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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

JOHN GATTO on behalf of himself and all others similarly situated, **Plaintiff,** **v.** **INTERNATIONAL VITAMIN CORPORATION AND NUTRA MANUFACTURING, LLC** **Defendants.**	**CASE NO.:** 8:21-cv-889 **CLASS ACTION** **COMPLAINT FOR DAMAGES, EQUITABLE, DECLARATORY, AND INJUNCTIVE RELIEF** **DEMAND FOR JURY TRIAL**

Plaintiff John Gatto ("Plaintiff"), on behalf of himself and all others similarly situated, brings this class action against International Vitamin Corporation ("IVC") and its subsidiary Nutra Manufacturing, LLC (collectively "IVC" or "Defendants"), and on the basis of personal knowledge, information and belief, and the investigation of counsel, alleges as follows:

INTRODUCTION

1. This is a proposed class action on behalf of a nationwide class and a New York sub-class of consumers seeking redress for Defendants' deceptive practices associated with the advertising, labeling and sale of its Triple Strength Fish Oil sold under the GNC brand ("Product" or "Supplement").

2. Fish is a major source of healthful long-chain omega-3 fats and are rich in other nutrients such as vitamin D and selenium, high in protein, and low in saturated fat. Numerous studies have shown that consuming fatty fish 2-3 times a week reduces the risk of heart disease and stroke, as well as provides a myriad of additional health benefits. Scientific consensus is that consuming fatty fish as part of the diet materially contributes to good health.

3. Unfortunately, most Americans do not, or cannot, consume fatty fish with such regularity and have instead turned to the consumption of fish oil.

4. Indeed, as of 2012, fish oil supplements had become the most commonly used non-vitamin, non-mineral dietary supplement sold in the U.S., and to this day remain one of the most popular dietary supplement offerings. By 2019, the global fish oil market was valued at $1.9 billion, and is currently estimated to reach $2.8 billion by 2027. It remains a lucrative business with numerous market participants vying for consumer attention and their spending dollars.

5. Defendants manufacture, label and sell a Product which they claim to be Triple Strength Fish Oil containing of 734 mg of Eicosapentaenoic Acid ("EPA") and

266 mg of Docosahexaenoic Acid ("DHA") – the essential omega-3 fatty acids that naturally occur in fish.

6. Contrary to what is represented on the label, however, this Product is not fish oil, nor does it contain a single milligram of EPA or DHA. What was once natural fish oil has been subjected to a chemical process by which its molecular structure and constituent parts have been substantially transformed and irrevocably altered into a synthesized product that does not otherwise exist in fish, or nature. Through a chemical process known as trans-esterification, an industrial solvent is introduced into the fish oil in order to break its natural triglyceride bonds and cleave the glycerol backbone from fatty acid molecules. Thereafter, ethanol is introduced to which the free fatty acids bond and form fatty acid ethyl esters. Fish oil is stripped of hundreds of its constituent sub ingredients, and the Omega-3s, which include DHA and EPA, are converted into ethyl esters. Critically, these newly formed Omega-3s are different

molecules than the Omerga-3s which exist naturally in fish oil. The new chemical by-products are universally recognized by their common or usual name -- Omega-3 Fatty Acid Ethyl Esters.

7. The most material representation on a dietary supplement label is the product name – the fundamental indicia of its contents. Once trans-esterified, fish oil is irrevocably transformed, such that it is no longer fish oil and therefore cannot be so named or labeled. To do so, as IVC has done, is false, misleading, deceptive, unlawful, and perpetrates an actionable fraud on the consuming public.

8. As alleged herein, Defendants' conduct is in breach of warranty, violates California's Business and Professions Code § 17200, *et. seq.,* California's Business & Professions Code § l7500, *et. seq.,* California Civil Code § 1750, *et seq*., N.Y. Gen. Bus. Law § 349 et seq., N.Y. Gen. Bus. Law § 350 et seq., and is otherwise grounds for restitution on the basis of quasi-contract/unjust enrichment.

9. Throughout the applicable class periods, Defendants falsely represented the fundamental nature of their Product, and as a result of this false and misleading labeling, were able to sell these Products to tens of thousands of unsuspecting consumers throughout New York and the United States.

JURISDICTION AND VENUE

10. Jurisdiction of this Court is proper under 28 U.S.C. § 1332(d)(2). Diversity jurisdiction exists as Plaintiff Gatto is a resident of Massapequa, New York and Defendant IVC is incorporated in Delaware and maintains its principal place of business in Irvine, California. The amount in controversy exceeds $5,000,000 for the Plaintiff and members of the Class collectively, exclusive of interest and costs, by virtue of the combined purchase prices paid by Plaintiff and members of the putative Class, and the profits reaped by Defendants from their transactions with Plaintiff and the Class, as a direct and proximate result of the wrongful conduct alleged herein, and by virtue of the injunctive and equitable relief sought.

11. Venue is proper within this judicial district pursuant to 28 U.S.C. § 1391 because a substantial portion of the underlying transactions and events complained of occurred and affected persons and entities located in this judicial district. Defendant IVC is headquartered here, and makes all relevant business decisions from this District. It has received substantial compensation affected transactions and business activity in this judicial district.

PARTIES

12. Plaintiff John Gatto is a resident of Massapequa, New York.

13. Mr. Gatto is a purchaser of Defendants' GNC Triple Strength Fish Oil.

14. Mr. Gatto believed the representations on the Product's label that, among other things, it was actual fish oil containing DHA and EPA.

15. He believed that Defendants lawfully marketed and sold the Product.

16. Mr. Gatto relied on Defendants' labeling and was misled thereby.

17. Mr. Gatto would not have purchased the Product, or would have purchased the Product on different terms, had he known the truth.

18. Mr. Gatto was injured in fact and lost money as a result of Defendants' improper conduct.

19. If Mr. Gatto has occasion to believe that Defendants' marketing and labeling is truthful, non-misleading, and lawful, he would consider purchasing the Product in the future.

20. Defendant Nutra Manufacturing, LLC is incorporated in Delaware and headquartered in Greenville, South Carolina. Nutra Manufacturing is an IVC company and manufactures vitamin, mineral, herbal, sports nutrition, and diet and energy products. The dietary supplements produced by Nutra Manufacturing for IVC are sold in various countries worldwide.[1]

[1] See, https://www.nutramfg.com/ (last visited April 12, 2021)

21. Defendant IVC is a Delaware corporation, headquartered in Irvine, California. IVC manufactures and/or supplies various dietary supplements as private label and store brand products to retailers nationwide.[2]

22. On March 1, 2019, non-party GNC entered into an agreement with IVC to sell Nutra to IVC through a series of transactions. See GNC Holdings, Inc., Form 8-K, filed with the United States Securities and Exchange Commission on March 7, 2019 ("Form 8-K").[3] At the time of the transaction, IVC took a majority 57.14% stake in Nutra with the parties' expectation that IVC would subsequently purchase the remainder over the next few years.

23. The Supply Agreement between Nutra and a subsidiary of non-party GNC entered on March 1, 2019 confirmed that Nutra would supply non-party GNC's private label products and would be responsible for, among other things, that all raw materials meet the required manufacturing specifications which include testing, quality control and labeling of the final products consistent with current Good Manufacturing Practices.[4] The Agreement further confirms that Nutra is controlled by IVC, which was and remains headquartered in Irvine, California.

GENERAL ALLEGATIONS

A. OMEGA-3 FATTY ACIDS

24. Omega-3 Fatty Acids ("Omega-3" or "OM3") are polyunsaturated carboxylic acids that provide numerous health benefits to the human body including a

[2] See, https://ivcinc.com/what-we-do/ (last visited April 12, 2021)

[3] https://www.sec.gov/Archives/edgar/data/0001502034/000119312519066485/d631916d8k.htm.

[4] Product Supply Agreement, Exhibit 10.3, Form 8-K available at https://www.sec.gov/Archives/edgar/data/1502034/000119312519066485/d631916dex101.htm.

variety of critical organs and systems (e.g., heart, brain, eyes, blood vessels, lungs, immune, endocrine, and reproductive systems).[5]

25. Among the 11 types of OM3s, the three most important to human physiology are alpha-linolenic acid ("ALA"), docosahexaenoic acid ("DHA") and eicosapentaenoic acid ("EPA").[6]

26. ALA Omega-3 fatty acids are primarily found in plant oils and generally used by the human body for energy. To be used for something other than energy, ALA must first be converted into EPA or DHA. Unfortunately, this conversion process is inefficient and results in only a small percentage of ALA being converted into EPA and DHA.

27. In contrast, the primary source of EPA and DHA are marine oils from fatty fish and other seafoods.

28. Although experts have not established a daily recommended amount for DHA and EPA, the National Institutes of Health, Office of Dietary Supplements ("NIH") acknowledges that many scientific studies show that eating fatty fish rich in DHA and EPA has beneficial effects with respect to a variety of adverse health conditions such as cardiovascular disease, age-related macular degeneration, Alzheimer's disease, dementia, dwindling cognitive function, rheumatoid arthritis,

[5] *Omega-3 Fatty Acids*, National Institutes of Health, Office of Dietary Supplements, available at https://ods.od.nih.gov/factsheets/Omega3FattyAcids-Consumer; H. Breivik, *Long-chain Omega-3 Specialty Oils*, Woodhead Publishing in Food Science, Technology and Nutrition at 11 (hereinafter "Breivik at ___")(Clinical research has suggested that Omega-3s help prevent cardiovascular disease, Alzheimer's, dementia, macular degeneration, and rheumatoid arthritis. There is also support that Omega-3s provide benefits for sufferers of arthritis, Crohn's disease and patients with neuropsychiatric disorders such as depression and schizophrenia).

