Maia C. Kats (*pro hac vice*)
JUST FOOD LAW
5335 Wisconsin Avenue, NW, Ste. 440
Washington, DC 20015
Telephone: (202) 243-7910

George Carpinello (*pro hac vice*)
Adam Shaw (*pro hac vice*)
BOIES SCHILLER FLEXNER LLP
333 Main Street
Armonk, NY 10504
Telephone: (914) 749-8378

Todd Maybrown (Bar No. 18557)
ALLEN, HANSEN, MAYBROWN & OFFENBECHER
600 University St, Suite 3020
Seattle, Washington 98101
Telephone: (206) 447-9681

Counsel for Plaintiffs and the Proposed Class

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

ANITA MEDAL, ESTHER YOO, GAYLE HAYES, ANTOINETTE STANIEWICZ, individually and on behalf of all others similarly situated, **Plaintiffs,** **v.** **AMAZON SERVICES, LLC,** **Defendant.**	**CASE NO.: 2:23-cv-01975-JHC** **FIRST AMENDED CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiffs Anita Medal, Esther Yoo, Gayle Hayes, and Antoinette Staniewicz (together, "Plaintiffs"), individually and on behalf of all others similarly situated, bring this Class Action Complaint against Defendant Amazon Services, LLC ("Defendant," "Amazon" or "Amazon.com"), and on the basis of personal knowledge, information, belief, and investigation of counsel, allege as follows:

NATURE OF THE ACTION

1. This is an action for violation of California consumer protection laws, and under common law negligent and strict product liability, relating to Defendant's unlawful, deceptive and misleading, sales of illegal drugs on its Amazon.com on-line marketplace.

2. Directly, under the Fulfilled by Amazon ("FBA") program, and otherwise, Amazon promoted, placed into the stream of commerce, sold and delivered to Plaintiffs, products purporting to be legal, safe, and therapeutic dietary supplements when the opposite was true: the products were defective drugs—illegal and unapproved by the FDA—that injured Plaintiffs monetarily and also exposed them to risk of physical injury, including to serious bodily harm. In doing so, Defendant engaged in transactions intended and which did result in the sale of deceptive and unlawful goods to consumers.

3. Plaintiffs were foreseeably injured by Defendant's conduct and suffered damages as a direct and proximate result of it.

PARTIES

A. Plaintiffs

4. Plaintiff Anita Medal resides Berkeley, California, and during the liability period and all times relevant resided in California.

5. During the relevant class period, including on June 14, 2019, December 2, 2021, April 6, April 15, May 15-16, May 22, and June 15-16, 2022, Ms. Medal purchased a multitude of illegal drugs masquerading as therapeutic dietary supplements from Amazon.com—directly, pursuant to its FBA program, or otherwise—including but not limited to: Nature's Nutrition Turmeric Curcumin claiming to be "tested and proven," to support "joint and heart health," and "brain function"; Doctor's Best Vitamin D-3 claiming to be "for healthy bones, teeth, heart, and immune support";

Puritan's Pride Co-Q10 claiming to"support[] heart health," "replenish what is lost with age or what statin medications deplete"; Safrel Vitamin B-12 claiming to "support[] nervous system function," "promote[] energy"; and NOW Supplements claiming to support a "healthy intestine").

6. Ms. Medal saw and believed the representations, on product labels and otherwise, that the Products harbored therapeutic value, and/or that they and the marketing claims were reviewed by and approved by the FDA. She also believed that the Products were lawful and legally sold into interstate commerce.

7. Ms. Medal relied on Amazon's stature, representations, and reputation, as well as the marketing and Product labels and its omissions from the same, and was misled thereby.

8. Ms. Medal purchased more of, and/or paid more for, the Products than she would have had she known the truth about the Products.

9. Ms. Medal was injured in fact and lost money as a result of Amazon's improper conduct. In addition, she was exposed to risk of serious bodily injury.

10. If Ms. Medal knew that Amazon's marketing and sale was lawful, truthful and non-misleading in the future, she would purchase dietary supplements from it. At present, however, she will not purchase dietary supplements because she cannot be confident that the marketing and sale of the Products is, or will be, legal, and truthful and non-misleading.

11. Plaintiff Esther Yoo resides Los Angeles, California, and during the liability period and all times relevant resided in California.

12. During the relevant class period, including on March 11, 2021, April 27, May 26, July 11, 14, and 25, 2022, January 8, May 11, September 13, and October 5, 2023, February 12, 13, March 7, and April 29, 2024, Ms. Yoo purchased a multitude of illegal drugs masquerading as therapeutic dietary supplements from Amazon.com—directly, pursuant to its FBA program, or otherwise—including but not limited to: Nature's Bounty Fish Oil 1200 mg ("Nature's Bounty Fish Oil Softgels contain the two most studied Omega-3 fatty acids," "Fatty acids are essential nutrients that help support the health of your cardiovascular system"); Mega Red Omega-3 Krill Oil ("Heart health support: excellent source of EPA and DHA Omega-3 fatty acids which may reduce the risk of coronary heart disease"); Centrum Men's Multi-Vitamin ("Specially crafted . . . to help build and

maintain strong bones," ". . . to provide immunity support, B Vitamins to support energy levels and metabolism, and Vitamin B6 and Vitamin D to support healthy muscle function"); Nutrafol Women's Hair Growth Supplement ("Clinically Proven for Visibly Thicker Hair and Scalp Coverage, Dermatologist Recommended"); Centrum Women's Multi-Vitamin ("Supports energy, immunity, metabolism + healthy appearance"); Nature's Bounty Ultra Strength Probiotic ("Ultra Strength Daily Probiotic Supplement, Support for Digestive, Immune and Upper Respiratory Health," "Clinically studied strains shown to support advanced digestive balance, healthy immune function"); Orthomol Vital M ("Supports Male Vitality – Formulated to enhance vitality and energy levels with a blend of essential micronutrients that help reduce tiredness and fatigue"); Orthomol Vital Immun ("Orthomol Immun is for the dietary management of nutrition-related immune deficiencies (e.g. recurrent respiratory infections"); and Orthomol Natal ("contains a complex of folic acid to support the mother's health and baby's cognitive development," "Important micronutrients for pre-pregnancy, pregnancy and breastfeeding").

13. Ms. Yoo saw and believed the representations, on product labels and otherwise, that the Products harbored therapeutic value, and/or that they and the marketing claims were reviewed by and approved by the FDA. She also believed that the Products were lawful and legally sold and received in interstate commerce.

14. Ms. Yoo relied on Amazon's stature, representations, and reputation, as well as the marketing and Product labels and its omissions from the same, and was misled thereby.

15. Ms. Yoo purchased more of, and/or paid more for, the Products than she would have had she known the truth about the Products.

16. Ms. Yoo was injured in fact and lost money as a result of Amazon's improper conduct. In addition, she was exposed to risk of serious bodily injury.

17. If Ms. Yoo knew that Amazon's marketing and sale was lawful, truthful and non-misleading in the future, she would purchase dietary supplements from it. At present, however, she will not purchase dietary supplements because she cannot be confident that the marketing and sale of the Products is, or will be, legal, and truthful and non-misleading.

18. Plaintiff Gayle Hayes resides in San Jose, California, and during the liability period and all times relevant resided in California.

19. During the relevant class period, including on March 23, April 23, May 24, and July 23, 2019, April 4, May 2, June 24, October 19, and November 30, 2020, June 21, 2021, and September 18, 2023, Ms. Hayes purchased a multitude of illegal drugs masquerading as therapeutic dietary supplements from Amazon.com—directly, pursuant to its FBA program, or otherwise—including but not limited to: Airborne Immune Support ("100 percent of your daily value of Zinc, which plays a central role in your immune system and is essential for the functioning and signaling of immune cells"); Hair Thickness Maximizer Saw Palmetto ("Stimulates and nourishes hair follicles for stronger, thicker & long lasting hair. Best capsule hair treatment for men & women."); Skinny Fit Super Youth Collagen Peptides ("HEALTHY SKIN, HEALTHY WEIGHT. Collagen and hyaluronic acid has shown an increase in skin elasticity and hydration, and supports cell regeneration, which supports youthful-looking skin. Apple cider vinegar supports a healthy metabolism and can aid in fat burn to help promote a healthy weight."); Sports Research Collagen Peptides ("RADIANT AND YOUTHFUL APPEARANCE: This collagen powder for women and men provides the protein and amino acids to support healthy nails, and also helps your skin look more radiant and youthful. Give yourself support from the inside out; JOINT SUPPORT: Amino acids support joint health and improve your body's response to strenuous exercise, making this collagen powder a great post-workout supplement and joint support supplement"); NeuroIGNITE Brain Supplement for Cognition ("Supports Cognition - NeuroIGNITE is formulated with nootropic ingredients like St. John's Wort and Ginkgo Biloba to support cognitive function and overall brain health, helping you stay sharp as you age"); Viva Natural Vitamin C ("Essential Immune Support Supplement," "Often going under the radar, ascorbic acid vitamin C is an essential nutrient for collagen synthesis.* Collagen is the holy grail of beauty and joint support, and adding a high potency vitamin C to your wellness routine can help your body make more of it").

20. Ms. Hayes saw and believed the representations, on product labels and otherwise, that the Products harbored therapeutic value, and/or that they and the marketing claims were reviewed by

and approved by the FDA. She also believed that the Products were lawful and legally introduced and received in interstate commerce.

21. Ms. Hayes relied on Amazon's stature, representations, and reputation, as well as its marketing and Product labels and its omissions from the same, and was misled thereby.

22. Ms. Hayes purchased more of, and/or paid more for, the Products than she would have had she known the truth about the Products.

23. Ms. Hayes was injured in fact and lost money as a result of Amazon's improper conduct. In addition, she was exposed to risk of serious bodily injury.

24. If Ms. Hayes knew that Amazon's marketing and sale was lawful, truthful and non-misleading in the future, she would purchase dietary supplements from it. At present, however, she will not purchase because she cannot be confident that the marketing and sale of the Products is, or will be, legal, and truthful and non-misleading.

25. Plaintiff Antoinette Staniewicz resides in Vacaville, California, and during the liability period and all times relevant resided, in, California.

26. During the relevant class period, including on December 1, 2022, Ms. Staniewicz purchased a multitude of illegal drugs masquerading as therapeutic dietary supplements from Amazon.com—directly, pursuant to its FBA program, or otherwise—including but not limited to: Mary Ruth's Iodine Organic Liquid Drops ("The body doesn't naturally produce iodine, so it is an essential part of any diet. Iodine deficiencies can lead to feeling fatigued and weak, dry and brittle hair, skin, and nails, and weight gain. . . . At particular risk for iodine deficiency are those on a vegan or vegetarian diet, or those pregnant and nursing. Iodine is crucial during pregnancy, when the body requires greater amounts of iodine to support the developing fetus. . . . This trace element is especially important for thyroid health, which regulates hormone production, which in turn plays an important role in metabolism. Support your body with this essential micronutrient"); Glutathione Super Antioxidant Supplement ("The mother of all antioxidants – fights free radicals, slows aging, boosts energy, improves skin health and more"); Vitablosom Liposomal Vitamin C ("Our liposomal vitamin c supplement is proven to be effective for heart and muscle. Energy levels and mood will be on the upswing.")

