EDELSBERG LAW, P.A.
Scott Edelsberg (State Bar No. 330990)
scott@edelsberglaw.com
Christopher Gold
(*pro hac vice* forthcoming)
chris@edelsberglaw.com
1925 Century Park E #1700
Los Angeles, CA 90067
Telephone: (305) 975-3320

Counsel for Plaintiff and the Proposed Class

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

CAROLINA GONZALEZ, individually and on behalf of all others similarly situated, *Plaintiff*, v. PROHEALTH, a California corporation, *Defendant*.	No. **CLASS ACTION COMPLAINT** **JURY DEMAND**

Plaintiff, individually and on behalf of all others similarly situated, files this Class Action Complaint against Defendant ProHealth ("Defendant"), and upon information and belief, alleges as follow:

NATURE OF THE ACTION

1. This is a consumer class action arising from Defendant's deceptive and unfair advertising, marketing, and sale of a worthless, misbranded drug, in violation of California's consumer protection laws.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(d)(2)(A), because at least one member of the Class is a citizen of a different state than Defendant, there are more than 100 members of the Class, and upon information and belief the aggregate amount in controversy exceeds $5,000,000.00 exclusive of interest and costs.

3. This Court has personal jurisdiction over Defendant because Defendant conducts business in this District and in the State of California.

4. Venue is also proper in this Court because Plaintiff resides in this District and a substantial part of the events or omissions giving rise to the claims occurred in this District.

PARTIES

5. At all relevant times, Plaintiff Carolina Gonzalez was a citizen of Miami, Florida.

6. At all relevant times, Defendant was a California corporation with its principal place of business at 555 Maple Ave., Carpinteria, California 93013.

FACTUAL ALLEGATIONS

7. Throughout the Class Period (defined below), Defendant marketed, advertised, and sold Full Spectrum™ St. John's Wort Extract ("Product").

8. During the Class Period, Defendant's website made the following claims regarding the Product:

a. "Effective for mild to moderate depression"; and

b. "Reduces anxiety"

9. The labeling of the Product purported to give directions for its intended use.

10. On February 18, 2021, the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN), sent a warning letter to Defendant in which it explained that the Product is misbranded under section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 352(f)(1) ("Warning Letter"):

> This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address www.prohealth.com in December 2020 and has determined that you take orders there for your Full Spectrum™ St. John's Wort Extract product. The claims on your website establish that your product is a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)] because it is intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product for introduction into interstate commerce violates the Act. You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.
>
> Examples of some of the website claims that provide evidence that your "Full Spectrum™ St. John's Wort Extract" is intended for use as a drug include:
>
> On the webpage for "Full Spectrum™ St. John's Wort Extract":
>
> - "Effective for mild to moderate depression"
> - "Reduces anxiety"
>
> Your Full Spectrum™ St. John's Wort Extract product is not generally recognized as safe and effective for the above referenced uses and, therefore, this product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.
>
> A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 C.F.R. § 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.
>
> Your Full Spectrum™ St. John's Wort Extract product is intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment

> without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your product safely for its intended purposes. Accordingly, your Full Spectrum™ St. John's Wort Extract product fails to bear adequate directions for its intended use and, therefore, the product is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. § 331(a)].
>
> The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your marketed products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.
>
> You should take prompt action to address the violations cited in this letter. Failure to promptly address these violations may result in legal action without further notice, including, without limitation, seizure and injunction.
>
> Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps that you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete addressing these violations within fifteen working days, state the reason for the delay and the time within which you will do so. Your reply should be sent via e-mail to FDAAdvisory@fda.hhs.gov.
>
> Sincerely,
>
> /S/
>
> William A. Correll Jr.
> Director
> Office of Compliance
> Center for Food Safety and Applied Nutrition
> Food and Drug Administration

11. Because the Product is a misbranded drug that is unlawful to sell, it is a worthless product. Further, the Product's advertising and labeling is deceptive because, as the Warning Letter notes, the Product is "not generally recognized as safe and effective for the above referenced uses" and because "it is impossible to write adequate directions for a layperson to use [the P]roduct safely for its intended purposes."

12. Plaintiff and the members of the Class purchased the Product during the Class Period and suffered damages as a result.

CLASS ALLEGATIONS

13. This action is brought and is properly maintained as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2), and (b)(3).

14. Plaintiff seeks to certify a nationwide class ("Class") defined as follows:

> **All persons who purchased the Product during the period beginning four years before the filing of this action and the date of class notice.**

15. In the alternative, Plaintiff seeks to certify a California Subclass ("Subclass") defined as:

> **All persons who purchased the Product in the state of California during the period beginning four years before the filing of this action and the date of class notice.**

16. The Class and the Subclass are collectively referred to as the "Class."

17. Excluded from the Class are Defendant, its subsidiaries and affiliates, its officers, directors and member of their immediate families and any entity in which Defendant has a controlling interest, the legal representatives, heirs, successors or assigns of any such excluded party, the judicial officer(s) to whom this action is assigned, and the members of their immediate families.

18. Plaintiff reserves the right to modify or amend the definition of the proposed Class and/or to add subclasses if necessary before this Court determines whether certification is appropriate.