[6] Other Omega-3s include: hexadecatrienoic acid (HTA); stearidonic acid (SDA); eicosatrienoic acid (ETE); eicosatetraenoic acid (ETA); heneicosapentaenoic acid (HPA); docosapentaenoic acid (DPA); tetracosapentaenoic acid; and tetracosahexaenoic acid.

high blood pressure, and variety of other conditions including, potentially, certain cancers.[7]

29. Between 2017 and 2019, the American Heart Association ("AHA") released three science advisories related to Omega-3s, all of which recommend adults consume one to two servings of seafood per week to reduce the risk of congestive heart failure, coronary artery disease, stroke, and sudden cardiac death. For people with existing coronary artery disease, the AHA recommends approximately 1g/day of EPA plus DHA, preferably from oily fish.[8]

30. In 2019 the U.S. Food and Drug Administration ("FDA") considered the weight of scientific evidence on the impact of OM3 and approved five qualified health claims relating to the consumption of the EPA/DHA and its effect on heart health.[9]

31. Unfortunately, Americans generally do not consume a sufficient amount of fatty fish necessary to maintain adequate levels of EPA and DHA. In response to this deficiency, health care professionals began recommending that Americans supplement their diets with fish oil.[10]

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[7] Available at https://ods.od.nih.gov/factsheets/Omega3FattyAcids-Consumer/

[8] Etherton, P., et al, *Omega-3 Fatty Acids and Cardiovascular Disease New Recommendations From the American Heart Association*, AHA Arteriosclerosis, Thrombosis, and Vascular Biology Journal (2003) available at https://www.ahajournals.org/doi/full/10.1161/01.ATV.0000057393.97337.AE; *See also*, National Institutes of Health, *Omega-3 Fatty Acids*, available at https://ods.od.nih.gov/factsheets/Omega3FattyAcids-HealthProfessional/#:~:text=For%20people%20with%20existing%20coronary,of%20a%20physician%20%5B80%5D.

[9] *FDA Announces New Qualified Health Claims for EPA and DHA Omega-3 Consumption and the Risk of Hypertension and Coronary Heart Disease*, June 19, 2019, available at https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-new-qualified-health-claims-epa-and-dha-omega-3-consumption-and-risk-hypertension-and.

[10] Mackay, *A Comparison of Synthetic Ethyl Ester Form Fish Oil vs. Natural Triglyceride Form*, available from http://www.promedics.ca/site/downloads/Triglycerides%20vs%20Ethyl%20Esters.pdf.

32. In 1995, fish oil supplements generated only $35 million in annual sales. By 2005, that number had increased to $310 million and by 2012, fish oil supplements had become the non-vitamin/non-mineral natural product most commonly taken by both adults and children with approximately 7.8 percent of adults (18.8 million) and 1.1 percent of children age 4 to 17 (664,000) regularly consuming fish oil supplements.[11] By 2019, the global fish oil market had grown to $1.9 billion, and is currently estimated to reach $2.8 billion by 2027.[12]

B. FISH OIL

33. Omega-3 fatty acids, including EPA and DHA, are found in a variety of fatty fish such menhaden, sardines, anchovies, salmon and tuna.[13] The oil from these fish is extracted by a fairly straightforward process which has been employed in a similar fashion since the early 1800s whereby fish were caught, cooked and a rock weighted process was used to press oil from the fish. By the 1850s, the rock weighted process was replaced with a hydraulic press.[14]

34. Today, the process remains relatively the same. Once fish are caught, they are on-boarded to a fishing vessel and quickly boiled. The fish are cooked and

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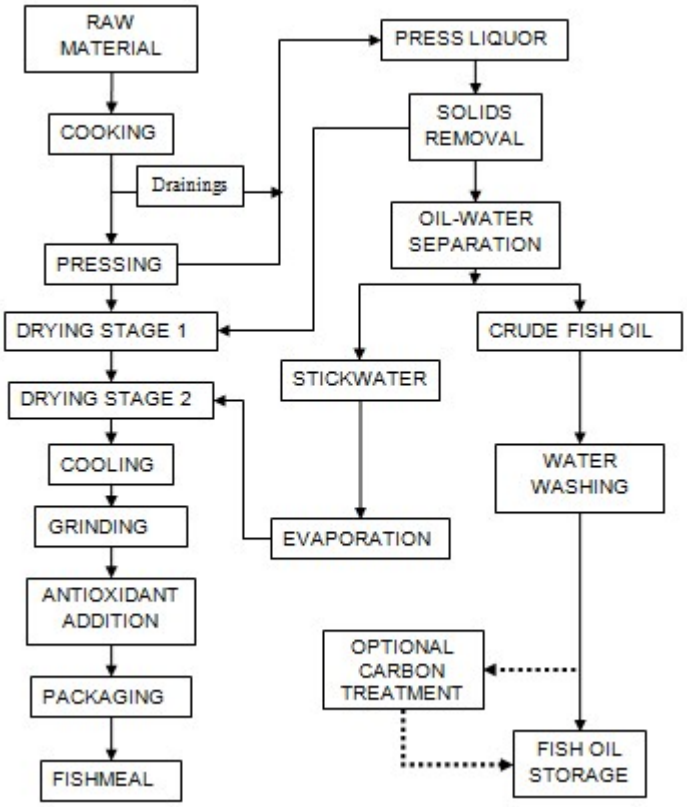
[11] NIH, *Omega-3 Supplements: In Depth*, National Center for Complementary and Integrative Health, available at https://www.nccih.nih.gov/health/omega3-supplements-in-depth#:~:text=Use%20of%20Omega%2D3%20Supplements%20in%20the%20United%20States&text=The%20survey%20findings%20indicated%20that,in%20the%20previous%2030%20days.

[12] Global Fish Oil Market (2020 to 2027) - Opportunity Analysis and Industry Forecast - ResearchAndMarkets.com, Business Wire, available at https://www.businesswire.com/news/home/20200909005847/en/Global-Fish-Oil-Market-2020-to-2027---Opportunity-Analysis-and-Industry-Forecast---ResearchAndMarkets.com#:~:text=The%20global%20fish%20oil%20market,and%20docosahexaenoic%20acids%20 (DHA).

[13] Hossain, M.A., *Fish as Source of Polyunsaturated Fatty Acids (PUFAs), Which One is Better-Farmed or Wild?*, Advance Journal of Food Science and Technology 3(6): 455, 459 (Table 2), 2011 ("Hossain Publication").

[14] Breivik at 28.

pressed, separating the water and oil from proteins and solids. Thereafter, the water is separated from the oil. The oil undergoes a polishing process (i.e., deacidifying, degumming, and washing the oil several times). It is subsequently bleached and deodorized. The resulting oil is ultimately encapsulated and sold as supplements. Below, a diagram representing the standard method for processing fish oil.[15]



35. Most significantly, common fish oil is ***derived using a physical, rather than a chemical process***, such that no chemical bonds are broken or created during

[15] Bimbo, A. (2011). *Marine oils; edible oil processing*. AOCS Lipid Library, December 2016, available at https://lipidlibrary.aocs.org/edible-oil-processing/marine-oils. The graph represents the wet reduction process -- the most common method used to convert raw fish into fish oil.

the extraction, bleaching or deodorizing process. "Fish oil is produced without solvent extraction [but rather] is pressed out of the cooked fish."[16]

36. The Omega-3 fatty acids in fish oil occur naturally in triglyceride form ("TAG"). Triglyceride is the term used to define the molecular structure which bond these fatty acids (i.e., EPA and DHA) to a glycerol backbone. Triglycerides are the natural molecular form that make up virtually all fats and oils in both animals and plants and which the human body can directly digest.[17]

37. Depending on the type of fish from which oil was derived, and the environmental conditions in which that fish was raised, the ratio of EPA and DHA can differ slightly, but typically will account for 30% of the fatty acid content (i.e.,180 mg of EPA and 120 mg of DHA per 1000 milligrams of oil).[18] Standard fish oil is often referred to as "18:12," representing the typical ratio of EPA to DHA by weight (18% of the oil by weight is EPA; and 12% of the oil by weight is DHA). The remaining 70% of the fish oil consists of saturated fats, other omega-3 fatty acids, omega-6 and omega-9 fatty acids.[19]

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[16] Breivik at 25.

[17] *See, e.g.,* Omega3 of Norway, available at https://norwayomega.com/omega3-fish-oil/#natural-triglycerides-vs-artificial-ethylesters (last visited April 14, 2021).

[18] NIH, *Omega-3 Fatty Acids, Fact Sheet for Health Professionals, National Institutes of Health, Office of Dietary Supplements ("NIH Fact Sheet")* available at https://ods.od.nih.gov/factsheets/Omega3FattyAcids-HealthProfessional.

[19] Lembke, P., *Production Techniques for Omega-3 Concentrates*, Omega-6/3 Fatty Acids: Functions, sustainability Strategy and Perspectives, DOI 10.1007/978-1-62703-215-5 (2013) available at https://www.puroomega.com/wp-content/uploads/2016/06/Lembke-2013-Production-Techniques-Omega-3-Human-Press-2013-pp353-364.pdf (last visited April 14, 2021).

C. OMEGA-3 FATTY ACID ETHYL ESTERS

38. In the early 1980's, the Japanese pharmaceutical company Mochida developed a large-scale method to synthesize EPA and DHA into an ethyl ester chemical form. The process, known as trans-esterification, enabled scientists to increase the yield of omega-3s from 30% to upwards of 70% as well as manipulate the ratio between EPA and DHA.[20] It also allowed chemists to use lower grade fish oil as the starting material as rancidity due to age, storage and processing of the oil are removed in the trans-esterification process.