27. Ms. Staniewicz saw and believed the representations, on product labels and otherwise, that the Products harbored therapeutic value, and/or that they and the marketing claims were reviewed by and approved by the FDA. She also believed that the Products were lawful and legally sold and received in interstate commerce.

28. Ms. Staniewicz relied on Amazon's stature, representations, and reputation, as well as the marketing and Product labels and its omissions from the same, and was misled thereby.

29. Ms. Staniewicz purchased more of, and/or paid more for, the Products than she would have had she known the truth about the Products.

30. Ms. Staniewicz was injured in fact and lost money as a result of Amazon's improper conduct. In addition, she was exposed to risk of serious bodily injury.

31. If Ms. Staniewicz knew that Amazon's marketing and sale was lawful, truthful and non-misleading in the future, she would purchase dietary supplements from it. At present, however, she will not purchase dietary supplements because she cannot be confident that the marketing and sale of the Products is, or will be, legal, and truthful and non-misleading.

B. Defendant

32. Defendant Amazon is a Delaware limited liability company with its principal place of business in Washington.

JURISDICTION AND VENUE

33. This Court has subject matter jurisdiction because this is a class action arising under the Class Action Fairness Act of 2005 ("CAFA"), which confers original jurisdiction on the federal courts for any class action in which any member of the Class is a citizen of a state different from any defendant, and in which the matter in controversy exceeds in the aggregate $5,000,000, exclusive of interest and costs. Plaintiffs allege that the total claims of individual Class members in this action are in excess of $5,000,000, as required by 28 U.S.C. § 1332(d)(2) & (6). Plaintiffs are citizens of California, whereas Defendant is a citizen of Washington, satisfying 28 U.S.C. § 1332(d)(2)(A). Furthermore, the total number of Class members is greater than 100, as required by 28 U.S.C. §§ 1332(d)(5)(B). Federal subject matter jurisdiction thus exists.

34. Amazon has minimum contacts with the United States, this judicial district, and Washington. Amazon maintains its headquarters in Washington and has intentionally availed itself of the laws of Washington by conducting a substantial amount of business in the state. This Court accordingly has personal jurisdiction over Amazon.

35. Venue is appropriate in this District pursuant to 28 U.S.C. § 1391(b)(1) because Amazon is headquartered and resides in this District. Venue is further appropriate in this district pursuant to the forum selection clause in Amazon's online "conditions of use," which are available when a consumer signs up for an Amazon account and makes purchases and pursuant to which Amazon sought transfer of this action. The conditions provide that "[a]ny dispute or claim relating in any way to your use of any Amazon Service will be adjudicated in the state or Federal courts in King County, Washington, and you consent to exclusive jurisdiction and venue in these courts."

DEFENDANT AMAZON'S BUSINESS PRACTICES

36. Defendant Amazon operates a marketplace for consumers–Amazon.com–that provides listings for consumer products, including products purporting to be dietary supplements (the "Products"), as they are defined by the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 et seq. (the "FFDCA" or the "Act"), as amended by the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103–417, 108 Stat. 4325 ("DSHEA").

37. The Amazon.com e-commerce marketplace enables Amazon and its partner merchants to connect with consumers anywhere and thereby exponentially expand sales opportunities for products—far beyond conventional brick-and-mortar and direct retail sales venues.

38. Typically such merchants enter into an agreement with Amazon to participate in its e-commerce marketplace by executing Amazon's Business Services Agreement as well as other related agreements. For those participating in its Fulfilled by Amazon Program, there are additional FBA policies and requirements that govern. The majority of Amazon product sales occur through its FBA Program.

39. Under the FBA Program, Amazon provides a number of services to its partner merchants, and/or engages in numerous relevant activities in furtherance of placing FBA products in the hands of consumers. These activities include, but are not limited to: stocking, maintaining and

storing an inventory of FBA products at Amazon fulfillment centers; retaining data on and tracking all product inventory sold and/ or stored in such fulfillment centers, warehouses, and facilities; sorting and shipping services for products, including using Amazon personnel to label and otherwise move products through its distribution process; delivery of FBA products to consumer doorsteps, via Amazon delivery vehicles, including in conjunction with other consumer purchases from Amazon; assignment of FBA Amazon Standard Identification Numbers ("ASIN") to products; provision of 24/7 customer service to consumers and purchasers of products; and processing of all product purchases, returns, and refunds. If a product is returned, it is sent back to Amazon and Amazon inspects and determines whether it can be returned to inventory and resold.

40. In addition, Amazon's Business Solutions Agreement with merchants provides, *inter alia*, that Amazon controls: formatting of product listings on its online marketplace and via Amazon banner ads elsewhere so as to maximize sales to consumers; all communications about the product or product sales with its e-commerce consumers, which must take place exclusively through its online platform; and the processing of all payments for all purchases of FBA products, including what the permissible means of purchase are, and remittance of payments to merchants minus Amazon's substantial service fees—which range on average between 15-40% of the purchase price.

41. As part of its business practices, Amazon also pledges to protect consumers. For example, Amazon's Fair Pricing Policy gives Amazon the right to take action against its partners and merchants for pricing that "harm[s] consumer trust."

42. So too, Amazon's "Industry-Leading Safety and Compliance Program" authorizes Amazon to ban or delist products that are unlawful and/or dangerous. As described by Amazon:

> Amazon strives to be Earth's most customer-centric company, where people can find and discover the widest possible selection of safe and authentic goods, and we work hard to earn and maintain your trust. In 2018 alone, we invested over $400 million to protect our store and our customers and built robust programs to ensure products offered are safe, compliant, and authentic. Amazon offers customers hundreds of millions of items, and we have developed, and continuously refine and improve, our tools that prevent suspicious, unsafe, or non-compliant products from being listed in our store.

https://www.aboutamazon.com/news/company-news/product-safety-and-compliance-in-our-store (last visited August 15, 2022).

43. Consumers who purchase products on Amazon.com reasonably believe that the products are consumer goods that are lawfully offered for sale by Amazon on Amazon's online marketplace, as opposed to unlawful and defective drugs, the sale of which is prohibited under the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 et seq. , as amended by the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103–417, 108 Stat. 4325.

A. Amazon's Sale of Illegal and Dangerous Drugs

44. Upon information and belief, Amazon is the largest purveyor of health and wellness products in the United States, including consumer goods purporting to be lawful dietary supplements. The majority of sales are pursuant to the FBA program, or of "FBA products."

45. The health and wellness business, including for dietary supplements, is exceptionally profitable.

46. According to a pre-pandemic 2021 Report of the Congressional Research Service, more than 57% of American adults use dietary supplements.[1]

47. During the pandemic, usage skyrocketed to 70%, with Amazon the prepotent sales leader.

48. In 2020, the dietary supplements market in the U.S. was valued at $55.75 billion. That same year, there were more than 80,000 dietary supplements on the market—a number that has almost certainly skyrocketed with new CBD and virus-related immunity products.[2]

[1] Congressional Research Service ("CRS") Report R43062, "Regulation of Dietary Supplements: Background and Issues for Congress," 1 (September 20, 2021) (internal citations omitted) (hereafter "CRS R43062").

[2] *Id*. *See also* "Supplement Market Hits Record Growth of 14.5%," *Globe Newswire*, June 28, 2021, https://www.globenewswire.com/fr/news-release/2021/06/28/2254146/0/en/Supplement-Market-Hits-Record-Growth-of-14-5-According-to-Nutrition-Business-Journal-s-2021-Supplement-Business-Report.html (last visited January 30, 2023).

49. In 2020, Amazon was expected to sell an estimated $30 billion in vitamins and supplements on its on-line marketplace according to press accounts.[3] Upon information and belief, sales surged during the coronavirus pandemic.

50. According to Amazon itself, its brand is so trusted and relied on by consumers that 75% of all shoppers use Amazon.com to discover new products and brands, and 52% of shoppers have so much trust in Amazon that they are more willing to purchase a new brand on Amazon.com than elsewhere.[4]

1. Illegal Drugs

51. On August 4, 2022, the FDA issued a warning letter to Amazon asserting that it sells and/or puts into interstate commerce unlawful drugs in the form of supplements that make unapproved disease claims. In relevant part the letter stated:

> This letter concerns your firm's distribution of products that violate the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"). As explained below, . . .your firm is responsible for introducing, delivering, or causing the introduction or delivery into interstate commerce of products that are unapproved new drugs under section 505(a) of the FD&C Act, 21 U.S.C. 355(a). [5]These products, which are drugs as defined by section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1) were introduced or delivered for introduction into interstate commerce by Amazon via your Fulfillment by Amazon service.[6]

52. The Products (as defined herein) are also misleading, misbranded, unapproved, and unlawful drugs that may not be placed in interstate commerce.

---

[3] *See* https://www.helium10.com/blog/selling-supplements-on-amazon-covid/#:~:text=Amazon's%20Personal%20Care%20%26%20Health%20products,billion%20in%20sales%20in%202020 (last visited Nov. 4, 2022).

[4] *See* https://www.sell.amazon.com/blog/grow-your-business/amazon-stats-growth-and-sales (last visited Nov. 4, 2022).

[5] *See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/amazoncom-inc-629452-08042022 (last visited January 30, 2023).

[6] Amazon distributed each of the products directly to individual U.S. consumers. Each of the products was "fulfilled" by Amazon; your website states, "With Fulfillment by Amazon (FBA), [sellers] store [their] products in Amazon's fulfillment centers, and [Amazon] pick[s], pack[s], ship[s], and provide[s] customer service for these products." *See* https://sell.amazon.com/fulfillment-by-amazon.html.

53. Under section 201(g)(1)(B) and (g)(1)(C) of the FFDCA (codified at 21 U.S.C. § 321(g)(1)(B) and (g)(1)(C)), a "drug" is defined, in part, as an "article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," or an "article[] (other than food) intended to affect the structure or any function of the body of man or other animals."

54. Drugs are subjected to careful scrutiny by the FDA to ensure both efficacy and safety, before they may lawfully enter interstate commerce. 21 U.S.C. §§ 331(d), 355(a).

