stores, pharmacies, big box stores, and over the Internet, without restriction. In addition, the Synthetically Produced Omega-3 Products can be purchased through doctor prescriptions. By contrast, Vascepa® can only be distributed pursuant to a prescription.

226. The ubiquitous presence of the Proposed Respondents' products in retail and consumer distribution channels has injured or threatened Amarin with injury. For example, in 2012, Amarin commissioned Hall & Partners, a New York City-based market research firm to

conduct a consumer direct-to-consumer market research program for Vascepa®. The sample included a total of 810 individuals with high triglycerides (200-499 mg/dL) and very high triglycerides (500+ mg/dL). When asked "[w]hich of the following medications are you currently taking to treat high triglycerides, whether treated alone or with another condition?," 41% responded that they took a prescription omega-3 product and 54% responded that they took a fish oil dietary supplement. **Confidential Exhibit 78.**

227. Proposed Respondents' unfair acts and unfair methods of competition also have resulted in lost sales and lost market share for Amarin's Vascepa® product in the physician prescription channel of distribution. In particular, a TVG Marketing Research & Consulting Study conducted in late 2015 indicates that physicians are more than three times more likely (28 percent to 8 percent) to recommend "Omega-3 Fish Oil Dietary Supplements" instead of prescribing Vascepa® when treating patients with elevated triglycerides. **Confidential Exhibit 79.** Moreover, certain Distributors, like Nordic Naturals, have an entire line of purported "Professional Products," that are specifically marketed to healthcare professionals. **Exhibits 80.** Proposed Respondents have induced doctors to recommend and patients to purchase Respondents' products in the mistaken belief that they are equivalent to FDA-approved products, with the threat or effect of lost sales and lost market share to Vascepa®.

228. Proposed Respondents' sales of Synthetically Produced Omega-3 Products resulting from unfair acts and unfair methods of competition have injured or threatened Amarin with injury. In the absence of Proposed Respondents' unfair acts and unfair methods of competition, sales of Vascepa® would displace a significant percentage of Proposed Respondents' sales of Synthetically Produced Omega-3 Products in the direct-to-consumer

channel of distribution, as consumers would seek prescriptions for Vascepa and other FDA-approved triglyceride-lowering drugs. And in the absence of Proposed Respondents' unfair acts and unfair methods of competition, sales of Vascepa® or other FDA-approved prescription triglyceride-lowering drugs would displace all of Proposed Respondents' sales of Synthetically Produced Omega-3 Products in the physician prescription channel of distribution.

229. Amarin has the capacity and/or inventory to supply the entire U.S. market demand for the Synthetically Produced Omega-3 Products (and similarly situated products), and Proposed Respondents' unfair acts prevent Amarin from making these sales. **Confidential Exhibit 70 at ¶ 23.**

C. Lost Profits And Price Erosion

230. Proposed Respondents' unfair acts and unfair methods of competition have contributed to Amarin's lost profits and to the price erosion of Vascepa®. FDA regulates "drugs" more stringently than "dietary supplements": drugs are subject to FDA approval, 21 U.S.C. § 505; and drug approval triggers the need for complying with the FDCA's drug registration and listing requirements, 21 U.S.C. § 360, the FDCA's drug manufacturing requirements, 21 U.S.C. § 351, and certain user fees. 21 U.S.C. § 379h. Moreover, FDA regulates drug labeling, promotional materials, and advertising stringently. FDA reviews drug labeling and approves claims that can be made regarding the product's use and conditions of use. 21 U.S.C. §§ 321(p), 505; 21 C.F.R. § 314.81. And promotional materials and advertising are submitted to FDA at the time of dissemination. Further, prescription drugs, such as Vascepa® can only be distributed pursuant to a prescription. 21 U.S.C. § 353(b).

231. By illegally importing and selling Synthetically Produced Omega-3 Products, the Proposed Respondents are able to avoid the substantial costs of obtaining FDA approval, maintaining FDA approval (*i.e.*, certain user fees), and complying with FDA's drug registration, listing, labeling/advertising, and manufacturing requirements. By contrast, Amarin has had to incur substantial costs in obtaining and maintaining FDA approval for Vascepa®, and for complying with FDA's various requirements.

232. All of Amarin's product revenue is derived from product sales of 1-gram and 0.5-gram size capsules of Vascepa®, net of allowances, discounts, incentives, rebates, chargebacks and returns. Amarin sells product to a limited number of major wholesalers and selected regional wholesalers and specialty pharmacy providers (collectively "Vascepa® Distributors") who resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions that are issued by authorized medical professionals. The commercial launch of 1-gram size Vascepa® capsules in the United States occurred in January 2013 and a smaller 0.5-gram size capsule was introduced in October 2016. Since 2014, Amarin has recognized revenue based on sales to its Vascepa® Distributors. Net product revenues based on sales of Vascepa® to distributors totaled $79.3 million and $58.1 million during the six months ended June 30, 2017 and 2016, respectively. Amarin's revenues would have been higher but for the Proposed Respondents' unfair acts and unfair methods of competition.

233. Amarin has not yet reached profitability on sales of Vascepa®, and anticipates incurring losses for an indefinite period of time. For the fiscal years ended December 31, 2016, 2015, and 2014, Amarin reported losses of approximately $86.4 million, $49.1 million, and $56.4 million, respectively, and the company has an accumulated deficit as of December 31,

2016 of $1.2 billion. For the three months ended March 31, 2017 and 2016, Amarin reported losses of approximately $20.9 million and $29.8 million, respectively.