39. Doing so, however, required the chemical alteration of fish oil on a molecular level, substantially transforming it from a natural product, into a synthetic product called Omega-3 Fatty Acid Ethyl Esters – a substance that is not found anywhere in nature, and which has not been comparably viewed by leading health authorities.

40. Importantly, trans-esterification begins only after fish has been processed into oil.[21] At that juncture, manufacturers have a choice – to sell fish oil as it is, or engage in the trans-esterification process as a means to boosting profits.

(1) *The Trans-Esterification Process*

41. The first step in the trans-esterification process involves a chemical reaction whereby the glycerol backbone of each triglyceride molecule in the fish oil is broken by introduction of an industrial chemical such as sodium hydroxide, resulting in free fatty acids and a free glycerol molecule.[22] The free fatty acid forms of EPA and

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[20] Klinik, M., *A Review of Omega-3 Ethyl Esters for Cardiovascular Prevention and Treatment of Increased Blood Triglyceride Levels*, Vasc Health Risk Manag (2006), doi: 10.2147/vhrm.2006.2.3.251.

[21] Breivik at 25.

[22] Douglas MacKay, ND, *A Comparison of Synthetic Ethyl Ester Form Fish Oil vs. Natural Triglyceride Form* ("MacKay Publication"), http://www.healthwiseonline.com/pdf/stuart_tomc_nordic_naturals_tg_vs_ee.pdf; Bimbo, A, *Marin*

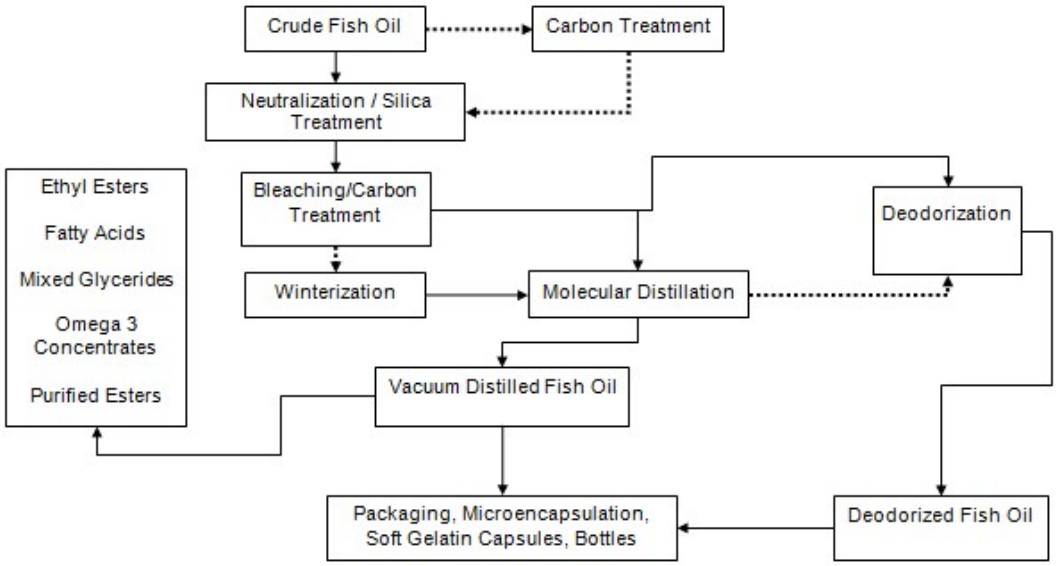
DHA, which are inherently unstable, are chemically reacted with ethanol (an industrial alcohol).[23] In a subsequent process known as molecular distillation, the mixture is heat distilled under a vacuum resulting in a condensate omega-3 ethyl ester solution.[24] The concentration of omega-3s in the solution depends on variables within the distillation process, but typically ranges from 50-70%.[2] The constituent compounds are DHA Ethyl Esters and EPA Ethyl Esters — which are molecularly distinct from the precursor DHA and EPA triglyceride ("TAG") molecules. The diagram below shows the most common trans-esterification process beginning with crude fish oil and resulting in the formation of ethyl esters.[25]

Oils, AOCS Lipid Library, available at https://lipidlibrary.aocs.org/edible-oil-processing/marine-oils.

[23] *See* MacKay Publication; *see also Triglycerides vs. Ethyl Ester Forms of Fish Oil*, Science Based Health, https://www.sciencebasedhealth.com/Fish-Oil-EE-vs-TG-omega-3s-which-is-better-W119.aspx.

[24] Molecular distillation is a type of short-path vacuum distillation, characterized by an extremely low vacuum pressure which is performed using a molecular still. This process is characterized by short term exposure of the distillate liquid to high temperatures in high vacuum in the distillation column and a small distance between the evaporator and the condenser. https://en.wikipedia.org/wiki/Molecular_distillation; *See also* Breivik, H., H. G.G., and B. Kristinsson, *Preparation of highly purified concentrates of eicosapentaenoic acid and docosahexaenoic acid*, JAOCS, 1997. 74(11): p. 1425-29; Breivik, H. *Concentrates. In: Long Chain Omega-3 Specialty Oils*, pp. 111-140, The Oily Press Bridgwater England (2007).

[25] Bimbo, A.P. *Processing of marine oils. In: Long Chain Omega-3 Specialty Oils*, pp. 77-109 (H. Breivik (ed.) The Oily Press Bridgwater England) (2007).



42. The trans-esterification process allows manufacturers to do one of several things that yield significant financial benefits: (1) Increase the levels of EPA-EE and DHA-EE far in excess of the 18/12 limit of TAG EPA and TAG DHA in fish oil. Where the standard fish oil yields only 30% DHA/EPA by volume, trans-esterification allows manufacturers to obtain DHA-EE and EPA-EE that yields upwards of 70% by volume; (2) Alter the natural ratios of DHA/EPA (i.e., 120 mg / 180 mg per 1000 mg) to create DHA-EE / EPA-EE in any ratio the manufacturer desires; (3) Use low grade crude fish oil generated from fish offal -- heads, viscera and other body parts discarded in preparing fish for consumption (i.e. fish waste) -- in lieu of a whole small oily fish (e.g., sardine, anchovy, menhaden) that are traditionally caught and processed for the production of fish oil. In addition to being low quality, offal produces small volumes of oil compared to whole fish because these edible species are primarily non-fatty fish.[26] For example, a study exploring the efficiency of extracting oil from the heads of two tuna species, found the crude oil yields are only between 1-2%, far less than the average 30% yield from whole fish species that are caught specifically for

[26] Bimbo, A. (2011). Marine oils; edible oil processing. AOCS Lipid Library, December 2016, available at http://lipidlibrary.aocs.org/OilsFats/content.cfm?ItemNumber=40332

rendering of fish oil.[27] Inconsistent and low yields, in addition to the fact that the raw materials consist of fish waste renders the resulting crude fish oil unsuitable for human consumption and requires trans-esterification to create a useable yield.[28]

43. At the end of the trans-esterification process, the crude fish oil has been substantially transformed into Fatty Acid Ethyl Esters consisting of DHA-EE, EPA-EE and other OM3 fatty acid ethyl esters. At this point, the solution may be encapsulated and sold as a dietary supplement, or further concentrated, refined and sold as a drug.[29]

44. Ultimately, once trans-esterified, fish oil is substantially and irrevocably transformed into Omega-3 fatty acid ethyl esters -- a substance that cannot be found in any part of any fish. Calling it "fish oil," therefore, is fraudulent, deceptive and misleading.

D. OMEGA-3 FATTY ACID ETHYL ESTERS ARE NOT FISH OIL

(1) *DHA & EPA Ethyl Esters are Different Molecules than DHA & EPA Found in Natural Fish Oil*

45. The trans-esterification process substantially and irrevocably transforms the Omega-3s in fish oil from their natural triglyceride form into Omega-3 fatty acid ethyl esters. Critically, these substances, (fish oil and omega-3 fatty acid ethyl esters), are distinguishable on a molecular level such that it is impossible as a matter of law or logic for them to share a common or usual name. Indeed, they do not. Along with

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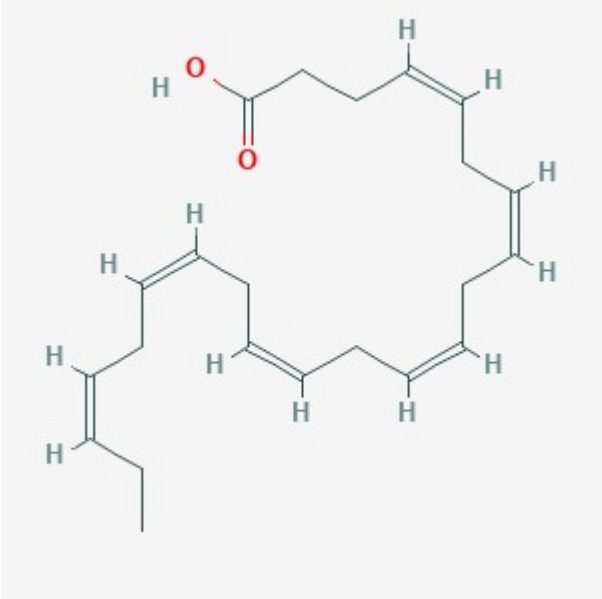
[27] Kasmiran, B. 2018.Comparison and evaluation of the quality of fish oil and fishmeal extracted from the heads of Yellowfin tuna (Thunnus albacares) and Albacore tuna (Thinnus alalunga). Nations University Fisheries Training Programme, Iceland, available at http://www.unuftp.is/static/fellows/document/britney16prf.pdf.