55. Section 403(r)(6) of the FFDCA (codified at 21 U.S.C. § 343(r)(6)), creates an exemption from classification as a drug—and the arduous FDA pre-approval requirement—for products "intended to affect the structure or function" of the body *if and only if* the supplement carries prominent disclaimers in order to notify consumers that such products are not intended or established to have therapeutic efficacy and have not been subjected to government review and approval for efficacy, safety, or truthfulness of marketing claims. 21 U.S.C. § 343(r)(6)(A), (C); *see also* 21 U.S.C. § 321(g)(1); 21 C.F.R. § 101.93(f)-(g).[7]

56. More specifically, in order to qualify as a dietary supplement instead of a drug requiring prior FDA approval before being placed on the market and sold to consumers, a product advertised with a structure function claim must bear a disclaimer on its label that reads:

> This statement has not been evaluated by the Food and Drug Administration.
> This product is not intended to diagnose, treat, cure, or prevent any disease.

21 U.S.C. § 343(r)(6); *see also* 21 C.F.R. § 101.93(c).

57. And to be legally compliant, the disclaimer must: (1) appear "on *each* panel or page" of a supplement *label or package* that bears a health-related claim; and (2) be "prominent." 21 C.F.R. § 101.93(d) (emphasis added); 21 U.S.C. § 343(r)(6).

58. Importantly, the FDA has expressly rejected any contention -

[7] Under DSHEA, dietary supplements are defined as a product that is not represented as a conventional food and which: is intended to supplement the diet; contains one or more botanicals, amino acids, and other substances or their constituents; is intended to be taken by mouth as a pill, capsule, powder, table, or liquid; and is labeled on the front panel as being a dietary supplement. 21 U.S.C. § 3321(ff).

> that repetition of the disclaimer on every panel or page where a statement made in accordance with section 403(r)(6) of the act appears is unnecessary. . . [T]he suggestions for the placement of a single disclaimer on a product label (e.g., under the nutrition label, adjacent to the most prominent claim) would not provide an acceptable alternative.

Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements, 62 Fed. Reg. 49,859, 49,864-65 (Sept. 23, 1997).

59. To appear "prominent," as required, the disclaimer must: (1) *not* be crowded by "voluntary" (optional) information or imagery; and (2) use bolded font of "at least" 1/16th of an inch in size. *Id*.; 21 C.F.R. § 101.93(e).

60. Where voluntary (non-mandated) claims on the label obscure the prominence of the disclaimer, the disclaimer fails. As articulated by the FDA:

> there will be instances in which statements under section 403(r)(6) of the act should *not be used* on a label [] because it is not feasible to accommodate both the required information and the statutory requirement for prominence for the disclaimer.

Id. at 49,865-66 (emphasis added).All of this is set forth clearly in the FDA's Guidance for Industry: A Dietary Supplement Labeling Guide.[8]

61. Failure to include mandatory disclaimers renders non-compliant products misbranded, and unapproved and unlawful drugs under federal law. 21 U.S.C. §§ 321(g)(1), 331(d), 343(r)(6), 355(a).

62. Drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA. 21 U.S.C. §§ 331(d), 355(a).

63. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is both safe and effective. *Id.*

64. California adopts federal labeling requirements under the Sherman Food, Drug and Cosmetic Law (the "Sherman Law"), Cal. Health & Safety Code § 109875, which provides that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal

[8] *See* FDA, Guidance for Industry: A Dietary Supplement Labeling Guide, April 2005, https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide-chapter-vi-claims (last visited January 30, 2023).

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.

65. The Products, as defined herein, are unapproved and, as explained below, do not bear requisite disclaimers. Upon information and belief, the Products also have not be subject to review and are not pre-approved for entrance into interstate commerce by the FDA.

a. The Consumer Protection Rationale Underlying the Disclaimer Requirement

66. The disclaimer requirement exists for a reason: to warn consumers. Importantly, it represents *the key* compromise between industry and the FDA that led to the enactment of DSHEA. The disclaimer enabled DSHEA to be passed by Congress in the first instance, and for dietary supplements to be marketed and sold without first clearing the arduous FDA drug review and approval process.

67. The warning itself stems from the FDA's express recognition that "few dietary supplements have been the subjects of adequately designed clinical trials." *See* Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000, 1003, 2000 WL 4559 (Jan. 6, 2000).

68. Stated otherwise, "many marketed supplements have not been the subjects of adequate studies to establish whether or not they are safe or effective, or the nature of the benefits they may provide." *Id*. at 1003. *See also* CRS R43062, 19 ("In general, there is a lack of peer-reviewed research on the effectiveness of many [] supplements;" citing as an example CBD products that purport to treat PTSD, anxiety, inflammation, arthritis, cancer, diabetes, Alzheimer, and other conditions").

69. Indeed, despite this widespread failure of substantiation, consumers routinely think the opposite is true. They harbor a very limited, if any, understanding of the distinctions between different types of drugs, *i.e.,* over-the-counter, pharmaceuticals, and supplements. Consumers (and many physicians) routinely misperceive that all of these are subjected to peer-reviewed studies on

their efficacy and safety, and that there is scientific consensus substantiating both efficacy and safety, in addition to government review and approval—when this is decidedly not the case.[9]

70. The prominent (bolded, boxed, unobscured, central) disclaimer addresses this critical misperception. This is why it forms the cornerstone of the DSHEA legislation governing dietary supplements: it is the byproduct of negotiations between the FDA and those in industry and Congress who sought more lax standards for dietary standards as compared to over-the-counter drugs ("OTC's) and pharmaceuticals—singularly exempting only the former from government review and pre-approval prior to marketing and sale.

71. Without the disclaimer, consumers are dangerously left with the misperception that products claiming to help their health in some way are therapeutic and safe, and reviewed and approved as such. Equally, consumers are left with the misimpression that they are purchasing lawful products.

72. Notably too, the fact that supplement marketing may not reference diseases explicitly is immaterial to the deception and illegality of products lacking requisite disclaimers because, as the FDA opined, it is "possible to describe almost all products intended to treat or prevent disease in terms of their effects on the structure or function of the body, without mentioning the disease itself." *See* 65 Fed. Reg. at 1005. In other words, a product that is marketed as "supporting metabolism and maintenance of blood sugar levels" is by implication a product targeting diabetes even if the word diabetes never appears on the label or packaging. Similarly, a product that supports memory and brain functions invokes Alzheimer's or dementia.

73. Put another way, by the FDA, disclaimers are needed regardless of whether or not a disease is expressly mentioned in labeling and marketing because "[m]ost disease treatment or prevention claims, including claims about serious and life-threatening diseases, can be described in a manner that will be easily understood by consumers without express reference to a specific disease. . . . The distinction between implied and express disease claims is thus, in many cases, a semantic one

[9] *See* CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*; *see also* CRS R43062, 20.

that has little, if any, practical meaning to consumers." *Id*. at 1013. The disclaimer is meant to remedy this.

74. Beyond deception and economic loss relating to purchases caused by deceptive and fraudulent marketing, products that lack requisite disclaimers expose consumers to risk of serious injury and bodily harm because they mislead consumers regarding efficacy and safety, thereby encouraging them to supplement and/or supplant their medicinal intake with dietary supplements that are contraindicated with other medicines, adulterated, or to self-diagnose and self-treat serious medical conditions—such as memory loss, diabetes, depression, prostrate conditions, arthritis, hypothyroidism, osteoporosis, etc.—without proper training, the benefit of a proper medical diagnosis, and/or helpful pharmaceuticals. This, in turn, exposes consumers to the huge risk of a misdiagnoses and/or failure to treat serious medical conditions with scientifically established (through peer review and consensus) treatments, thereby leading to exacerbated illness and unintended bodily consequences up to and including death. So too, supplements may and often do contain substances that are contraindicated for their conditions and/or prescribed medicines, while lacking any clinically proven benefit. Consumer exposure to serious and tangible physical danger from such Products is especially exacerbated by the price differential (i.e., the Products have a very low price point as compared to doctors' appointments, potential hospitalization, and/or prescription drugs, thereby undermining inclinations and incentives to seek medical care. *Id*. at 1001, 1044-45.

75. The medical and legal press is replete with examples of the above potential for medical danger and physical harm. For example, as the woefully under-resourced FDA recently informed, by way of a Warning Letter to Amazon dated October 28, 2022, certain products "promoted and sold" by Amazon "for joint pain and arthritis" contained hidden ingredients that when taken with NSAIDs can cause "heart attack and stroke, as well as serious gastrointestinal damage, including bleeding, ulceration, and fatal perforation of the stomach and intestines," and that the FDA had received reports of "liver toxicity and death" following consumption.[10]

[10] *Id*., https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/amazoncom-inc-631751-10282022.

76. Another of the myriad examples is the Uniformed Services' recent research and report on immunity supplements, funded by the Consortium for Health and Military Performance and Operation Supplement Safety. Initiated to investigate immunity supplement sales on Amazon.com with respect to ingredient contents, because "Cold, flu, and immunity dietary supplement product sales have skyrocketed since the start of the COVID-19 pandemic," the report found that a *majority* of the Amazon.com products tested contained ingredients not labeled, or lacked ingredients that were labeled, or contained adulterated ingredients. The Report concluded that, "[q]uality control measures seem insufficient for most select dietary supplement products. The public has a right to know that they are buying what is stated on the label."[11]

77. In short, the *purpose of the disclaimer is to "make sure that consumers understand that structure/function claims are not reviewed by FDA prior to marketing, and to caution consumers that dietary supplements bearing such claims are not for therapeutic uses*." *Id.* at 1007 (emphasis added).

2. Amazon's Illegal Drugs

78. Amazon and its partners systematically omit and/or promote and sell Products lacking the mandatory disclaimers from Product labels, rendering them dangerous, illegal, defective, and unapproved drugs that cannot be lawfully introduced, sold, or delivered into the stream of commerce.

