UNITED STATES DISTRICT COURT DISTRICT OF UTAH

UNITED STATES OF AMERICA,

Plaintiff,

v.

LAUREN BUSCH,

Defendant.

Case No. 2:23-cv-00009

STIPULATED ORDER FOR PERMANENT INJUNCTION, CIVIL PENALTY JUDGMENT, AND OTHER RELIEF Plaintiff, the United States of America, acting upon notification and authorization to the Attorney General by the Federal Trade Commission ("FTC" or "Commission") filed its Complaint for Permanent Injunction, Civil Penalties, and Other Relief ("Complaint") in this matter for a permanent injunction, civil penalties, and other relief, pursuant to Sections 5(a)(1), 5(m)(1)(A), 12, 13(b), and 16(a)(1) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a)(1), 45(m)(1)(A), 52, 53(b), and 56(a)(1), and Section 1401 of the COVID-19 Consumer Protection Act of the 2021 Consolidated Appropriations Act ("CCPA"), Pub. L. No. 116-260, § 1401, 134 Stat. 1182, 3275-76 (2020). Defendant has waived service of the summons and the Complaint. Plaintiff and Defendant stipulate to the entry of this Stipulated Order granting the parties' Joint Motion for Permanent Injunction, Civil Penalty Judgment, and Other Relief ("Order") to resolve all matters in dispute in this action between them. (ECF No. 2.)

THEREFORE, IT IS ORDERED as follows:

FINDINGS

- 1. This Court has jurisdiction over this matter.
- 2. The Complaint charges that Defendant engaged in unfair or deceptive acts or practices in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), and disseminated false advertisements in or affecting commerce for the purpose of inducing, or which were likely to induce, the purchase of doTERRA supplements and essential oil products in violation of Section 12 of the FTC Act, 15 U.S.C. § 52.
- 3. Under the CCPA, for the duration of the ongoing novel coronavirus (COVID-19) public health emergency, it is unlawful for any person, partnership, or corporation to engage in a deceptive act or practice in or affecting commerce in violation of Section 5(a) of the FTC Act, 15

U.S.C. § 45(a), that is associated with the treatment, cure, prevention, mitigation, or diagnosis of COVID-19. CCPA § 1401(b)(1).

- 4. A violation of Section 1401(b)(1) of the CCPA is treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under Section 18(a)(1)(B) of the FTC Act, 15 U.S.C. § 57a(a)(1)(B). CCPA § 1401(c)(1).
- 5. Defendant neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Order. Only for purposes of this action, Defendant admits the facts necessary to establish jurisdiction.
- 6. Defendant waives any claim that she 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 agrees to bear her own costs and attorney fees.
- 7. Defendant and Plaintiff 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(s)" means any Food, Drug or Dietary Supplement.
- B. "Defendant" means Lauren Busch.
- C. "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.
- D. "Drug" means: (1) articles recognized in the official United States Pharmacopoeia, 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.
- E. "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.
- F. "Food" means: (1) articles used for food or drink for man or other animals; (2) chewing gum; and (3) articles used for components of any such article.

ORDER

I. BAN AGAINST COVID-19 CLAIMS

IT IS ORDERED that Defendant, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, is permanently restrained and enjoined from making any representation that such product prevents or reduces the likelihood of infection with, or community transmission of, the SARS-CoV-2 virus; reduces the severity or duration of COVID-19; counteracts inflammation or other purported negative effects of COVID-19 vaccines; or otherwise cures or treats COVID-19, unless the Food and Drug Administration has specifically approved the representation.

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

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, or assisting others in making, expressly or by implication, any representation, other than representations covered under the Section of this Order titled Ban Against COVID-19 Claims, that such product 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.

III. PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Defendant, Defendant's 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, any representation, other than representations covered under the Sections of this Order titled Ban Against COVID-19 Claims and Prohibited Representations: Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence 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.

For purposes of this Section, "competent and reliable scientific evidence" means tests, analyses, research, or studies: (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product, or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth 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.

IV. PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study

("test") upon which Defendant relies to substantiate any claim covered by this Order, Defendant

must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

- A. all protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;
- B. all documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;
- C. documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;
- D. all documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and
- E. all documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by:

(1) Defendant; (2) Defendant's agents, representatives, or employees; (3) any other person or entity in active concert or participation with Defendant; (4) any person or entity affiliated with or acting on behalf of Defendant; (5) any supplier of any ingredient contained in the product at

issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Section, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

V. PROHIBITED MISREPRESENTATIONS REGARDING TESTS, STUDIES, OTHER RESEARCH, OR INGREDIENTS

IT IS FURTHER ORDERED that Defendant, Defendant's 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 misrepresenting, in any manner, expressly or by implication:

- A. that the performance or benefits of any Covered Product are scientifically or clinically proven or otherwise established; or
- B. the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

VI. FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Defendant, Defendant's agents, employees, and attorneys, or all other persons in active concert or participation with any of them from:

A. for any Drug product, making a representation that is approved for inclusion in labeling for such Drug product under a new drug application or biologics license application

approved by the Food and Drug Administration, or, for any nonprescription Drug product authorized by Section 505G of the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 355h, to be marketed without an approved new drug application, making a representation that is permitted or required to appear in its labeling in accordance with Section 505G(a)(1)-(3) of the FDCA, 21 U.S.C. § 355h(a)(1)-(3), or a final administrative order under Section 505G(b) of the FDCA, 21 U.S.C. § 355h(b); and

B. for any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VII. MONETARY JUDGMENT FOR CIVIL PENALTY

IT IS FURTHER ORDERED that:

- A. Judgment in the amount of Fifteen Thousand Dollars (\$15,000) is entered in favor of Plaintiff against Defendant, as a civil penalty.
- B. Defendant is ordered to pay to Plaintiff, by making payment to the Treasurer of the United States, Fifteen Thousand Dollars (\$15,000) which, as Defendant stipulates, her undersigned counsel holds in escrow for no purpose other than payment to Plaintiff. Such payment must be made within 7 days of entry of this Order by electronic fund transfer in accordance with instructions previously provided by a representative of Plaintiff.
- C. Defendant relinquishes dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

- D. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission, including in a proceeding to enforce its rights to any payment or monetary judgment pursuant to this Order.
- E. Defendant agrees that the judgment represents a civil penalty owed to the government of the United States, is not compensation for actual pecuniary loss, and, therefore, as to Defendant, it is not subject to discharge under the Bankruptcy Code pursuant to 11 U.S.C. § 523(a)(7).
- F. Defendant acknowledges that her Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendant previously submitted to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

VIII. ORDER ACKNOWLEDGMENTS

IT IS FURTHER ORDERED that Defendant obtain acknowledgments of receipt of this Order:

- A. Defendant, within 7 days of entry of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury;
- B. For 5 years after entry of this Order, Defendant, for any business that Defendant is the majority owner or controls directly or indirectly, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order and all agents and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Section titled

Compliance Reporting. Delivery must occur within 7 days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which Defendant delivered a copy of this Order,

Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this

Order.

IX. COMPLIANCE REPORTING

IT IS FURTHER ORDERED that Defendant make timely submissions to the Commission:

- A. Ninety days after entry of this Order, Defendant must submit a compliance report, sworn under penalty of perjury:
 - 1. Defendant must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission and Plaintiff may use to communicate with Defendant; (b) identify all of Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales; (d) describe in detail whether and how Defendant is in compliance with each Section of this Order; and (e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.
 - 2. Additionally, Defendant must: (a) identify all telephone numbers and all physical, postal, email and Internet addresses, including all residences;

- (b) identify all business activities, including any business for which Defendant performs services whether as an employee or otherwise and any entity in which Defendant has any ownership interest; and (c) describe in detail Defendant's involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.
- B. For 10 years after entry of this Order, Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:
 - 1. Defendant must report any change in: (a) any designated point of contact; or (b) any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.
 - 2. Additionally, Defendant must report any change in: (a) name, including aliases or fictitious name, or residence address; or (b) title or role in any business activity, including any business for which Defendant performs services whether as an employee or otherwise and any entity in which Defendant has any ownership interest, and identify the name, physical address, and any Internet address of the business or entity.
- C. Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against Defendant within 14 days of its filing.

- D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on:" and supplying the date, signatory's full name, title (if applicable), and signature.
- E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: United States v. Lauren Busch.

X. RECORDKEEPING

IT IS FURTHER ORDERED that Defendant must create certain records for 10 years after entry of the Order and retain each such record for 5 years. Specifically, for any business that Defendant is a majority owner or controls directly or indirectly, Defendant must create and retain the following records:

- A. accounting records showing the revenues from all products sold;
- B. personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;
- C. records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

- D. all records necessary to demonstrate full compliance with each Section of this Order, including all submissions to the Commission; and
- E. a copy of each unique advertisement or other marketing material making any representation covered by Sections I, II, III, and V of this Order.

XI. COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendant's compliance with this Order:

- A. Within 14 days of receipt of a written request from a representative of the Plaintiff or the Commission, Defendant must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission and Plaintiff are also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.
- B. For matters concerning this Order, the Commission and Plaintiff are authorized to communicate directly with Defendant. Defendant must permit representatives of the Commission and Plaintiff to interview any employee or other person affiliated with Defendant who has agreed to such an interview. The person interviewed may have counsel present.
- C. The Commission and Plaintiff may use all other lawful means, including posing, through its representatives as consumers, suppliers, or other individuals or entities, to Defendant or any individual or entity affiliated with Defendant, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission or Plaintiff, any consumer reporting agency must furnish consumer reports concerning Defendant, pursuant to Section 604(1) of the Fair Credit Reporting Act, 15 U.S.C. §1681b(a)(1).

XII. RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this stipulated Order.

SO ORDERED this 1st day of March, 2023.

Dustin B. Pead

UNITED STATES/MAGISTRATE JUDGE