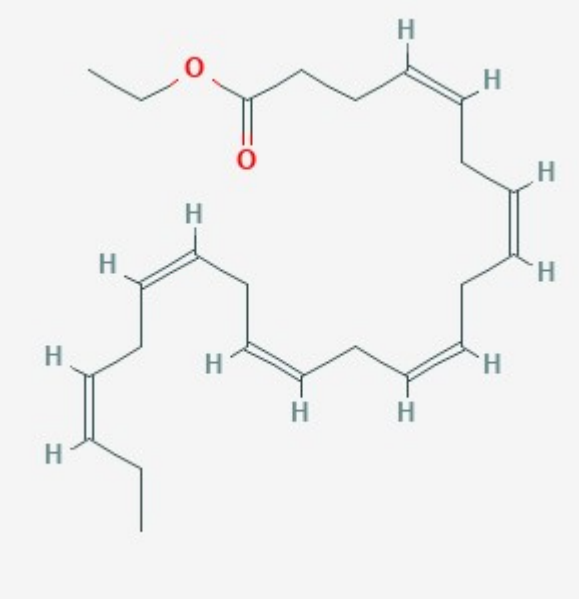
[28] Alfio, V, et al, *From Fish Waste to Value: An Overview of the Sustainable Recovery of Omega-3 for Food Supplements*, Molecules. 2021 Feb; 26(4): 1002. Published online 2021 Feb 13. doi: 10.3390/molecules26041002 available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7918619/

[29] *See e.g.*, Lovaza Prescribing information available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021654s023lbl.pdf.

their molecular differences, they have different common or usual names which must be properly represented on labeling of any dietary supplement in which they are contained. To do otherwise is deceptive, misleading, fraudulent and illegal.

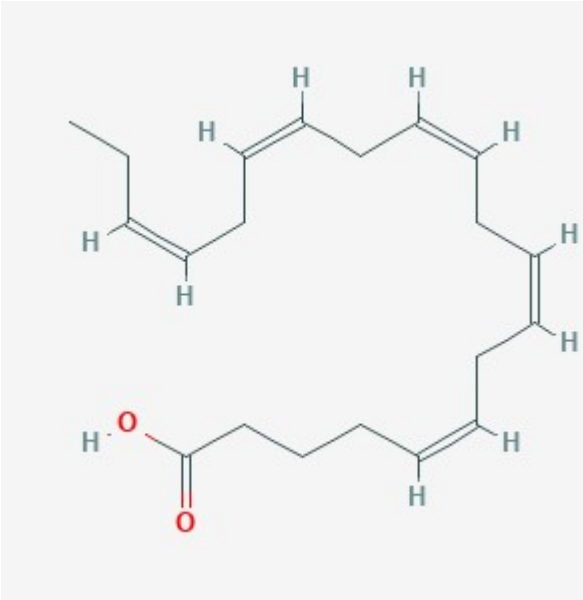
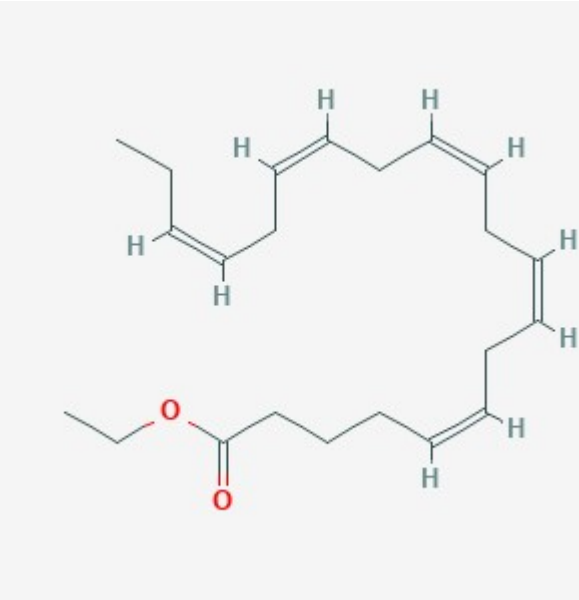
	DHA[30]	**DHA-EE**[31]
Empirical Formulae	**$C_{22}H_{32}O_2$**	**$C_{24}H_{36}O_2$**
Molecular Weight	328.50 g/mol	356.55 g/mol
Synonyms	Docosahexaenoic acid Doconexent, Cervonic acid, Doconexento Doconexentum Doxonexent Docosahexaenoate	Docosahexaenoic acid ethyl ester Ethyl docosahexaenoate Cervonic acid ethyl ester
Molecular Structures		





[30] See NIH, National Library of Medicine available at https://pubchem.ncbi.nlm.nih.gov/compound/445580

[31] See NIH, National Library of Medicine available at https://pubchem.ncbi.nlm.nih.gov/compound/9831416

	EPA[32]	EPA-EE[33]
Empirical Formulae	$C_{20}H_{30}O_2$	$C_{22}H_{34}O_2$
Molecular Weight	302.5 g/mol	330.51
Synonyms	Eicosapentaenoic acid Icosapent, 10417-94-4 Icosapento Icosapentum Timnodonic acid	Eicosapentaenoic acid ethyl ester Epadel Ethyl eicosapentaenoate Ethyl eicosapentaenoic acid Ethyl icosapentaenoate Ethyl icosapentate Ethyl-eicosapentaenoic acid Ethyl-EPA Icosapentaenoate icosapentate Icosapent ethyl Timnodonic acid ethyl ester
Molecular Structures		

[32] Pub Chem, available at https://pubchem.ncbi.nlm.nih.gov/compound/446284

[33] Pub Chem, available at https://pubchem.ncbi.nlm.nih.gov/compound/9831415

46. As demonstrated above, these molecules are distinct in every regard. They have different molecular weights, chemical structures, physical properties and common/usual names.

(2) Monographs

47. The United States Pharmacopeia ("USP") is one of the most comprehensive sources for medicine and dietary supplement standards in the world. The USP National Formulary ("USP-NF") provides over 5000 reference standards for medicines and over 300 reference standards for dietary supplements. The standards are used to help ensure the quality of these products and their ingredients, and to protect the safety of patients.[34]

48. Among its quality standards, the USP-NF provides a series of monographs which articulate the quality expectations for "identity, strength, purity, and performance" of certain drugs and dietary supplements. *Id*. Included among the USP references for dietary substances are monographs for Docosahexaenoic Acid Ethyl Ester (500 mg); Docosahexaenoic Acid (250 mg); Eicosapentaenoic Acid (300 mg); Eicosapentaenoic Acid Ethyl Ester; Fish Oil Omega-3 Acid Ethyl Esters Concentrate; Omega-3-Acid Ethyl Esters; and Fish Oil (1 g).

49. Figure A below juxtaposes the mass spectra of the USP monograph for fish oil with that of IVC's Triple Strength Fish Oil.[35] As demonstrated below, fish oil is an amazingly complex natural product which consists of hundreds of constituent ingredients. In contrast, the IVC Product is a synthetic construct consisting primarily of DHA-EE and EPA-EE. Each peak represents a different molecule with a unique mass to charge ratio (m/z). From a macro perspective, the monographs undeniably

[34] https://www.usp.org/about/public-policy/overview-of-monographs

[35] United States Pharmacopeia – National Formulary Catalog # 1270424, available at https://store.usp.org/OA_HTML/ibeCCtpItmDspRte.jsp?sitex=10020:22372:US&item=33515

demonstrate that these are distinct products. From a granular perspective, the monographs highlight the fact that, despite their representation to the contrary, the IVC Product contains no DHA or EPA, much less in the amounts claimed.

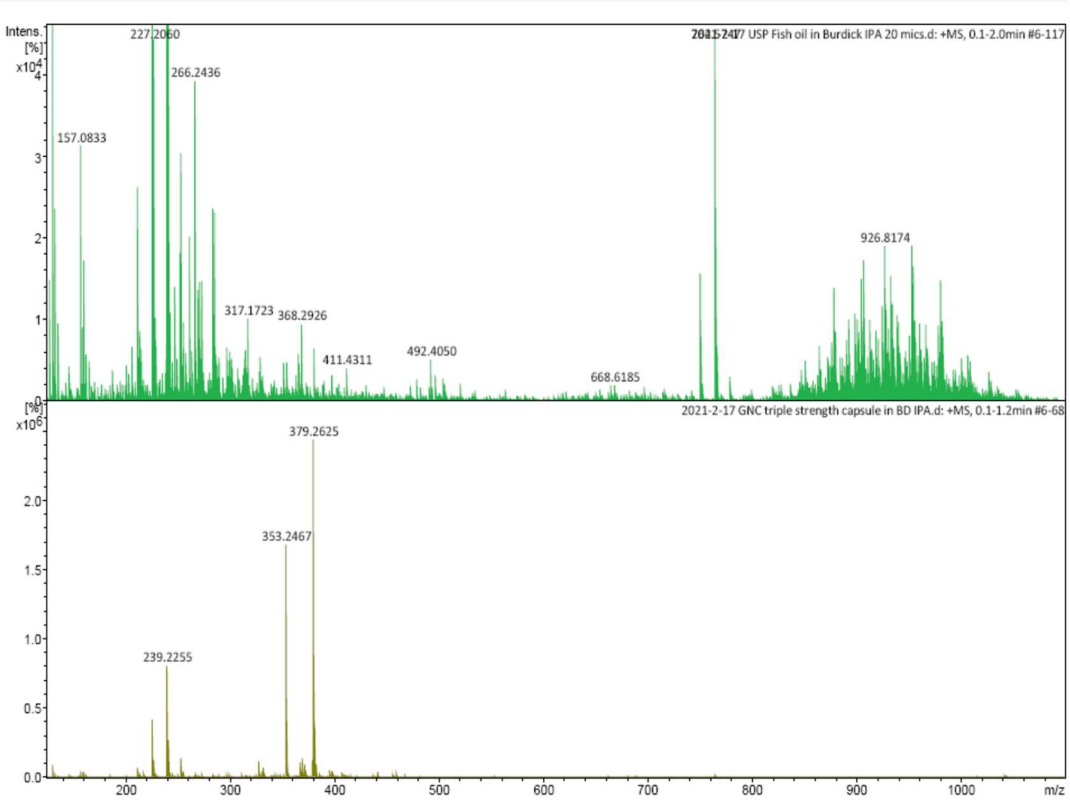


Figure A: Comparison of USP fish oil standard with IVC's Triple Strength Fish Oil.