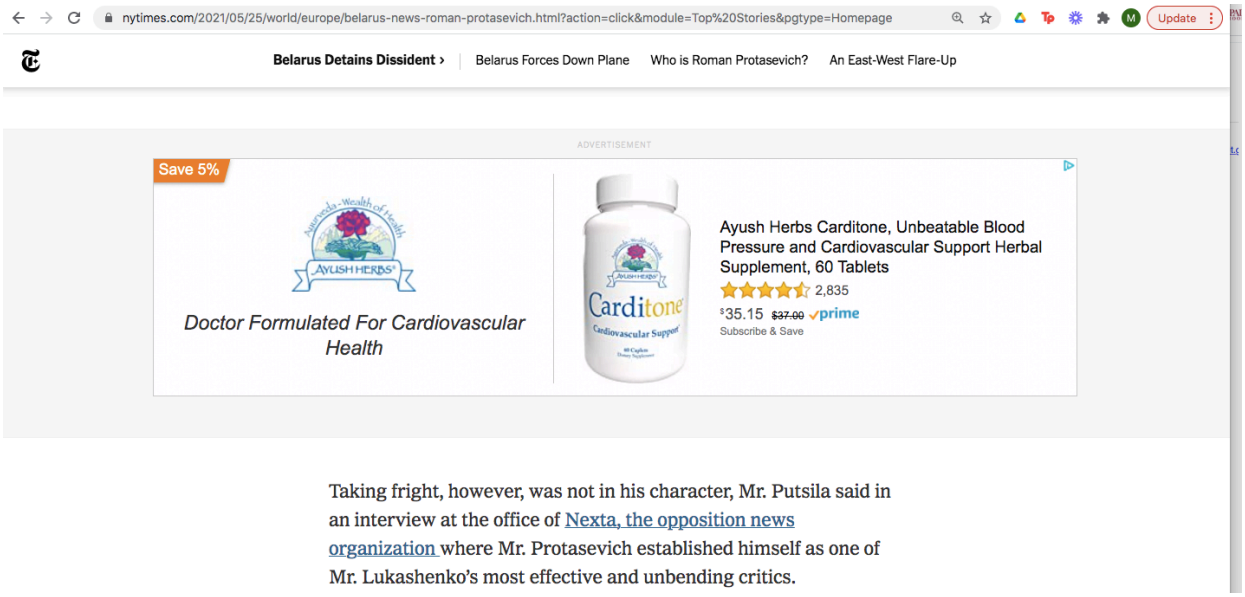
79. Upon information and belief, Amazon's practice given its market power has led to a proliferation of like violations and illegal sale of products by others and in other marketplaces–that is a proliferation of products claiming implicitly to treat, cure, or prevent various diseases and viruses including but not limited to diabetes, high blood pressure, Alzheimer, arthritis, depression, prostate cancer, and others, but which are neither scientifically established as safe or efficacious under the established protocol for drugs, nor are they subject to FDA review and approval.

80. By way of example, Amazon promotes Carditone with purported structure/ function claims on various Amazon banner ads directing consumers to the Amazon.com marketplace,

[11] *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9366544/?report (last visited January 30, 2023).

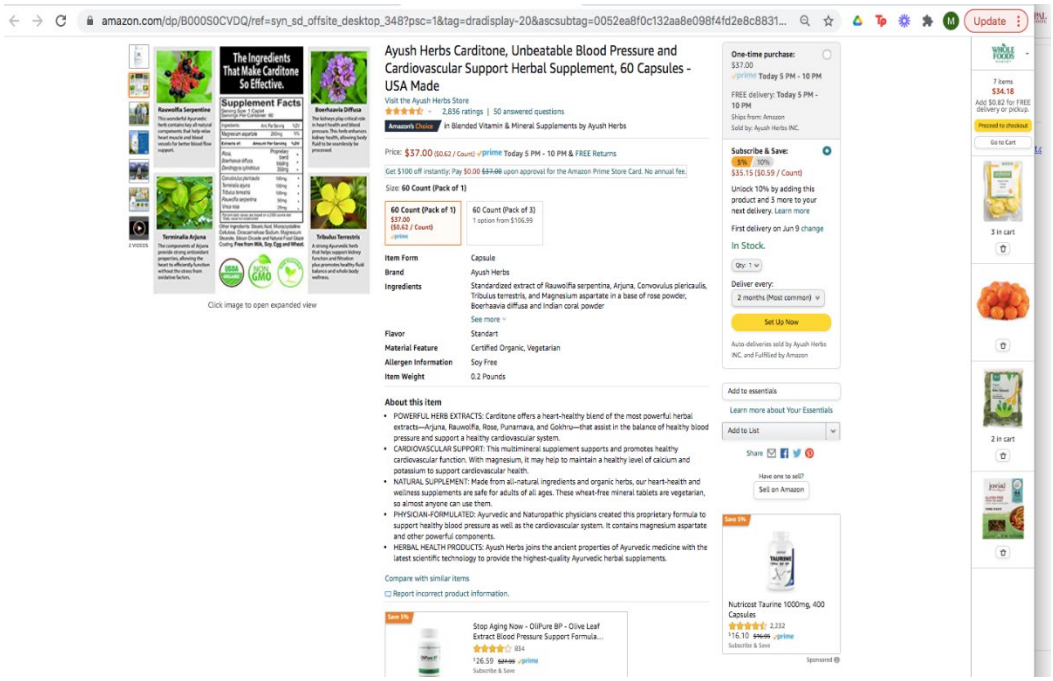
including the claims "Cardiovascular Support," "Unbeatable Blood Pressure and Cardiovascular Support Herbal Supplement," and "Doctor Formulated for Cardiovascular Health." *See* Image 1.

Image 1



81. Similarly, the Amazon.com entry promotes Carditone as "Recommended By Doctors," "Doctor Recommended," "For Essential Heart Health," "Amazon's Choice," and used to "maintain healthy blood pressure levels." The packaging claims that it provides "Doctor-Recommended All-Natural Blood Pressure Support." *See* images 2-3.

Images 2-3


amazon.com/dp/B000S0CVDQ/ref=syn_sd_offsite_desktop_348?psc=1&tag=dradisplay-20&ascsubtag=0052ea8f0c132aa8e098f4fd2e8c8831...
Update
The Ingredients That Make Caritone So Effective.
Supplement Facts
Rauwolfia Serpentina
Boerhaavia Diffusa
Terminalia Arjuna
Tribulus Terrestris
Click image to open expanded view
Ayush Herbs Carditone, Unbeatable Blood Pressure and Cardiovascular Support Herbal Supplement, 60 Capsules - USA Made
Visit the Ayush Herbs Store
2,836 ratings | 50 answered questions
Amazon's Choice in Blended Vitamin & Mineral Supplements by Ayush Herbs
Price: $37.00 ($0.62 / Count) prime Today 5 PM - 10 PM & FREE Returns
Get $100 off instantly: Pay $0.00 $37.00 upon approval for the Amazon Prime Store Card. No annual fee.
Size: 60 Count (Pack of 1)
60 Count (Pack of 1) $37.00 ($0.62 / Count) prime
60 Count (Pack of 3) 1 option from $106.99
Item Form Capsule
Brand Ayush Herbs
Ingredients Standardized extract of Rauwolfia serpentina, Arjuna, Convovulus plericaulis, Tribulus terrestris, and Magnesium aspartate in a base of rose powder, Boerhaavia diffusa and Indian coral powder
See more
Flavor Standart
Material Feature Certified Organic, Vegetarian
Allergen Information Soy Free
Item Weight 0.2 Pounds
About this item
POWERFUL HERB EXTRACTS: Carditone offers a heart-healthy blend of the most powerful herbal extracts—Arjuna, Rauwolfia, Rose, Punarnava, and Gokhru—that assist in the balance of healthy blood pressure and support a healthy cardiovascular system.
CARDIOVASCULAR SUPPORT: This multimineral supplement supports and promotes healthy cardiovascular function. With magnesium, it may help to maintain a healthy level of calcium and potassium to support cardiovascular health.
NATURAL SUPPLEMENT: Made from all-natural ingredients and organic herbs, our heart-health and wellness supplements are safe for adults of all ages. These wheat-free mineral tablets are vegetarian, so almost anyone can use them.
PHYSICIAN-FORMULATED: Ayurvedic and Naturopathic physicians created this proprietary formula to support healthy blood pressure as well as the cardiovascular system. It contains magnesium aspartate and other powerful components.
HERBAL HEALTH PRODUCTS: Ayush Herbs joins the ancient properties of Ayurvedic medicine with the latest scientific technology to provide the highest-quality Ayurvedic herbal supplements.
Compare with similar items
Report incorrect product information.
One-time purchase: $37.00
FREE delivery: Today 5 PM - 10 PM
Subscribe & Save: 5% 10% $35.15 ($0.59 / Count)
Unlock 10% by adding this product and 3 more to your next delivery. Learn more
First delivery on Jun 9 change
In Stock.
Deliver every: 2 months (Most common)
Set Up Now
Auto-deliveries sold by Ayush Herbs INC. and Fulfilled by Amazon
Add to essentials
Learn more about Your Essentials
Add to List
Share
Have one to sell?
Sell on Amazon
Nutricost Taurine 1000mg, 400 Capsules
$16.10
Stop Aging Now - OliPure BP - Olive Leaf Extract Blood Pressure Support Formula...
$26.59
Sponsored


2 VIDEOS
2 pack
Ayurveda-Wealth of Health
AYUSH HERBS
Carditone
Doctor Recommended, All-Natural
BLOOD PRESSURE
Support
2 x 60 Caplets
Cardiovascular Support
60 Caplets
Dietary Supplement
Roll over image to zoom in
Ayush Herbs - Carditone 60 caplets (Pack of 2)
Visit the Ayush Herbs Store
3,456 ratings
55 answered questions
Amazon's Choice for "carditone 120 caplets 2 p...
Price: $74.00 ($0.62 / Count) prime One-Day & FREE Returns
Get $60 off instantly: Pay $14.00 $74.00 upon approval for the Amazon Prime Store Card. No annual fee.
Size: 60 Count (Pack of 2)
60 Count (Pack of 1) $37.00 ($0.62 / Count) prime
60 Count (Pack of 2) $74.00 ($0.62 / Count) prime
60 Count (Pack of 3) $111.00 ($0.62 / Count) prime

