JS-6

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

REJUVICA LLC, a California limited liability company, also d/b/a Rejuvica Health;

KYLE ARMSTRONG, individually and as an owner, officer, or member of REJUVICA LLC; and

KYLE DILGER, individually and as an owner, officer, or member of REJUVICA LLC,

Defendants.

Case No. 8:23-cv-01286-CJC-JDE

ORDER FOR PERMANENT INJUNCTION, MONETARY RELIEF, AND OTHER RELIEF

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed its Complaint For Permanent Injunction, Monetary Judgment, and Other Relief ("Complaint"), for a permanent injunction, monetary relief, and other relief in this matter, pursuant to Sections 5(a)(1), 12, 13(b), and 19 of the Federal Trade

Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a)(1), 52, 53(b), and 57b, and Section 8023 of the Opioid Addiction Recovery Fraud Prevention Act of 2018, 15 U.S.C. § 45d ("OARFPA"). The Commission and Defendants stipulate to the entry of this Stipulated Order for Permanent Injunction, Monetary Relief, and Other Relief ("Order") to resolve all matters in dispute in this action between them.

THEREFORE, IT IS ORDERED as follows:

FINDINGS

1. This Court has jurisdiction over this matter.

2. The Complaint charges that Defendants participated in deceptive acts or practices in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45, 52, in the advertising, marketing, and sale of Sobrenix, and in the advertising and marketing of other Rejuvica products. The Complaint also charges that the Defendants' deceptive acts or practices in the advertising, marketing, and sale of Sobrenix violated Section 8023 of OARFPA.

3. Defendants neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Order. Only for purposes of this action, Defendants admit the facts necessary to establish jurisdiction.

4. Defendants waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agree to bear their own costs and attorney fees.

5. Defendants and the Commission waive all rights to appeal or otherwise challenge or contest the validity of this Order.

DEFINITIONS

For the purpose of this Order, the following definitions apply:

A. "Covered Product" means any Dietary Supplement, Food, or Drug.

B. "Dietary Supplement" means: (1) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

C. "Drug" means: (1) articles recognized in the official United States Pharmacopeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

D. "Essentially Equivalent Product" means a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients) in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; provided that the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

E. "Food" means: (1) any article used for food or drink for humans or other animals; (2) chewing gum; and (3) any article used for components of any such article.

F. "Defendants" means all of the Individual Defendants and the Corporate Defendant, individually, collectively, or in any combination.

1. "Corporate Defendant" means Rejuvica LLC, also d/b/a Rejuvica Health, and its successors and assigns.

2. "Individual Defendants" means Kyle Armstrong and Kyle Dilger.

ORDER

I. PROHIBITED REPRESENTATIONS: REGARDING HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

IT IS ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product are permanently restrained and enjoined from making, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation that such product or service:

A. Reduces or eliminates cravings for alcohol;

B. Enables users to reduce or eliminate their consumption of alcohol;

C. Assists users to regain control of their problematic drinking;

D. Cures, mitigates, or treats any substance use disorder or symptom of a substance use disorder; or

E. Cures, mitigates, or treats any disease;

unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this

Section, competent and reliable scientific evidence must consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II. PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from making, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation, other than representations covered under the Section of this Order entitled Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered

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