50. In addition to the USP, numerous industry and scientific authorities independently confirm the differences between fish oil and omega-3 fatty acid ethyl esters.

51. Codex Alimentarius Commission ("Codex") was created in 1963 by two U.N. organizations, the Food and Agriculture Organization and the World Health Organization. Its main purpose is to protect the health of consumers and to ensure fair practices in international trade in food through the development of food standards, codes of practice, guidelines and other recommendations. Codex standards and

guidelines are developed by committees, which are open to all member countries. Member countries review and provide comments on Codex standards and related texts at several stages in the development process. In the United States, public meetings are held to receive comments on Codex drafts and comments are invited from all interested parties. Although Codex standards and related texts are voluntary, they do provide a template for laws and are used by the World Trade Organization as an agreed benchmark in global trade disputes.[36]

52. FDA participates and exercises leadership in the Codex Alimentarius Commission. The objective of FDA's participation in Codex is to develop science-based international food safety, labeling, and other pertinent standards that provide consumer protection, labeling information, and prevention of economic fraud and deception that are consistent with U.S. regulations and laws.

53. FDA uses procedures that promote consumer protection and transparency, as it works with the U.S. Codex Office to develop U.S. Delegation positions on matters before relevant Codex committees.[37]

54. In 2017, the Codex Alimentarius Committee adopted standards for fish oil. It was a long process that started in 2011 "involving many discussions on the finer details which was important to clarify as the purpose of this Standard is to protect consumer health and promote fair practices in the trade of fish oil."[38] Significantly,

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[36] FDA, *Responses to Questions about Codex and Dietary Supplements*, available https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/responses-questions-about-codex-and-dietary-supplements#what (last visited April 13, 2021).

[37] FDA, *FDA's Participation in Codex*, available at https://www.fda.gov/food/international-cooperation-food-safety/fdas-participation-codex (last visited April 13, 2021).

[38] IFFO, *CODEX Standard for Fish Oil*, available at https://www.iffo.net/codex-standard-fish-oil (last visited April 13, 2021).

the Codex, like the USP, recognizes and draws a distinction between natural fish oil and trans-esterified products.[39]

55. Similarly, the Global Organization for EPA and DHA omega-3s ("GOED"), the largest and most significant trade group of the Omega-3 industry, also maintains a series of monographs which, like the USP and CODEX, differentiate between TAG, EE and rTG Omega-3s as well a series of particular fish oils (e.g., Salmon, Tuna, Anchovy, etc). It provides members "technical guidance on specific and recommended test methodologies and quality parameters for a number of EPA and/or DHA containing product classes currently covered under the GOED Voluntary Monograph."[40] EPA/DHA-containing product classes currently covered by this GOED Voluntary Monograph [include]: Refined EPA and/or DHA Omega-3 Oil Triglycerides, EPA and/or DHA Omega-3 Oil Ethyl Ester Concentrates, EPA and/or DHA Omega-3 Oil Triglyceride Concentrates, Tuna Oil, Salmon Oil and Anchovy Oil. Consistent with the USP and Codex, GOED's monographs confirm that fish oil is not synonymous with fatty acid ethyl esters and cannot be so named.

(3) U.S. Customs and Border Protection

56. The U.S. Customs and Border Protection ("CBP") is one of the world's largest law enforcement organizations whose duties include the facilitation of lawful international trade.[41] Among other things, the CPB is responsible for the interpretation

[39] Section 2.2 defines "Fish oils" as those derived from one or more species of fish or shellfish.[39] In contrast, Section 2.6 defines "Concentrated fish oils ethyl esters" as those derived from fish oils described in Section 2.1 to 2.4 and are primarily composed of fatty acids ethyl esters. See, *Report of the U.S. Delegate, 25th Session, Codex Committee on Fats and Oils, United States Department of Agriculture*, available at https://www.usda.gov/sites/default/files/documents/delegates-report-02272017.pdf (last visited April 13, 2021).

[40] GOED Voluntary Monograph, Version 7.2, March 15, 2021 , available at https://goedomega3.com/goed-monograph (last visited April 13, 2021).

[41] See, U.S. Customs and Border Protection available at https://www.cbp.gov/about (last visited April 13, 2021).

and enforcement of the Harmonized Tariff Schedule of the United States ("HTS") which is a hierarchical structure for describing all goods in trade for duty, quota, and statistical purposes.[42]

57. The CPB has issued more than 20,000 rulings related to the proper interpretation of products and where they may be classified under the HTS.

58. On several occasions the CPB considered the appropriate tariff classification for Omega-3 Acid Ethyl Esters. Consistently, the CPB recognized that trans-esterification substantially transforms fish oil into a different product which results in a different tariff classification.

59. In 2011, the CPB tested and reviewed a product that was described as "a gelatin capsule containing 1000 milligrams of fish oil, said to be derived from anchovy, sardine, herring or other fish species." The CPB determined that the "fish oil" had been substantially transformed from its original fish oil source -- "the crude fish oil has been refined and chemically modified by deodorizing, ethylating (conversion of triglycerides to ethyl esters), distillation, winterizing/cold filtrating, bleaching and drumming." Accordingly, while the petitioner sought to classify the trans esterified product under Section 1504.20.4000 of the HTS which pertains to "fish-liver oils and their fractions, whether or not refined, ***but not chemically modified***," the CPB concluded that "[b]ased on the manufacturing process of the fish oil, they will be classified elsewhere…. The applicable subheading for these products will be 2106.90.9998, HTSUS, which provides for food preparations not elsewhere specified or included…other…other…other. The duty rate will be 6.4 percent ad valorem." (emphasis added).[43]

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[42] United States International Trade Commission, available at https://www.usitc.gov/harmonized_tariff_information (last visited April 13, 2021).

[43] Customs Ruling, N171795, July 5, 2011, available at https://rulings.cbp.gov/search?term=N171795&collection=ALL&sortBy=RELEVANCE&pageSize

60. Just as an apple cannot be called a pear, an omega-3 acid ethyl ester cannot be called fish oil. As the industry's "leading manufacturer of vitamin and nutritional supplements [and the] #1 private label manufacturer in the United States," IVC is obligated by law to label its Products truthfully and accurately. At bottom, this Product is a fatty acid ethyl ester. Labeling and selling it as fish oil is false, misleading, deceptive and unlawful.

SPECIFIC LABELING VIOLATIONS

61. The Federal Food, Drug & Cosmetic Act ("FDCA") broadly regulates the sale of food and beverages to the consuming public. 21 U.S.C §301. It was promulgated in significant part to prevent consumer deception and was principally implemented through the creation of a uniform system of labeling on which consumers could rely to make informed purchasing decisions.

62. The FDCA prohibits the misbranding of any food. 21 U.S.C. §331(b). Generally, a food is misbranded if, among other things, its labeling is false or misleading. 21 U.S.C. § 343.

63. The Nutrition Labeling and Education Act of 1990 amended the FDCA by requiring that most foods, including dietary supplements, bear nutrition labeling. Subsequently, the Dietary Supplement Health and Education Act of 1994 ("DSHEA")

=30&page=1; *See also,* HQ H295287 (June 18, 2020) available at https://rulings.cbp.gov/search?term=HQ%20H295287&collection=ALL&sortBy=RELEVANCE&pageSize=30&page=1 ("CBP has a long-standing position that in order to be classified in Chapter 15, HTSUS, as fats or oils, products must predominantly be composed of triglycerides. See Headquarters Ruling Letter ("HQ") H102457, dated September 8, 2010; HQ 963166, dated December 11, 2001; HQ 965396, dated July 23, 2002; HQ 964531, dated March 14, 2002; HQ 965699, dated September 25, 2002; New York Ruling Letter ("NY") N234974, dated November 19, 2012…. Accordingly, only products composed primarily of triglycerides are classifiable under heading 1515, HTSUS."); *See, also,* United States Pharmacopeia – National Formulary monograph catalog confirming different HTSUS as between fish oil and Omega-3 Fatty Acids.

amended the Act, in part, by defining "dietary supplements," adding specific labeling requirements for dietary supplements, and providing for optional labeling statements.

64. Dietary supplements must bear labeling in accordance with applicable provisions of FDCA. The IVC Product labels not only violate the clear mandates of the FDCA, but are independently false, misleading, and operate as a deception on the consuming public.

(1) *Fish Oil is not the Common or Usual Name of these Products*

65. The principal display panel ("PDP") of the IVC Product describes the supplement as "Triple Strength Fish Oil" containing "1000 mg of EPA/DHA Omega-3s.

Section 21 C.F.R. 101.3 states in relevant part:

> (a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity. (b) Such statement of identity shall be in terms of: (1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof, (2) The common or usual name of the food; or, in the absence thereof (3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

66. The statement of identity for a dietary supplement is the name that appears on the label of the dietary supplement. As a general matter, the statement of identity of a dietary supplement is the name specified by federal law or regulation, or, if no such name is specified, its common or usual name. If the dietary supplement has no common or usual name and its nature is not obvious, the statement of identity must be an appropriately descriptive term.[44]

[44] See, 21 U.S.C. 321(ff)(2)(C), 21 U.S.C. 343(s)(2)(B), 21 CFR §101.1 and 21 CFR §101.3; FDA Dietary Supplement Labeling Guide "FDA Labeling Guide") available at

67. As demonstrated in great detail herein, Fish Oil and Omega-3 Acid Ethyl Esters are not the same. They are different on a molecular level and have different common and usual names.