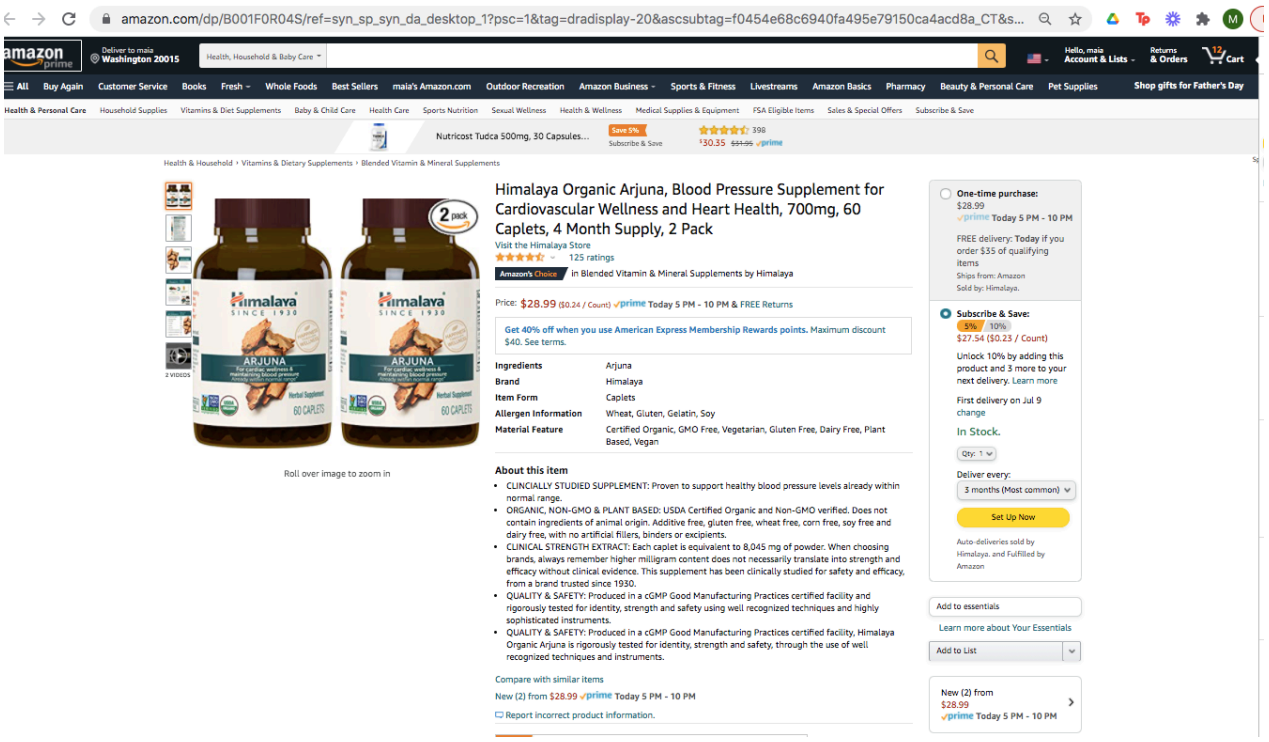
82. Carditone labels and packaging do not carry the disclaimer mandated for dietary supplements by the FDA and state law and therefore the Product constitutes an unapproved and unlawful drug that cannot be sold in commerce.

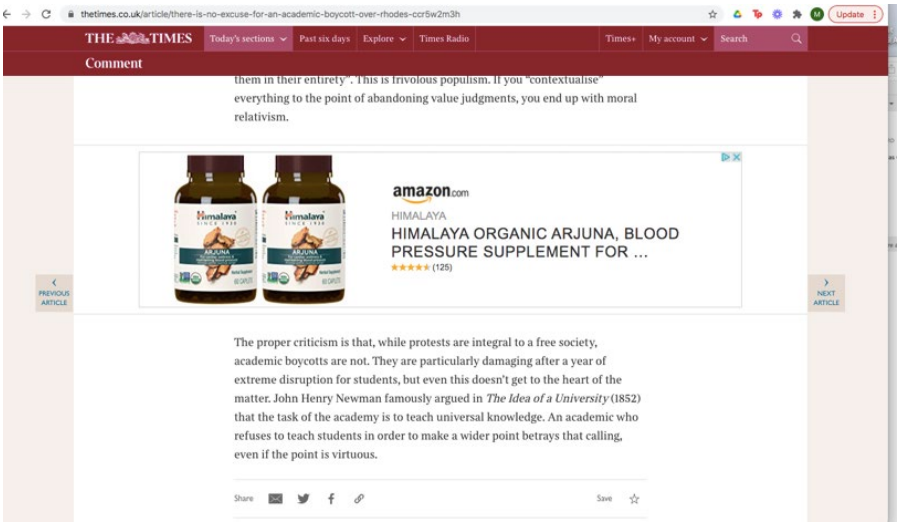
83. As with other Products on Amazon.com, people who self-diagnosis and treat with Carditone are at risk of serious bodily injury in addition to suffering economic injury caused by purchasing an illegal and defective drug from Amazon.com.

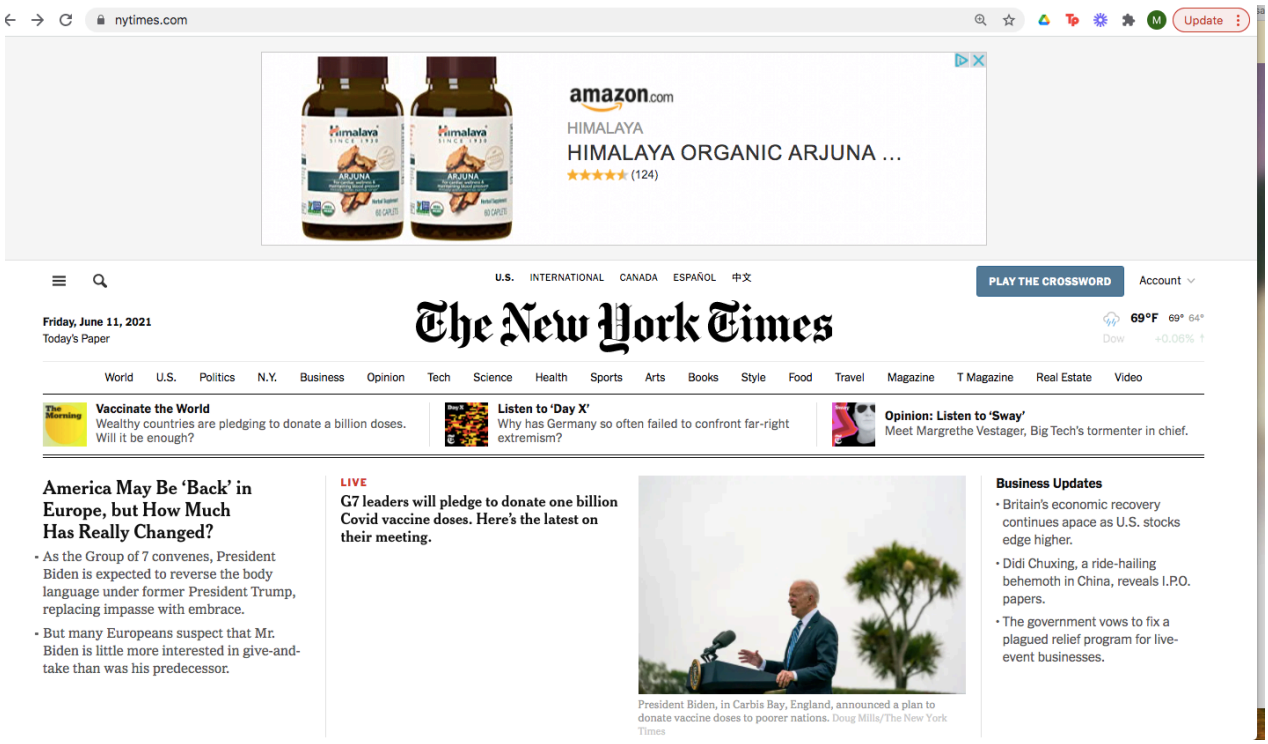
84. Other Amazon Products follow the identical labeling and advertising protocol – that is they systematically lack label and package requisite disclaimers despite lack of government review and approval with respect to their efficacy and safety. As such, they too are dangerous and defective, and constitute illegal drugs that are not lawfully entering or sold in the stream of commerce.

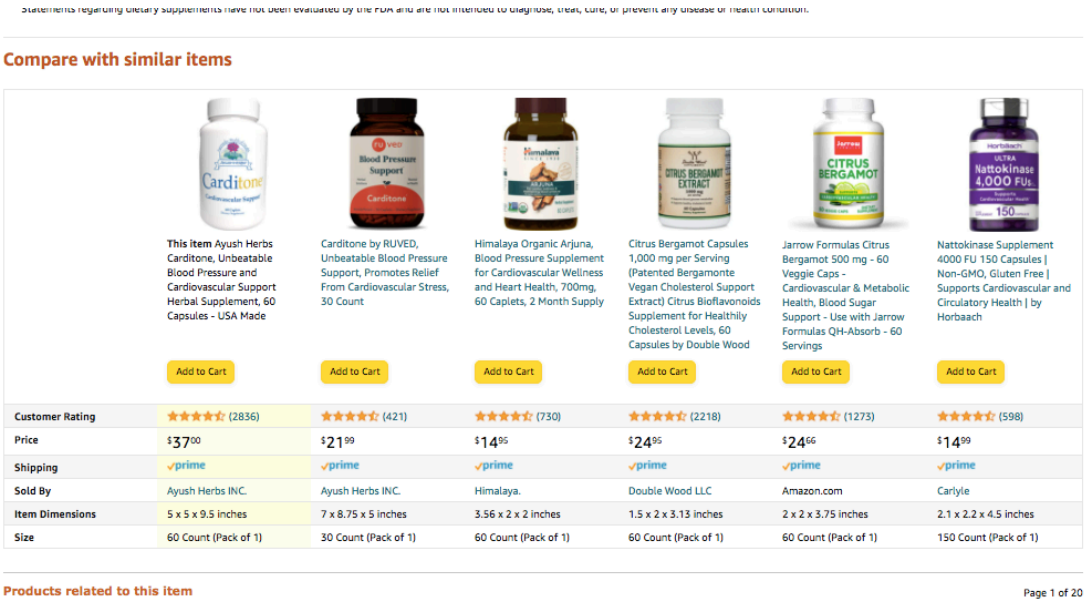
85. By way of another Product example, Amazon heavily markets Himalya Organic Arjuna as beneficial to "Heart Health" and "Blood Pressure," and further boosts its credibility and purported efficacy with the statement that the product is "clinically studied for safety and efficacy." The Product also lacks requisite disclaimers. *See* Image 4-7.

Images 4-7




thetimes.co.uk/article/there-is-no-excuse-for-an-academic-boycott-over-rhodes-ccr5w2m3h
THE TIMES
Comment
them in their entirety". This is frivolous populism. If you "contextualise"
everything to the point of abandoning value judgments, you end up with moral
relativism.
amazon.com
HIMALAYA
HIMALAYA ORGANIC ARJUNA, BLOOD PRESSURE SUPPLEMENT FOR ...
(125)
The proper criticism is that, while protests are integral to a free society, academic boycotts are not. They are particularly damaging after a year of extreme disruption for students, but even this doesn't get to the heart of the matter. John Henry Newman famously argued in The Idea of a University (1852) that the task of the academy is to teach universal knowledge. An academic who refuses to teach students in order to make a wider point betrays that calling, even if the point is virtuous.


nytimes.com
amazon.com
HIMALAYA
HIMALAYA ORGANIC ARJUNA ...
(124)
U.S. INTERNATIONAL CANADA ESPAÑOL 中文
PLAY THE CROSSWORD
Account
Friday, June 11, 2021
Today's Paper
The New York Times
69°F
World U.S. Politics N.Y. Business Opinion Tech Science Health Sports Arts Books Style Food Travel Magazine T Magazine Real Estate Video
Vaccinate the World
Wealthy countries are pledging to donate a billion doses. Will it be enough?
Listen to 'Day X'
Why has Germany so often failed to confront far-right extremism?
Opinion: Listen to 'Sway'
Meet Margrethe Vestager, Big Tech's tormenter in chief.
America May Be 'Back' in Europe, but How Much Has Really Changed?
As the Group of 7 convenes, President Biden is expected to reverse the body language under former President Trump, replacing impasse with embrace.
But many Europeans suspect that Mr. Biden is little more interested in give-and-take than was his predecessor.
LIVE
G7 leaders will pledge to donate one billion Covid vaccine doses. Here's the latest on their meeting.
President Biden, in Carbis Bay, England, announced a plan to donate vaccine doses to poorer nations. Doug Mills/The New York Times
Business Updates
Britain's economic recovery continues apace as U.S. stocks edge higher.
Didi Chuxing, a ride-hailing behemoth in China, reveals I.P.O. papers.
The government vows to fix a plagued relief program for live-event businesses.