234. This cumulated deficit in operating losses is typical of pharmaceutical companies that introduce a new drug into the market. They reflect the fact that to legally enter the pharmaceutical market with a drug like Vascepa® involves years of development, hundreds of millions of dollars in research and development costs, and several years of operating losses, as well as the risk of development failure. Pharmaceutical companies like Amarin typically recover their development costs over time through increasing volumes of sales. Amarin's losses, however, are exacerbated by Proposed Respondents' conduct. Put differently, Amarin's operating losses would have been smaller, or Amarin would have become profitable more quickly, but for the Proposed Respondents' unfair acts or unfair methods of competition.

235. The details of Amarin's production volumes and inventories of Vascepa® are contained in **Confidential Exhibit 70**, at **¶¶ 21-23**. Amarin has entered into long-term supply agreements with multiple FDA-approved API suppliers and encapsulators, which include the potential for capacity expansion aimed at creating sufficient volumes to meet future demand for Vascepa®. Amarin's ability to meet those growth projections (and to achieve profitability) is inhibited by Proposed Respondents' unfair acts and unfair methods of competition.

236. Proposed Respondents' sales of the Synthetically Produced Omega-3 Products resulting from unfair acts and unfair methods of competition also have had a substantial adverse impact on Vascepa® pricing. While Vascepa® pricing may be affected by insurance coverage and offered discounts, the fact that Vascepa® and Proposed Respondents' products are sold in the

same or similar channels of distribution also has adverse impacts on Vascepa® pricing. Amarin Corporation plc 2016 10K Statement at 41, attached as **Exhibit 81.**

237. The adverse price effects of the Synthetically Produced Omega-3 Products also is evident from Amarin's coupon discount sales program. According to that program, a consumer with commercial insurance can pay as little as $9.00 for a 90-day supply prescription of Vascepa®. **Exhibit 25.** The percentage of Vascepa® prescriptions covered by Amarin's coupon program is set forth in the attached **Confidential Exhibit 23.** Amarin's coupon program was designed to make Vascepa price competitive with Synthetically Produced Omega-3 Products and to discourage physicians and pharmacists from directing consumers to purchase Synthetically Produced Omega-3 Products based on price. As a result, Amarin has suffered price erosion from the unfairly traded Synthetically Produced Omega-3 Products with respect to at least the sales covered by Amarin's coupon program.

238. In sum, the Proposed Respondents' importation and sale of Synthetically Produced Omega-3 Products has injured and/or threatened Amarin with substantial injury by (i) damaging the Vascepa® brand by exploiting Vascepa®'s status as an FDA-approved drug, (ii) causing lost sales and market share to Vascepa, and (iii) diminishing Amarin's profitability and eroding Vascepa®'s prices.

XII. RELIEF

WHEREFORE, by reason of the foregoing, Complainants request that the Commission:

A. Institute an immediate investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to the Proposed Respondents' violations of

Section 337 based on the importation and sale in the United States of the Synthetically Produced Omega-3 Products;

B. Schedule and conduct a hearing on permanent relief pursuant to 19 U.S.C. § 1337(d) and (f) of the Tariff Act of 1930, as amended;

C. Find that Synthetically Produced Omega-3 Products are violating Section 337 of the Tariff Act because they violate the Lanham Act and the standards set forth in the FDCA in that they are sold as "dietary supplements" in the United States, without meeting the definition of "dietary supplement" in the FDCA. Further find that the Synthetically Produced Omega-3 Products are violating Section 337 of the Tariff Act because they meet the definition of "drugs," under the FDCA, by virtue of the fact that they are articles: (i) recognized in the USP/NF, (ii) intended to affect disease (*e.g.*, they are marketed with drug comparison claims, as well as other "disease" claims), *see* **Tables 1 and 2,** (iii) intended to affect the structure or function of the body (*e.g.*, they are marketed with claims that they support healthy heart, brain, and joint function, among other structure/function claims), *see* **Tables 1 and 2,** and/or (D) intended for use as a component of any articles specified in clauses (i)-(iii). 21 U.S.C. § 321(g)(1).

D. Issue a permanent General Exclusion Order excluding from entry into the United States all Synthetically Produced Omega-3 Products pursuant to 19 U.S.C. § 1337(d);

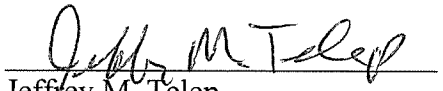
E. Issue a permanent Limited Exclusion Order specifically directed to each named Proposed Respondent and its subsidiaries and affiliates, pursuant to 19 U.S.C. § 1337(d), excluding from entry into the United States the Synthetically Produced Omega-3 Products through direct or indirect means;

F. Issue a permanent cease-and-desist order pursuant to 19 U.S.C. § 1337(f), prohibiting each Proposed Respondent and its subsidiaries and affiliates from directly or indirectly engaging in the importation, the use, the offering for sale, the sale after importation, or otherwise transferring within the United States, the Synthetically Produced Omega-3 Products;

G. Require Respondents to post a bond to secure Complainants' interests during any Presidential review of a Commission exclusion order; and

H. Issue such other and further relief as the Commission deems just and proper under the law, based upon the facts determined by the investigation and the authority of the Commission.

Respectfully submitted,



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Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

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