68. It is indisputable that the IVC Products were trans-esterified – a process that substantially transformed what was once natural fish oil containing OM3s in triglyceride form into a synthetic product consisting of fatty acid ethyl esters.

69. Consumers wishing to ingest Omega-3s have numerous choices. Principal among them, whether to take an Omega-3 supplement or consume a marine oil (e.g., fish, krill, algae). Each product is molecularly different and has an array of qualities that differ from one another. These qualities differentiate the products in the marketplace and are material to consumers' purchasing decisions. IVC's failure to identify their Products by their common and usual name, obfuscated the most important information that is conveyed about a product – its name and contents. By failing to properly name its Products, IVC has deceived Plaintiff and members of the class, depriving them of a consumer's most basic right – to make an informed purchasing decision.

(2) *The Supplement Fact Section is False and Misleading*

70. Unfortunately for Plaintiff and members of the class, the misrepresentation on the Principal Display Panel is further exacerbated by misrepresentations on the Supplement Facts panel on the back of the label.

https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide-chapter-ii-identity-statement.


CODE 735334 GRG
Directions: As a dietary supplement, take one softgel capsule daily with food.

Supplement Facts

Serving Size One Softgel Capsule

Amount Per Serving		% Daily Value
Calories	15	
Total Fat	1.5 g	2%†
Cholesterol	0 mg	
Total Omega-3s	1065 mg	*
Total EPA + DHA	1000 mg	*
EPA (Eicosapentaenoic Acid) Omega-3	734 mg	*
DHA (Docosahexaenoic Acid) Omega-3	266 mg	*
Other Omega-3s	65 mg	*

† Percent Daily Values are based on a 2,000 calorie diet.
* Daily Value not established.

Ingredients: Fish Oil, Softgel & Enteric Coating (Gelatin, Glycerin, Stearic Acid, Sodium Alginate, Ethylcellulose, Medium Chain Triglycerides, Oleic Acid), Mixed Tocopherols.

CONTAINS: Fish (Anchovy, Mackerel, Sardine, Smelt, Salmon, Tuna, Cod or a Combination Thereof).

Gf GLUTEN FREE

No Sugar, No Starch, No Artificial Colors, No Artificial Flavors, No Preservatives, Sodium Free, No Wheat, Gluten Free, No Corn, No Dairy, Yeast Free, Cholesterol Free.

- Enteric coated to help control fishy burps - guaranteed
- Free of mercury, lead, heavy metals and PCBs
- From wild, deep ocean fish

71. Supplement manufacturers are generally required to disclose all ingredients contained in their products. 21 C.F.R. §101.36. The obligation to describe those ingredients by their common or usual name applies with same force in the Supplement Fact section as it does on the principal display panel. As detailed above, the common or usual name of the contents of these Products is Omega-3 fatty acid ethyl esters. The Supplement Facts also erroneously claim the Product contains EPA and DHA, which it does not. As detailed above, this Product contains 0 mg of Eicosapentaenoic acid (EPA) and 0 mg Docosahexaenoic acid (DHA). Once trans-esterified, the EPA in fish was substantively modified into ethyl icosapentate (aka Eicosapentaenoic acid ethyl ester) (EPA-EE) a molecule separate and distinct from EPA. Similarly, the Docosahexaenoic acid (DHA) in fish oil, once trans-esterified,

was substantively modified into ethyl docosahexaenate (aka Docosahexaenoic acid ethyl ester) (DHA-EE), a molecule sperate and distinct from DHA. Although both DHA-and DHA-EE may be listed by any number of synonyms, critically, none of their synonyms are shared. Failure to properly identify EPA-EE and DHA-EE as constituent ingredients violates the mandates of the FDCA and independently renders the Products' Supplement Fact section false and misleading under state consumer protection laws.

72. As detailed above, trans-esterification substantially transformed "fish oil" into an Omega-3 acid ethyl ester. This transformation also affected all the individual components of the fish oil either by eliminating them entirely, or transforming them into fatty acid ethyl esters. Each of these omegas, although once triglycerides are now ethyl esters, different molecules with different common and usual names.

(3) *IVC Fails to List All the Ingredients in the Products*

73. While the Product principally contains EPA-EE and DHA-EE, it also contains 65 mg of other omega-3s which IVC fails to identify and list in the Supplement Fact Sections in contravention of its obligations under the FDCA.

74. Section 21 C.F.R. §101.36 applies specifically to the nutrition labeling of dietary supplements. It divides dietary ingredients into two categories – those that have a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) as established in §101.9(c) (referred to as "(b)(2)-dietary ingredients") and those that do not have an RDI/DRV (referred as "other ingredients"). 21 CFR §§101.36(b)(2) and (3).

75. Dietary ingredients for which no daily values have been established must be listed by their common or usual names when they are present in a dietary supplement. They must be identified as having no Daily Values by use of a symbol in the column for % Daily Value that refers to the footnote Daily Value Not Established. 21 CFR 101.36(b)(2)(iii)(F) and (b)(3).

76. OM3s, in any form, do not have an RDI/DVR and therefore are considered other dietary ingredients. Their constituent components must be listed pursuant to 21 C.F.R. §101.36(b)(3).

77. IVC's failure to include these sub-components in the Supplement Fact Section further deprives consumers of material information relevant to making informed purchasing decisions. Failure to include this information operates as a fraud and deception on the consuming public and is violation of the law.

(4) *Other Labeling Misrepresentations*

78. The FDCA deems dietary supplements to be misbranded if their labeling is false or misleading in any way. 21 U.S.C. § 343.

79. In addition to the above, the PDP claims it is "Triple Strength." While comparative nutrient content claims are generally allowed, they require notice of the comparable product. Here, IVC not only fails to identify such a product, even if one were to assume the comparator is a standard 1000 mg fish oil capsule, such a representation would also be false and misleading as IVC's Product contains 0 mg of EPA and 0 mg of DHA and it's not fish oil.

ECONOMIC INJURY

80. Plaintiff sought to buy products that were lawfully labeled, marketed and sold.

81. Plaintiff saw and relied on Defendants' misleading labeling of their Products.

82. Plaintiff believed that the Product purchased contained real fish oil.

83. Plaintiff believed that the Product was lawfully marketed and sold.

84. In reliance on the claims made by Defendants regarding the qualities of their Product, Plaintiff paid for a Product which he did not receive and/or paid a price premium.

85. As a result of his reliance on Defendants' misrepresentations, Plaintiff received a Product that lacked the promised ingredient which he reasonably believed it contained.

86. Plaintiff received a Product that was unlawfully marketed and sold.

87. Plaintiff lost money and thereby suffered injury as he would not have purchased this Product and/or paid as much for it absent the misrepresentation.

88. Defendants know that the statement of identity and contents of a dietary supplement are material to a consumer's purchasing decision.

89. Plaintiff altered his position to his detriment and suffered damages in an amount equal to the amounts he paid for the Product, and/or in additional amounts attributable to the deception.

90. By engaging in the false and deceptive conduct alleged herein Defendants reaped, and continue to reap financial benefits in the form of sales and profits from their Product.

91. Plaintiff would be willing to purchase IVC Products again in the future should he be able to rely on Defendants' labeling and marketing as truthful and non-deceptive.

CLASS ACTION ALLEGATIONS

92. Plaintiff brings this action on behalf of himself and on behalf of classes of all others similarly situated consumers defined as follows:

a. **National**: All persons in the United States who purchased Class Products in the United States during the Class Period.

b. **New York:** All persons in New York who purchased the Class Products in New York during the Class Period.

c. **Class Period** is the maximum time allowable as determined by the statute of limitation periods accompanying each cause of action.

93. Plaintiff brings this Class pursuant to Federal Rule of Civil Procedure 23(a), and 23(b)(1), 23(b)(2), 23(b)(3) and 23(c)(4).

94. Excluded from the Classes are: (i) Defendants and their employees, principals, affiliated entities, legal representatives, successors and assigns; and (ii) the judges to whom this action is assigned.

95. Upon information and belief, there are tens of thousands of members of the Class. Therefore, individual joinder of all members of the Class would be impracticable.

96. There is a well-defined community of interest in the questions of law and fact affecting the parties represented in this action.

97. Common questions of law or fact exist as to all members of the Class. These questions predominate over the questions affecting only individual Class members. These common legal or factual questions include but are not limited to:

a. Whether Defendants marketed, packaged, or sold the Class Products to Plaintiff and those similarly situated using false, misleading, or deceptive statements or representations;
b. Whether Defendants omitted or misrepresented material facts in connection with the sales of their Products;
c. Whether Defendants participated in and pursued the common course of conduct complained of herein;
d. Whether Defendants have been unjustly enriched as a result of their unlawful business practices;
e. Whether Defendant's actions violate the Unfair Competition Law, Cal. Bus. & Prof. Code §§17200, *et seq*. (the "UCL");
f. Whether Defendant's actions violate the False Advertising Law, Cal. Bus. & Prof. Code §§17500, *et seq*. (the "FAL");
g. Whether Defendant's actions violate the Consumers Legal Remedies Act, Cal. Civ. Code §§1750, *et seq*. (the "CLRA");

h. Whether Defendants' actions violate the N.Y. Gen. Bus. Laws § 349, *et. seq.*;

i. Whether Defendants' actions violate N.Y. Gen. Bus. Laws § 350 *et. seq.*;

j. Whether Defendants' actions constitute breach of express warranty;

k. Whether Defendants should be enjoined from continuing the above-described practices;

l. Whether Plaintiff and members of the Class are entitled to declaratory relief; and

m. Whether Defendants should be required to make restitution, disgorge profits, reimburse losses, and pay damages as a result of the above-described practices.