Statements regarding dietary supplements have not been evaluated by the FDA and are not intended to diagnose, treat, cure, or prevent any disease or health condition.

Compare with similar items

	This item Ayush Herbs Carditone, Unbeatable Blood Pressure and Cardiovascular Support Herbal Supplement, 60 Capsules - USA Made	Carditone by RUVED, Unbeatable Blood Pressure Support, Promotes Relief From Cardiovascular Stress, 30 Count	Himalaya Organic Arjuna, Blood Pressure Supplement for Cardiovascular Wellness and Heart Health, 700mg, 60 Caplets, 2 Month Supply	Citrus Bergamot Capsules 1,000 mg per Serving (Patented Bergamonte Vegan Cholesterol Support Extract) Citrus Bioflavonoids Supplement for Healthily Cholesterol Levels, 60 Capsules by Double Wood	Jarrow Formulas Citrus Bergamot 500 mg - 60 Veggie Caps - Cardiovascular & Metabolic Health, Blood Sugar Support - Use with Jarrow Formulas QH-Absorb - 60 Servings	Nattokinase Supplement 4000 FU 150 Capsules | Non-GMO, Gluten Free | Supports Cardiovascular and Circulatory Health | by Horbaach
	Add to Cart	Add to Cart	Add to Cart	Add to Cart	Add to Cart	Add to Cart
Customer Rating	(2836)	(421)	(730)	(2218)	(1273)	(598)
Price	$37.00	$21.99	$14.95	$24.95	$24.66	$14.99
Shipping	prime	prime	prime	prime	prime	prime
Sold By	Ayush Herbs INC.	Ayush Herbs INC.	Himalaya.	Double Wood LLC	Amazon.com	Carlyle
Item Dimensions	5 x 5 x 9.5 inches	7 x 8.75 x 5 inches	3.56 x 2 x 2 inches	1.5 x 2 x 3.13 inches	2 x 2 x 3.75 inches	2.1 x 2.2 x 4.5 inches
Size	60 Count (Pack of 1)	30 Count (Pack of 1)	60 Count (Pack of 1)	60 Count (Pack of 1)	60 Count (Pack of 1)	150 Count (Pack of 1)

Products related to this item

Page 1 of 20

86. The defective and illegal nature of Amazon products is common to all Products—across a myriad of conditions and ailments. Diabetes, like many other medical conditions, is extremely expensive to treat pharmaceutically and pursuant to a doctor's care, making relatively inexpensive options appear appealing. Memory loss is similar, and fears of it are common among the elderly—rendering them easy prey for misleading marketing. Fraudulent impressions of product efficacy and therapeutic value are further enhanced by Amazon's publication of medical and clinical claims and symbols. Indeed, many products are even labeled with what appears as an "FDA" certification. *See* Images 8-16.

Images 8-26

Roll over image to zoom in

Visit the Pharmaganics Store

Diabetes Doctor 24 Hour Daily Support

4.4 ★★★★☆ 190 ratings

Amazon's Choice for "diabetes doctor blood sugar 24 h..."

Price: $34.99 ($34.99 / Count) prime
& FREE Returns

Get $60 off instantly: Pay $0.00 ~~$34.99~~ upon approval for the Amazon Prime Store Card. No annual fee.

Size: **1 Pack**

1 Pack	60 Count (Pack of 4)
$34.99 ($34.99 / Count) prime	$104.97 ($26.24 / Count) prime

Brand	Pharmaganics
Product Benefits	Eye Health,Metabolism,Energy
Item Form	Capsule
Unit Count	1.00 Count

About this item

- REVOLUTIONARY BLEND & POTENT DOSES: Every ingredient and dose based on medical research studies and recommended by top doctors.
- POWERFUL 7-in-1 BLEND: Natural and pure vitamins, herbs, and minerals for healthy blood sugar support. Each daily dose includes Cinnamon,

One-time purchase:
$34.99 ($34.99 / Count)
prime
FREE delivery: **Saturday, Feb 5**
Ships from: Amazon
Sold by: King Miggy

Subscribe & Save:
$34.99 ($34.99 / Count)
prime
Save up to 5% on auto-deliveries. Learn more
Get it Saturday, Feb 5

In Stock.

Qty: 1

Deliver every:
1 month (Most common)

Set Up Now

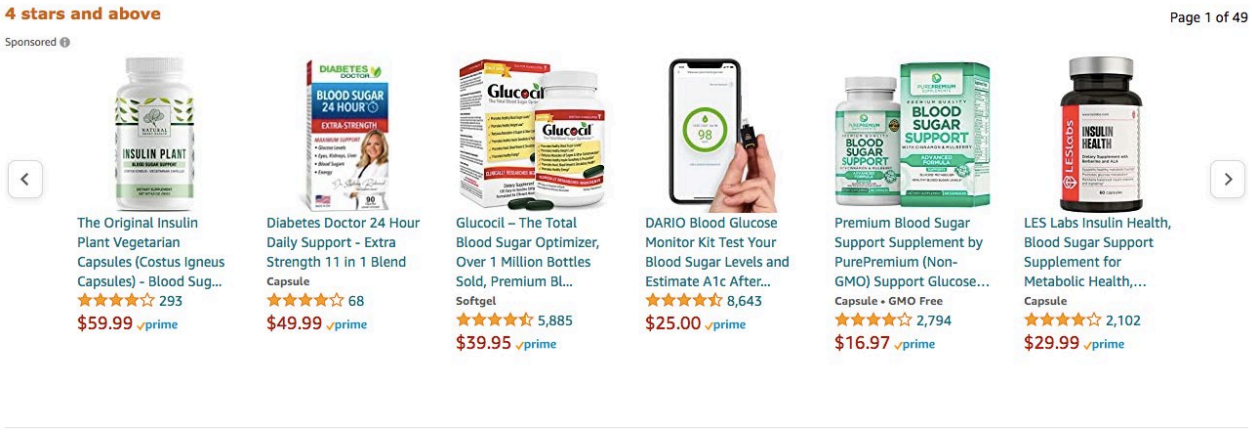
Auto-deliveries sold by Diabetes Doctor and Fulfilled by Amazon

Add to essentials

Learn more about Your Essentials

Roll over image to zoom in

Roll over image to zoom in



Roll over image to zoom in

Brand: Glucocil

Glucocil – The Total Blood Sugar Optimizer, Over 1 Million Bottles Sold, Premium Blood Sugar Support Supplement, Extra Strength Softgels*, Targets All 3 Essentials for Normal Blood Sugar, Since 2008

5,885 ratings | 90 answered questions

Price: $39.95 ($0.33 / Count) prime Overnight & FREE Returns

Get $60 off instantly: Pay $0.00 ~~$39.95~~ upon approval for the Amazon Prime Store Card. No annual fee.

Item Package Quantity: 1

1	2	3
$39.95 ($0.33 / Count)	$79.90 ($39.95 / Count)	$119.85 ($39.95 / Count)

Brand	Glucocil
Product Benefits	Weight Loss
Item Form	Softgel
Dosage Form	Softgel
Allergen Information	Salmon Free
Unit Count	120 Count
Item Dimensions LxWxH	2.14 x 2.14 x 5.2 inches

About this item

- FULL SPECTRUM OF BENEFITS TO PEOPLE WITH BLOOD SUGAR CONCERNS: (1) Promotes normal blood sugar levels, (2) Promotes weight loss, (3) Reduces absorption of sugars & other carbohydrates, (4) Promotes healthy insulin sensitivity & production, (5) Promotes healthy cholesterol, heart, blood vessels & circulation, and (6) Promotes healthy energy.
- HOW GLUCOCIL WORKS: Not many people know that there are 3 Essentials for keeping your blood sugar normal: (1) Reduce sugar absorption from food, (2) Reduce the liver's sugar production, and (3) Increase the body's use of sugar for energy. Target any one of the 3 Essentials and you'll improve your blood sugar levels. But target all 3 Essentials together, and you'll help keep your levels within the normal range. ONLY GLUCOCIL TARGETS ALL 3

One-time purchase: $39.95 ($0.33 / Count) prime Overnight

FREE delivery: Overnight
Ships from: Amazon
Sold by: Neuliven Health, Inc.

Subscribe & Save: 5% 10%
$37.95 ($0.32 / Count)
prime
Save 5% now and up to 10% on repeat deliveries.
• No fees
• Cancel anytime
Learn more
Get it Thursday, Feb 3

In Stock.

Qty: 1
Deliver every: 2 months (Most common)
Set Up Now

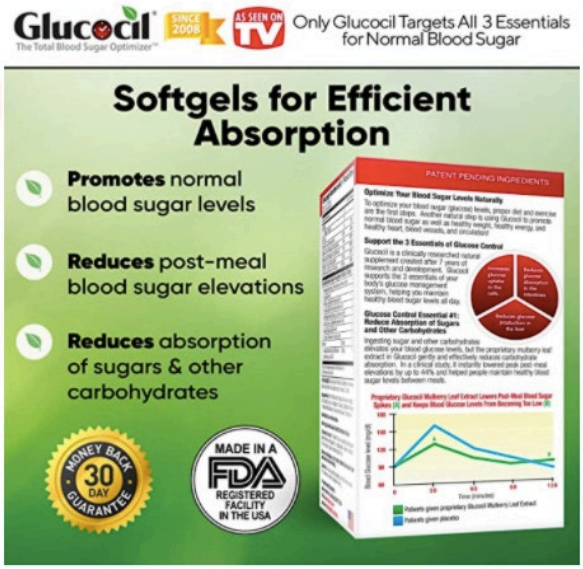
Auto-deliveries sold by Neuliven Health, Inc. and Fulfilled by Amazon

Add to essentials
Learn more about Your Essentials
Add to List

New (2) from $39.95 prime Overnight 4 AM - 8 AM

Share

Have one to sell?



Prevagen Improves Memory - Regular Strength 10mg, 30 Chewables |Orange-2 Pack| with Apoaequorin & Vitamin D | Brain Supplement for Better Brain Health, Supports Healthy Brain Function and Clarity

1,487 ratings | 10 answered questions

Amazon's Choice for "memory supplement"

Price: $71.20 ($1.19 / Count) prime Overnight & FREE Returns

Get $60 off instantly: Pay $11.20 ~~$71.20~~ upon approval for the Amazon Prime Store Card. No annual fee.