19. ***Numerosity.*** The precise number of members for the Class are unknown to Plaintiff at this time and can only be determined through appropriate discovery. Based upon information and belief, Plaintiff alleges that the number of potential class members are geographically distributed across the country and the state and are so numerous that joinder would be impracticable.

20. ***Commonality.*** Common questions of law and fact exist as to all members of the

Class and predominate over any questions affecting only individual Class members. Those common questions of fact and law include, but are not limited to, the following: (a) whether Defendant's sold a misbranded drug; (b) whether Defendant's marketing, advertising, and sale of the Product would deceive a reasonable consumer; (c) whether Plaintiff suffered damages caused by Defendant and the measure of those damages; (d) whether Plaintiff is entitled to injunctive relief; and (e) whether Defendant was unjustly enriched.

21. ***Typicality.*** Plaintiff's claims are typical of the claims of all other members of the Class because all such arise from Defendant's false and deceptive marketing, advertising, and sale of a misbranded Product, and Plaintiff is not subject to any unique defenses.

22. ***Adequacy of representation.*** Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff has retained counsel highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action. Plaintiff has no known conflicts of interest with any members of the Class; its interests and claims are not antagonistic to those of any other Class members; nor are its claims subject to any unique defenses.

23. ***Superiority.*** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense that would be involved in individual litigation of their claims. It would, thus, be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single United States District Court, and presents no unusual management difficulties under the circumstances here.

COUNT I

Violation of the Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq*.

24. Plaintiff realleges and incorporates by reference the allegations above as though fully set forth herein.

25. The Consumer Legal Remedies Act ("CLRA") "shall be liberally construed and applied to promote its underlying purposes, which are to protect consumers against unfair and deceptive business practices and to provide efficient and economical procedures to secure such protection." Cal. Civ. Code § 1760.

26. Plaintiff and the other Class members are consumers as defined by Cal. Civ. Code § 1761(d).

27. The Product is a good as defined by Cal. Civ. Code § 1761(a).

28. As alleged herein, Defendant deceptively marketed, advertised, and sold a Product that: (1) is not effective for its promoted use; (2) includes false and deceptive instructions for use on its label; and (3) is a misbranded drug under the FDCA and, thus, is worthless.

29. In doing so, Defendant violated the CLRA by engaging in the following practices proscribed by Cal. Civ. Code § 1770(a) in transactions that were intended to result in, and did result in, the sale of goods to consumers, including Plaintiff and other Class members:

a. Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he or she does not have (§ 1770(a)(5)); and

b. Advertising goods or services with intent not to sell them as advertised (§ 1770(a)(9)).

30. Defendant's deceptive practices would deceive a reasonable consumer.

31. Defendant's deceptive practices relate to material facts.

32. Plaintiff and the Class members purchased Defendant's Product and, thus, suffered damages in that they overpaid to purchase a deceptively advertised and labeled, and unlawful product.

33. Plaintiff and the Class members would not have purchased the Product but for Defendant's deceptive acts and practices alleged herein.

34. Plaintiff provided notice to Defendant pursuant to Cal. Civ. Code § 1782. *See* **Exhibit A**.

35. Pursuant to Cal. Civ. Code § 1780(d), Plaintiff has prepared and attached an affidavit stating facts showing that this action has been commenced in a county described as a proper place for the trial. *See* **Exhibit B**.

36. Pursuant to Cal. Civ. Code § 1782(d), Plaintiff seeks an order enjoining the above described wrongful acts and practices and for restitution and disgorgement. Plaintiff also seeks actual, punitive, and statutory damages, as well as costs and attorneys' fees pursuant to Cal. Civ. Code §§ 1780(e) and 1021.5.

COUNT II

Unjust Enrichment

37. Plaintiff realleges and incorporates by reference the allegations above, except for those in the preceding count, as though fully set forth herein.

38. Plaintiff pleads this claim in the alternative.

39. Plaintiff has conferred a substantial monetary benefit on Defendant, as alleged herein.

40. Defendant knowingly and willingly accepted and retained such monetary benefit from Plaintiff.

41. The circumstances are such that it would be inequitable for Defendant to retain that benefit without paying Plaintiff the value thereof.

42. Without intervention by this Court, Defendant will be unjustly enriched at the expense of, and to the detriment of, Plaintiff.

43. Plaintiff has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff, individually and on behalf of the Class, demands relief and

judgment as follows:

1. For an Order certifying this action as a Class Action and appointing Plaintiff as Class Representative and her counsel as Class Counsel;

2. For an award of compensatory damages for the Class in amounts owed by Defendant;

3. For declaratory and injunctive relief to be entered for Plaintiff and the Class;

4. For all other damages according to proof;

5. For an award of attorney's fees and expenses as appropriate pursuant to applicable law;

6. For costs of suit incurred herein;

7. For pre and post judgment interests on any amounts awarded;

8. For other and further forms of relief as this Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all issues so triable.

Dated: June 11, 2021

Respectfully submitted,

By: */s/ Scott Edelsberg*

Scott Edelsberg
(State Bar No. 330990)
scott@edelsberglaw.com
Christopher Gold
(*pro hac vice* forthcoming)
chris@edelsberglaw.com
EDELSBERG LAW, P.A.
1925 Century Park E #1700
Los Angeles, CA 90067
Telephone: (305) 975-3320
chris@edelsberglaw.com