98. Plaintiff's claims are typical of the claims of the Class, in that Plaintiff was a consumer who purchased Defendants' Product. Plaintiff is no different in any relevant respect from any other Class member who purchased the Product, and the relief sought is common to the Class.

99. Plaintiff is an adequate representative of the Class because his interests do not conflict with the interests of the members of the Class he seeks to represent, and he has retained counsel competent and experienced in conducting complex class action litigation. Plaintiff and his counsel will adequately protect the interests of the Class.

100. A class action is superior to other available means for the fair and efficient adjudication of this dispute. The damages suffered by each individual Class member likely will be relatively small, especially given the cost of the Products at issue and the burden and expense of individual prosecution of the complex litigation necessitated by Defendants' conduct. Thus, it would be virtually impossible for members of the Class individually to effectively redress the wrongs done to them.

Moreover, even if members of the Class could afford individual actions, it would still not be preferable to class-wide litigation. Individualized actions present the potential for inconsistent or contradictory judgments. By contrast, a class action presents far fewer management difficulties and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

101. In the alternative, the Class may be certified because Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making appropriate preliminary and final equitable relief with respect to each Class.

102. The requirements for maintaining a class action pursuant to Rule 23(b)(2) are also met, as Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

FIRST CAUSE OF ACTION

Unlawful Business Practices
Violation of The Unfair Competition Law ("UCL")
Bus. & Prof. Code §§17200, *et seq*.

103. Plaintiff incorporates each and every allegation contained in the paragraphs above as if restated herein.

104. The UCL defines unfair business competition to include any "unlawful, unfair or fraudulent" act or practice, as well as any "unfair, deceptive, untrue or misleading" advertising. Cal. Bus. Prof. Code §17200.

105. A business act or practice is "unlawful" if it violates any established state or federal law.

106. Defendants' acts, omissions, misrepresentations, practices, and/or non-disclosures concerning the Products alleged herein, constitute "unlawful" business acts and practices in that they violate the Federal Food, Drug, and Cosmetic Act, 21

U.S.C. §§301, et seq. and its implementing regulations, including, at least, the following sections:

a. 21 U.S.C. §343(a), which deems food misbranded when its labeling contains a statement that is false or misleading in any particular;

b. 21 C.F.R. §102.5(a)-(d), which prohibits the naming of foods so as to create an erroneous impression about the presence or absence of ingredient(s) or component(s) therein;

c. 21 U.S.C. §§331and 333, which prohibits the introduction of misbranded foods into interstate commerce.

d. 21 C.F.R. §101.3 and 21 C.F.R. §101.36 as described above, pertaining to, *inter alia,* use of common or usual names.

107. California has expressly adopted federal labeling requirements as its own pursuant to the Sherman Food, Drug, and Cosmetic Law, CAL. HEALTH & SAFETY CODE § 109875 et seq. (the "Sherman Law"), the Sherman Law, which provides that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food regulations of this state." CAL. HEALTH & SAFETY CODE § 110100.

108. Each of IVC's violations of federal law and regulations violates California's Sherman Food, Drug, and Cosmetic Law, CAL. HEALTH & SAFETY CODE § 109875 et seq. (the "Sherman Law"), including, but not limited to, the following sections:

109. Section 110100 (adopting all FDA regulations as state regulations);

110. Section 110290 ("In determining whether the labeling or advertisement of a food . . . is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account.");

111. Section 110390 ("It is unlawful for any person to disseminate any false advertisement of any food. . . . An advertisement is false if it is false or misleading in any particular.");

112. Section 110395 ("It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food . . . that is falsely advertised.");

113. Section 110398 ("It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.");

114. Section 110400 ("It is unlawful for any person to receive in commerce any food . . . that is falsely advertised or to deliver or proffer for delivery any such food . . . ."); and

115. Section 110660 ("Any food is misbranded if its labeling is false or misleading in any particular.").

116. Each of the challenged omissions, statements, and actions by IVC violates the FDCA, and the Sherman Law, and, consequently, violates the "unlawful" prong of the UCL.

117. IVC's conduct is further "unlawful" because it violates California's False Advertising Law, CAL. BUS. & PROF. CODE § 17500 et seq. (the "FAL"), and California's Consumers Legal Remedies Act, CAL. CIV. CODE § 1750 et seq. (the "CLRA"), as discussed in the claims below.

118. By committing the unlawful acts and practices alleged above, Defendants have engaged, and continue to be engaged, in unlawful business practices within the meaning of California Business and Professions Code §§17200, *et seq.*

119. Through their unlawful acts and practices, Defendants have obtained, and continues to unfairly obtain, money from members of the Class. As such, Plaintiff requests that this Court cause Defendants to restore this money to Plaintiff and all members of the Class, to disgorge the profits Defendants made on these transactions, and to enjoin Defendants from continuing to violate the Unfair Competition Law or

violating it in the same fashion in the future. Otherwise, the Class may be irreparably harmed and denied an effective and complete remedy if such an order is not granted.

SECOND CAUSE OF ACTION

Unfair Business Practices
Violation of The Unfair Competition Law
Bus. & Prof. Code §§ 17200, *et seq*.

120. Plaintiff incorporates each and every allegation contained in the paragraphs above as if restated herein.

121. The UCL defines unfair business competition to include any "unlawful, unfair or fraudulent" act or practice, as well as any "unfair, deceptive, untrue or misleading" advertising. Cal. Bus. Prof. Code §17200.

122. A business act or practice is "unfair" under the Unfair Competition Law if the reasons, justifications and motives of the alleged wrongdoer are outweighed by the gravity of the harm to the alleged victims.

123. Defendants have violated, and continue to violate, the "unfair" prong of the UCL through their misleading description of the Products. The gravity of the harm to members of the Class resulting from such unfair acts and practices outweighs any conceivable reasons, justifications, or motives of Defendants for engaging in such deceptive acts and practices. By committing the acts and practices alleged above, Defendants engaged, and continued to engage, in unfair business practices within the meaning of California Business and Professions Code §§17200, *et seq.*

124. Through their unfair acts and practices, Defendants obtained, and continued to unfairly obtain, money from members of the Class. As such, Plaintiff has been injured and requests that this Court cause Defendants to restore this money to Plaintiff and the members of the Class, to disgorge the profits Defendants made on their Products, and to enjoin Defendants from continuing to violate the Unfair Competition Law or violating it in the same fashion in the future. Otherwise, the Class may be

irreparably harmed and denied an effective and complete remedy if such an Order is not granted.

THIRD CAUSE OF ACTION

Fraudulent Business Practices Violation of The Unfair Competition Law Bus. & Prof. Code §§ 17200, *et seq*.

125. Plaintiff incorporates each and every allegation contained in the paragraphs above as if restated herein.

126. The UCL defines unfair business competition to include any "unlawful, unfair or fraudulent" act or practice, as well as any "unfair, deceptive, untrue or misleading" advertising. Cal. Bus. & Prof. Code §17200.

127. A business act or practice is "fraudulent" under the Unfair Competition Law if it actually deceives or is likely to deceive members of the consuming public.

128. Defendants' acts and practices of mislabeling their Products in a manner to suggest they principally contained their characterizing ingredients.

129. As a result of the conduct described above, Defendants have been, and will continue to be, unjustly enriched at the expense of Plaintiff and members of the proposed Class. Specifically, Defendants have been unjustly enriched by the profits they have obtained from Plaintiff and the Class from the purchases of their Products.

130. Through their fraudulent acts and practices, Defendants have improperly obtained, and continue to improperly obtain, money from members of the Class. As such, Plaintiff requests that this Court cause Defendants to restore this money to Plaintiff and the Class, to disgorge the profits Defendants have made, and to enjoin Defendants from continuing to violate the Unfair Competition Law or violating it in the same fashion in the future. Otherwise, the Class may be irreparably harmed and denied an effective and complete remedy if such an Order is not granted.

FOURTH CAUSE OF ACTION

False Advertising

Violation of California Business & Professions Code §§ l7500, *et seq*.

131. Plaintiff incorporates each and every allegation contained in the paragraphs above as if restated herein.

132. Defendants use advertising and packaging to sell its Products. Defendants disseminate advertising regarding their Products which by their very nature are deceptive, untrue, or misleading within the meaning of California Business & Professions Code §§17500, *et seq.* because those advertising statements contained on the labels are misleading and likely to deceive, and continue to deceive, members of the putative Class and the general public.

133. In making and disseminating the statements alleged herein, Defendants knew or should have known that the statements were untrue or misleading, and acted in violation of California Business & Professions Code §§17500, *et seq*.

134. The misrepresentations and non-disclosures by Defendants of the material facts detailed above constitute false and misleading advertising and therefore constitute a violation of California Business & Professions Code §§17500, *et seq*.

135. Through their deceptive acts and practices, Defendants have improperly and illegally obtained money from Plaintiff and the members of the Class. As such, Plaintiff requests that this Court cause Defendants to restore this money to Plaintiff and the members of the Class, and to enjoin Defendants from continuing to violate California Business & Professions Code §§17500, *et seq.*, as discussed above. Otherwise, Plaintiff and those similarly situated will continue to be harmed by Defendant's false and/or misleading advertising.

136. Pursuant to California Business & Professions Code §17535, Plaintiff seeks an Order of this Court ordering Defendants to fully disclose the true nature of their misrepresentations. Plaintiff additionally requests an Order: (1) requiring Defendants to disgorge its ill-gotten gains, (2) award full restitution of all monies

wrongfully acquired by Defendants and (3), interest and attorneys' fees. Plaintiff and the Class may be irreparably harmed and denied an effective and complete remedy if such an Order is not granted.