May be available at a lower price from other sellers, potentially without free Prime shipping.

Brand	Prevagen
Product Benefits	Brain Health
Item Form	Tablet
Dosage Form	Capsule
Flavor	Orange
Age Range (Description)	Adult

See more

About this item

- In a double-blinded, placebo-controlled trial, Prevagen demonstrated the ability to improve aspects of

One-time purchase: $71.20 ($1.19 / Count) prime Overnight

FREE delivery: Overnight

Ships from: Amazon

Sold by: Prevagen Official Store

Subscribe & Save: $71.20 ($1.19 / Count)

prime

Save up to 5% on auto-deliveries. Learn more

Get it Thursday, Feb 3

In Stock.

Qty: 1

Deliver every: 2 months (Most common)

Set Up Now

Auto-deliveries sold by Prevagen Official Store and Fulfilled by Amazon

Roll over image to zoom in

Immune Support Supplement with Vitamin C 1000mg Zinc Elderberry Ginger Beta Carotenes, Immunity Boo for Adults, Natural Immune Defense Antioxidant Vitar by BioSchwartz, 90 Capsules

Visit the BioSchwartz Store

4.5 ★ 6,186 ratings | 32 answered questions

Amazon's Choice for "immunity supplements"

Price: $17.97 ($0.20 / Count)

Save 30% on 3 select item(s) Shop items

Pay ~~$17.97~~ $0.00 for this order. Get a **$60 Amazon Gift Card** instantly upon approval for Prime Store Card.
No annual fee. Learn more

May be available at a lower price from other sellers, potentially without free Prime shipping.

Brand BioSchwartz

Puritan's Pride CoQ10 200mg, Supports Heart Health, 240 Rapid Release Softgels

Visit the Puritan's Pride Store

4.5 ★ 12,315 ratings | 95 answered questions

Amazon's Choice for "puritan's pride coq10"

Price: $46.84 ($0.20 / Count)

Coupon: Save an extra 25% on your first Subscribe and Save order. Terms

With Amazon Business, you would have saved **$126.03** in the last year. Create a free account
May be available at a lower price from other sellers, potentially without free Prime shipping.

Size: **240 Count (Pack of 1)**

120 Count (Pack of 1)
$26.60
($0.22 / Count)

240 Count (Pack of 1)
$49.30

Roll over image to zoom in

Roll over image to zoom in

Nature's Bounty Fish Oil 1200 mg, Twin Pack, Supports Heart Health With Omega 3 EPA & DHA, 360 Rapid Release Softgels

Visit the Nature's Bounty Store

4.4 out of 5 stars 78,633 ratings | 317 answered questions

#1 Best Seller in Fish Oil Nutritional Supplements

What's the Deal with DHEA?

DHEA is a substance produced in the adrenal gland. It supports production of other hormonal changes, making it very important for your body.*

Supplement your health with DHEA.

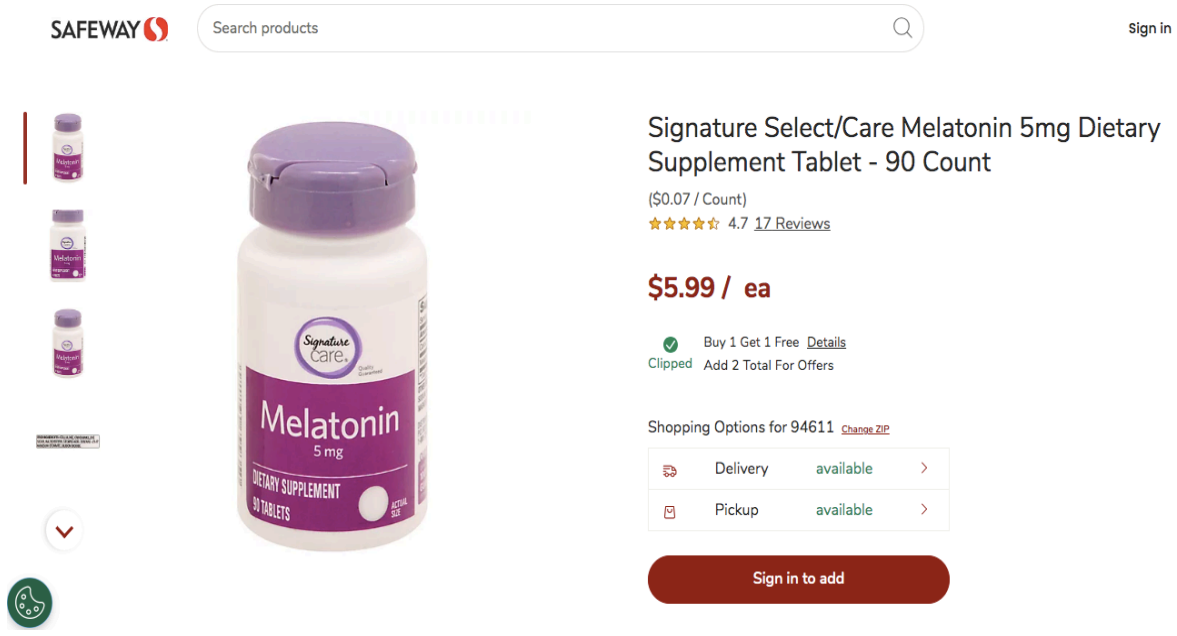
Fun Fact

DHEA stands for dehydroepiandrosterone.

- Supports balanced hormonal levels*
- Supports healthy mood*
- Supports immune function

87. By contrast, others lawfully label their supplements by either (a) not making structure function claims about efficacy or for any health or bodily function whatsoever, or (b) by properly providing the required disclaimer below each structure function representation. See Images 27-28.

Images 27-28



Target Up & Up

B. Defendant's Duty and Plaintiffs' Injury

88. Plaintiffs relied on Amazon and trusted that the Amazon.com marketplace would sell only products that are legal—that is, compliant with the law, safe, and that are not deceptive concerning their therapeutic qualities.

89. Amazon's name, power, and reputation, as well as the stated policies governing its marketplace and partners, created additional levels of trust in it.

90. Amazon's name and reputation, in addition to its banner ads, bring consumers to its site.

91. Amazon has a duty to Plaintiffs, given its position in the market, and/or its pledges to protect them, as well as its knowledge that consumers seeking to improve or maintain their health would rely on Amazon and its marketing to purchase the Products, and do so assuming the Products' legality, safety, and therapeutic efficacy.

92. Amazon breached its duty by selling defective and illegal Products to Plaintiffs, and by misleading them to believe that the Products were lawful and/or possessed well-established therapeutic value and had been FDA reviewed and approved.

93. Plaintiffs were foreseeably and directly harmed by Amazon's conduct because they received defective, dangerous, and economically valueless or less valuable Products instead of the class of product Plaintiffs were led by Amazon to believe they would receive.

94. Furthermore, by selling defective and illegal drugs to Plaintiffs, without their knowledge and/or without the requisite disclaimers, Defendant breached a legal duty under federal and state law separate and distinct from its obligations to the Plaintiffs under the UCL, CLRA and injured Plaintiffs and/or exposed them to risk of injury beyond.

95. If Plaintiffs had known that the Products were illegal drugs that were prohibited in interstate commerce, and/or that the FDA had not conducted a review of their efficacy and/or safety but instead mandated that a disclaimer as to lack of therapeutic efficacy appear prominently on the label, they would not have purchased Products and been injured thereby economically—whether by way of the purchase price or a price premium—or exposed themselves to the risk of serious physical injury.

96. By engaging in the unlawful, false, misleading and deceptive conduct alleged herein, Defendant intended to reap, reaped, and continues to reap, massive financial benefits in the form of gargantuan sales and profits from the Products.

97. Plaintiffs would be willing to purchase dietary supplements from Amazon again in the future should they be able to rely on Defendant to provide legal dietary supplements, and supplements that are properly marketed, including with respect to therapeutic claims.

CLASS ACTION ALLEGATIONS

98. Pursuant to Rules 23(a), (b)(2), and (b)(3) of the FEDERAL RULES OF CIVIL PROCEDURE ("Rule"), Plaintiffs bring this action individually and on behalf of a proposed class defined as follows:

> All persons residing in the State of California who purchased one or more Products from Amazon.com during the applicable limitations period.

99. Excluded from the Class are: (a) Defendant; (b) Defendant's board members, executive-level officers, and attorneys, and immediate family members of any of the foregoing persons; (c) governmental entities; (d) the Court, the Court's immediate family, and Court staff; and (e) any person that timely and properly excludes himself or herself from the Class in accordance with Court-approved procedures.

100. Certification of Plaintiffs' claims for class-wide treatment is appropriate because Plaintiffs can prove the elements of the claims on a class-wide basis using the same evidence as individual Class members would use to prove the elements in individual actions alleging the same claims.

101. **Numerosity**. The Class consists of many thousands of persons throughout the state of California. The Class is so numerous that joinder of all members is impracticable, and the disposition of the Class's claims in a class action will benefit the parties and the Court.

102. **Commonality and Predominance**. Common questions of law and fact predominate over any questions affecting only individual Class members. These common questions have the capacity to generate common answers that will drive resolution of this action. These common questions may include but are not limited to whether:

a. Amazon is responsible for the conduct alleged herein;

b. Amazon's conduct constitutes the violations of law alleged herein;

c. Amazon owed a duty of care to Class members;

d. Amazon's conduct transgressed important public policy;

e. Amazon violated any legal obligation separate from its duty to Class members;

f. Amazon misrepresented the character of its Products to Class members;

g. Amazon acted willfully, recklessly, negligently, or with gross negligence in committing the violations of law alleged herein;

h. Plaintiffs and the Class members are entitled to injunctive relief; and

i. Plaintiffs and the Class members are entitled to restitution and damages.

103. Because Plaintiffs received through interstate commerce from Amazon drugs that are unlawful, and/or were deceived through the same conduct by Amazon about the true character of its Products, all Class members were subject to the same wrongful conduct.

104. Absent Amazon's unlawful conduct, and/or material deceptions, misstatements, and/or omissions, Plaintiffs and the other Class members would not have purchased the Products, purchased as many as they did, and/or paid as much for the Products.

105. **Typicality**. Plaintiffs' claims are typical of the claims of the Class because Plaintiffs and the Class members all purchased the Products and were injured thereby. The claims of Plaintiffs

and the Class members are based on the same legal theories and arise from the same unlawful, and/or false and misleading conduct.

106. **Adequacy of Representation**. Plaintiffs are adequate representatives of the Class because their interests do not conflict with those of the Class members. Each Class member seeks damages reflecting a similar and discrete purchase, or similar and discrete purchases, that each Class member made. Plaintiffs have retained competent and experienced class action counsel who intend to prosecute this action vigorously. Plaintiffs and their counsel will fairly and adequately protect the Class members' interests.

107. **Injunctive or Declaratory Relief**. The requirements for maintaining a class action pursuant to Rule 23(b)(2) are met, as Defendant 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.

108. **Superiority**. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all Class members is impracticable. The amount at stake for each Class member, while significant, is such that individual litigation would be inefficient and cost prohibitive. Additionally, adjudication of this controversy as a class action will avoid the possibility of inconsistent and potentially conflicting adjudication of the claims asserted herein. Plaintiffs anticipate no difficulty in the management of this action as a class action.

109. **Notice to the Class**. Plaintiffs and their counsel anticipate that notice to the proposed Class will be effectuated through recognized, Court-approved notice dissemination methods, which may include United States mail, electronic mail, Internet postings, and/or published notice.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

Breach of Implied Warranty
Cal. Com. Code § 2314
(On behalf of Plaintiffs and the putative class)

110. Plaintiffs incorporate by reference the above allegations as if fully set forth herein.

111. Defendant, through its acts set forth herein, in the sale, marketing, and promotion of the Products made representations to Plaintiffs and the Class that, among other things, the Products were lawful and therapeutic dietary supplements as opposed to illegal and defective drugs, the sale

of which is prohibited under the Federal Food, Drug, and Cosmetic Act and California Sherman Law.

112. Defendant is a merchant with respect to the goods of this kind which were sold to Plaintiffs and the Class, and there were, in the sale to Plaintiffs and the Class, implied warranties that those goods were merchantable.

113. However, Defendant breached that implied warranty in that the Products at issue are not lawful and therapeutic dietary supplements as set forth in detail herein.

114. As an actual and proximate result of Defendant's conduct, Plaintiffs and the Class did not receive goods as impliedly warranted by Defendant to be merchantable in that they did not conform to promises and affirmations made on the container or label of the goods.

115. As a result, Plaintiffs seek actual damages, including, without limitation, expectation damages.

116. Therefore, Plaintiffs pray for relief as set forth below.

SECOND CAUSE OF ACTION
Violation of California's Unfair Competition Law
CAL. BUS. & PROF. § 17200 et seq.
Unlawful Conduct Prong
(On Behalf of Plaintiffs and the California Class)

117. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

118. Plaintiffs bring this claim on behalf of the California Class for violation of the "unlawful" prong of California's Unfair Competition Law, CAL. BUS. & PROF. CODE § 17200 *et seq.* (the "UCL").

119. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice." CAL. BUS. & PROF. CODE § 17200.

120. Defendant's acts, omissions, misrepresentations, practices, and non-disclosures concerning the Products, as alleged herein, constitute "unlawful" business acts and practices in that they violate the FFDCA, as amended by DSHEA, and implementing regulations, including, at least, the following sections:

a. The requirement under 21 C.F.R. § 101.93(b) that dietary supplements include a disclaimer on each package or label panel stating a structure/function claim notifying

the consumer that the FDA has not reviewed or approved of such claims and that the supplement is not intended to treat, cure, or prevent any disease;

b. The requirement that each disclaimer be prominent and not obscured or by voluntary claims and information. *Id.*; 21 U.S.C. § 403(r)(6)(C);

c. The requirement that all drugs receive pre-approval prior to being marketed and sold. 21 U.S.C. § 343(r)(6);

d. The prohibition on introduction of misbranded dietary supplements into interstate commerce. 21 U.S.C. §§ 331, 333; and

e. The requirement prohibiting marketing claims that are "false or misleading in any particular." 21 U.S.C. § 343(a)(1); 21 C.F.R. § 101.93(a)(3).

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

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

b. 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.");

c. 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.");

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

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

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

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

122. Each of the challenged omissions, statements, and actions by Defendant violates the FFDCA, as amended by DSHEA, and the Sherman Law, and, consequently, violates the "unlawful" prong of the UCL.

123. Defendant'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").

124. Defendant leveraged its omissions and deception to induce Plaintiffs and the members of the California Class, to purchase Products that were of different characteristics, value, and/or quality than advertised.

125. Defendant's unlawful sales and deceptive marketing and labeling caused Plaintiffs and the members of the California Class to suffer injury in fact and to lose money or property, as it denied them the benefit of the bargain. Had Plaintiffs and the members of the California Class been aware of Defendant's unlawful tactics and Products, they would not have purchased the Products, purchased as much of the Products, or paid as much for them.

126. In accordance with California Business and Professions Code section 17203, Plaintiffs seek an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices and to commence a corrective actions.

127. Plaintiffs also seek an order for the disgorgement and restitution of all monies from the sale of the Products that Defendant unjustly acquired through acts of unlawful, unfair, and/or fraudulent competition.

128. Therefore, Plaintiffs pray for relief as set forth below.

THIRD CAUSE OF ACTION
Violation of California's Unfair Competition Law
CAL. BUS. & PROF. § 17200 et seq.
Unfair and Fraudulent Conduct Prongs
(On Behalf of Plaintiffs and the California Class)

129. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

130. Plaintiffs bring this claim on behalf of the California Class for violation of the "unfair" and "fraudulent" prongs of the UCL.

131. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice." CAL. BUS. & PROF. CODE § 17200.

132. Defendant's false and misleading representations concerning the Products as alleged herein constitute "unfair" business acts and practices because such conduct is immoral, unscrupulous, and offends public policy. Further, the gravity of Defendant's conduct outweighs any conceivable benefit of such conduct.

133. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant, as alleged herein, constitute "fraudulent" business acts and practices, because its conduct is false and misleading to reasonable consumers, including Plaintiffs and the members of the California Class.

134. Defendant's conduct is likely to deceive reasonable consumers about the Products' characteristics and value.

135. Defendant either knew or reasonably should have known that its conduct was likely to deceive reasonable consumers.

136. In accordance with California Business & Professions Code section 17203, Plaintiffs seek an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices and to commence a corrective campaign.

137. Plaintiffs also seek an order for the disgorgement and restitution of all monies from the sale of Products that were unjustly acquired through acts of unlawful, unfair, and/or fraudulent competition.

138. Therefore, Plaintiffs pray for relief as set forth below.

FOURTH CAUSE OF ACTION

Violation of California's Consumers Legal Remedies Act
CAL. CIV. CODE § 1750 et seq.
(On Behalf of Plaintiffs and the California Class)

139. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

140. Plaintiffs bring this claim on behalf of the California Class for violation of the CLRA, seeking both injunctive and monetary relief.

141. The CLRA adopts a statutory scheme prohibiting various deceptive practices in connection with the conduct of a business providing goods, property, or services primarily for personal, family, or household purposes.

142. Defendant's policies, acts, and practices were designed to, and did, result in the purchase and use of the Products primarily for personal, family, or household purposes, and violated and continue to violate the following sections of the CLRA:

a. Section 1770(a)(5), which prohibits representing that goods have a particular composition or contents that they do not have;

b. Section 1770(a)(7), which prohibits representing that goods are of a particular standard, quality, or grade if they are of another;

c. Section 1770(a)(9), which prohibits advertising goods with intent not to sell them as advertised; and

d. Section 1770(a)(16), which prohibits representing that the subject of a transaction has been supplied in accordance with a previous representation when it has not.

143. As a result, in accordance with California Civil Code section 1780(a)(2), Plaintiffs and the members of the California Subclass have suffered irreparable harm and seek injunctive relief in the form of an order:

a. Enjoining Defendant from continuing to engage in the deceptive practices described above;

b. Requiring Defendant to provide public notice of the true nature of its Supplements;

c. Enjoining Defendant from such deceptive business practices in the future; and

d. Paying damages to Plaintiffs and other class members.

144. On or about August 24, 2022, Plaintiffs transmitted 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. As of this date, Amazon has not taken any action to address the demand. Accordingly, in addition to the injunctive relief, Plaintiffs seek damage pursuant to Civil Code ¶ 1780(a).

145. Therefore, pray for relief as set forth below.

FIFTH CAUSE OF ACTION

VIOLATION OF CALIFORNIA'S FALSE ADVERTISING LAW

CAL. BUS. & PROF. § 17500 et seq.

False Advertising

(On Behalf of Plaintiffs and the California Class)

146. Plaintiffs repeat each and every allegation contained in the paragraphs above and incorporate such allegations by reference herein.

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

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

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

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

151. Pursuant to California Business & Professions Code § 17535, Plaintiffs seek an Order of this Court: (1) requiring Defendant to disgorge its ill-gotten gains; (2) awarding full restitution of all monies wrongfully acquired by Defendant; and (3) awarding interest and attorneys' fees. Plaintiffs and the Class may be irreparably harmed and denied an affective and complete remedy if such an Order is not granted.

152. Therefore, Plaintiffs pray for relief as set forth below.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and behalf of members of the Class, respectfully request the Court to enter an Order:

A. Certifying the proposed Class under Rules 23(a), (b)(2), and (b)(3), as set forth above;

B. Declaring that Defendant is financially responsible for notifying the Class members of the pendency of this suit;

C. Declaring that Defendant has committed the violations of law alleged herein;

D. Providing for any and all injunctive relief the Court deems appropriate;

E. Awarding statutory damages in the maximum amount for which the law provides;

F. Awarding monetary damages, including but not limited to any compensatory, incidental, or consequential damages in an amount that the Court or jury will determine, in accordance with applicable law;

G. Providing for any and all equitable monetary relief the Court deems appropriate;

H. Awarding punitive or exemplary damages in accordance with proof and in an amount consistent with applicable precedent;

I. Awarding Plaintiffs their reasonable costs and expenses of suit, including attorneys' fees;

J. Awarding pre- and post-judgment interest to the extent the law allows; and

K. For such further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all causes of action or issues so triable.

JUST FOOD LAW PLLC

DATED: March 11, 2025

BY: /s/ Maia Kats

Maia Kats
5335 Wisconsin Avenue, NW, Ste. 440
Washington, DC 20015
Telephone: (202) 243-7910
Email: maiakats@justfoodlaw.com

George Carpinello (*pro hac vice*)
Adam Shaw (*pro hac vice*)
BOIES SCHILLER FLEXNER LLP
333 Main Street
Armonk, NY 10504
Telephone: (914) 749-8378
Email: gcarpinello@bsllp.com
Email: ashaw@bsllp.com

Todd Maybrown, Bar No. 18557
ALLEN, HANSEN, MAYBROWN & OFFENBECHER
600 University St, Suite 3020
Seattle, Washington 98101
Telephone: (206) 447-9681
Email: todd@ahmlaywers.com

Counsel for Plaintiffs and the Proposed Class