FIFTH CAUSE OF ACTION
Violation of the Consumers Legal Remedies Act
California Civil Code §§ 1750, *et seq*.

137. Plaintiff incorporates each and every allegation contained in the paragraphs above as if restated herein.

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

139. Plaintiff and each member of the proposed Class are "consumers" within the meaning of Civil Code §1761(d).

140. The purchases of the Products by consumers constitute "transactions" within the meaning of Civil Code §1761(e) and the Products constitute "goods" within the meaning of Civil Code §1761(a).

141. Defendants have violated, and continue to violate, the CLRA in at least the following respects:

a. §1770(5) pertaining to misrepresentations regarding the characteristics of goods sold—specifying that misleading representations regarding ingredients violate the CLRA;
b. §1770(7) pertaining to misrepresentations regarding the standard, quality, or grade of goods sold; and
c. § 1770(9) pertaining to goods advertised with the intent not to provide what is advertised.

142. Defendants knew, or should have known, that the labeling of their Products violated consumer protection laws, and that these statements would be relied upon by Plaintiff and the members of the Class.

143. The representations were made to Plaintiff and all members of the Class. Plaintiff relied on the accuracy of the representations on Defendants' labels which formed a material basis for his decision to purchase the Products. Moreover, based on the very materiality of Defendants' misrepresentations uniformly made on or omitted from their Product labels, reliance may be presumed or inferred for all members of the Class.

144. Defendant carried out the scheme set forth in this Complaint willfully, wantonly, and with reckless disregard for the interests of Plaintiff and the Class, and as a result, Plaintiff and the Class have suffered an ascertainable loss of money or property.

145. Plaintiff and the members of the Class request that this Court enjoin Defendants from continuing to engage in the unlawful and deceptive methods, acts and practices alleged above, pursuant to California Civil Code §1780(a)(2). Unless Defendants are permanently enjoined from continuing to engage in such violations of the CLRA, future consumers of Defendants' Products will be damaged by their acts and practices in the same way as have Plaintiff and the members of the proposed Class.

146. In conjunction with the Complaint, Plaintiff will serve a CLRA demand pursuant to Civil Code §1782, notifying Defendant of the conduct described herein and that such conduct was in violation of particular provisions of Civil Code §1770. Absent a proper remedy, Plaintiff will amend his complaint to seek damages pursuant to Civil Code § 1780(a).

SIXTH CAUSE OF ACTION

Breach of Express Warranty
On Behalf of the New York Sub Class

147. Plaintiff incorporates each and every allegation contained in the paragraphs above as if rewritten herein.

148. Plaintiff's express warranty claims are based on violations of N.Y. CLS UCC § 2-313 and § 2-607. Defendants were afforded reasonable notice of this claim in advance of the filing of this complaint.

149. Defendant made express warranties to Plaintiff and members of the Class that the Products they purchased consisted of real fish oil in its triglyceride form; that its constituent components were DHA and EPA (as opposed to DHA-EE and EPA-EE).

150. The express warranties made to Plaintiff and members of the Class appear on every Product label. This warranty regarding the nature of the Product marketed by Defendant specifically relates to the goods being purchased and became the basis of the bargain.

151. Plaintiff and the Class purchased the Products in the belief that they conformed to the express warranties that were made on the Products' labels.

152. Defendant breached the express warranties made to Plaintiff and members of the Class by failing to supply goods that conformed to the warranties it made. As a result, Plaintiff and members of the Class suffered injury and deserve to be compensated for the damages they suffered.

153. Plaintiff and the members of the Class paid money for the Products. However, Plaintiff and the members of the Class did not obtain the full value of the advertised Products. If Plaintiff and other members of the Class had known of the true nature of the Products, they would not have purchased them or paid less for them. Accordingly, Plaintiff and members of the Class have suffered injury in fact and lost money or property as a result of Defendants' wrongful conduct.

154. Plaintiff and the Class are therefore entitled to recover damages, punitive damages, equitable relief such as restitution and disgorgement of profits, and declaratory and injunctive relief.

SEVENTH CAUSE OF ACTION

VIOLATION OF N.Y. GEN. BUS. LAW § 349, *Et Seq.*
On Behalf of the New York Subclass

155. Plaintiff incorporates each and every allegation contained in the paragraphs above as if rewritten herein.

156. Plaintiff brings this claim on behalf of the New York Class for violation of New York's Consumer Protection from Deceptive Acts and Practices Law, N.Y. GEN. BUS. LAW § 349 et seq.

157. New York General Business Law Section 349 ("GBL § 349") declares unlawful "[deceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state ... "

158. Defendants' labeling and marketing of the Product, as alleged herein, constitutes "deceptive" acts and practices within the meaning of GBL §349.

159. Plaintiff and Class Members have been injured inasmuch as they paid for and/or paid a premium for a Product that, contrary to its label, was not fish oil and did not contain its claimed amount of DHA and EPA.

160. GBL § 349(h) provides in relevant part that "any person who has been injured by reason of any violation of [GBL § 349] may bring an action in his own name to enjoin such unlawful act or practice, an action to recover his actual damages or fifty dollars, whichever is greater, or both such actions. The court may, in its discretion, increase the award of damages to an amount not to exceed three times the actual damages up to one thousand dollars, if the court finds the defendant willfully or knowingly violated this section. The court may award reasonable attorney's fees to a prevailing plaintiff.

161. In accordance with §349(h), Plaintiff seeks an order enjoining Defendants from continuing the unlawful deceptive acts and practices set forth above.

162. Absent a Court order enjoining the unlawful deceptive acts and practices, Defendants will continue their false and misleading marketing campaign and, in doing so, irreparably harm each member of the Class.

163. As a consequence of Defendants' deceptive acts and practices, Plaintiff and other members of the Class suffered an ascertainable loss of monies. By reason of the foregoing, Plaintiff and other members of the Class seek actual damages or statutory damages of $50 per violation, whichever is greater, as well as punitive damages. N.Y. GEN. BUS. LAW § 349(h).

EIGHTH CAUSE OF ACTION
N.Y. GEN. BUS. LAW § 350, *Et Seq.*
On Behalf of the New York Subclass

164. Plaintiff incorporates each and every allegation contained in the paragraphs above as if rewritten herein.

165. N.Y. Gen. Bus. Law § 350 declares false advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state to be unlawful. The term 'false advertising' means advertising, including labeling, of a commodity, or of the kind, character, terms or conditions of any employment opportunity if such advertising is misleading in a material respect. In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity or employment to which the advertising relates under the conditions proscribed in said advertisement, or under such conditions as are customary or usual. 91. N.Y. Gen. Bus. Law § 350-a(l).

166. Defendants' labeling and advertisements contain untrue and materially misleading statements regarding the contents of the Supplement.

167. Plaintiff and members of the Class have been injured inasmuch as they relied upon the labeling and advertising and paid a premium for a product that did not conform to its representations. Accordingly, Plaintiff and the Class Members received less than what they bargained and/or for which they paid a premium.

168. Defendants' advertising and product labeling induced the Plaintiff and Class Members to buy their Product.

169. Defendants knew, or by exercising reasonable care should have known, that their statements and representations as described in this Complaint were untrue and/or misleading.

170. Defendants made the material misrepresentations described in this Complaint on its Product labels.

171. As a result of Defendants' false or misleading labeling and advertising, Plaintiff and Class Members are entitled to monetary damages, statutory damages, injunctive relief, restitution, disgorgement of all monies obtained by means of IVC's unlawful conduct, interest, and attorneys' fees and costs.

NINTH CAUSE OF ACTION

Restitution Based On Quasi-Contract/Unjust Enrichment

172. Plaintiff incorporates each and every allegation contained in the paragraphs above as if rewritten herein.

173. Defendants' conduct in enticing Plaintiff and the Class to purchase their Products with false and misleading packaging is unlawful because the statements contained on the Defendants' Product labels are untrue.

174. Defendants took monies from Plaintiff and the Class for these Products and have been unjustly enriched at the expense of Plaintiff and the Class as result of their unlawful conduct alleged herein, thereby creating a quasi-contractual obligation

on Defendants to restore these ill-gotten gains to Plaintiff and the Class. It is against equity and good conscience to permit Defendants to retain the ill-gotten benefits received from Plaintiff and Class members.

175. As a direct and proximate result of Defendants' unjust enrichment, Plaintiff and the Class are entitled to restitution or restitutionary disgorgement in an amount to be proved at trial.

PRAYER FOR RELIEF

THEREFORE, Plaintiff, on behalf of himself and on behalf of the other members of the Class and for the Counts so applicable on behalf of the general public request an award and relief as follows:

A. An order certifying that this action is properly brought and may be maintained as a class action, that Plaintiff be appointed Class Representative, and Plaintiff's counsel be appointed Lead Counsel for the Class.

B. Restitution in such amount that Plaintiff and all members of the Class paid to purchase Defendants' Product or restitutionary disgorgement of the profits Defendant obtained from those transactions, for Causes of Action for which they are available.

C. Compensatory damages for Causes of Action for which they are available.

D. Statutory penalties for Causes of Action for which they are available.

E. Punitive Damages for Causes of Action for which they are available.

F. A declaration and Order enjoining Defendant from marketing and labeling their Products deceptively, in violation of laws and regulations as specified in this Complaint.

G. An Order awarding Plaintiff his costs of suit, including reasonable attorneys' fees and pre and post judgment interest.

H. An Order requiring an accounting for, and imposition of, a constructive trust upon all monies received by Defendant as a result of the unfair, misleading, fraudulent and unlawful conduct alleged herein.

I. Such other and further relief as may be deemed necessary or appropriate.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all causes of action or issues so triable.

DATED: May 13, 2021

Respectfully submitted,

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