2023110

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Joseph J. Simons, Chairman**
Noah Joshua Phillips
Rohit Chopra
Rebecca Kelly Slaughter
Christine S. Wilson

In the Matter of

MARC CHING,
Individually, and also d/b/a
WHOLE LEAF ORGANICS.

DECISION AND ORDER

DOCKET NO. 9394

Findings

1. The Respondent is Marc Ching, doing business as Whole Leaf Organics. His principal office or place of business is at 14900 Magnolia Blvd, #57347, Sherman Oaks, California 91413.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "Covered Product" means Thrive, CBD-EX, CBD-RX, and CBD-Max or any other Drug, Food, or Dietary Supplement.

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 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.

D. "Essentially equivalent product" means a product

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. "Respondent" means Marc Ching, also doing business as Whole Leaf Organics.

Provisions

I. Prohibited Disease Claims

IT IS ORDERED that Respondent, and Respondent'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, or sale of any Covered Product must not make any representation, expressly or by implication, that such product (1) treats, prevents or reduces the risk of COVID-19; (2) treats cancer; or (3) cures, mitigates, or treats any disease in humans, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Provision, "competent and reliable scientific evidence" means 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 (1) be randomized, double-blind, and placebo-controlled; and (2) be 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 relevant field as relevant to an assessment of such testing as described in the Provision titled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Respondent will have the burden of proving that a product satisfies the definition of an Essentially Equivalent Product.

II. Prohibited Health Benefit Claims

IT IS FURTHER ORDERED that Respondent, and Respondent'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, or sale of any Covered Product must not make any representation, other than representations covered under the Provision titled Prohibited Disease Claims, expressly or by implication, about the health benefits, performance, or efficacy of such product, unless the representation is non-misleading, including that, at the time such representation is made, 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 Provision, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) 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 described in the Provision of this Order titled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Respondent will have the burden of proving that a product satisfies the definition of an Essentially Equivalent Product.

III. 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 Respondent relies to substantiate any claim covered by this Order, Respondent 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

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entity in active concert or participation with Respondent; (4) any person or entity affiliated with or acting on behalf of Respondent; (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 Provision, "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.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondent, Respondent must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Respondent's size and complexity, the nature and scope of Respondent's activities, and the sensitivity of the personal information collected from or about the participants.

IV. Prohibited Misrepresentations Regarding Tests, Studies, or Other Research

IT IS FURTHER ORDERED that Respondent, and Respondent'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, or sale of any product must not make any misrepresentation, expressly or by implication:

A. About the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research, including that studies, research, or trials prove that any Covered Product (1) treats, prevents or reduces the risk of COVID-19; or (2) treats cancer; or

B. That any benefit of such product is scientifically or clinically proven or otherwise established.

V. FDA Approved Claims

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

A. For any Drug, making a representation that is approved in labeling for such Drug under any tentative final or final monograph promulgated by the Food and Drug Administration ("FDA"), or under any new Drug application approved by the FDA; and

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

VI. Notices to Customers

IT IS FURTHER ORDERED that Respondent must notify customers as follows:

A. Within 30 days after the effective date of this Order, Respondent must notify all consumers who purchased Thrive, on or after March 1, 2020 through the effective date of this Order, by mailing or emailing each a notice as shown in Attachment A:

1. The heading of the notice and the subject line for any email must read "Important Notice about Thrive Court Settlement," and the email must be sent to each recipient individually from an address with the wholeleaforganics.com domain.

2. The Whole Leaf Organics name and return address, for any mailing, must appear on the front of the envelope, the customer's name and address must be printed on the front of the envelope or be visible through a window in the envelope, and the words "Important Notice about Thrive Court Settlement" must be printed in easily noticed text near the customer's name and address.

3. The notice must not include any other materials or message about Respondent, or otherwise concern his goods or services.

B. Within 30 days after the effective date of this Order, Respondent must notify all consumers who purchased CBD-EX, CBD-RX, or CBD-Max, on or after December 1, 2018 through the effective date of this Order, by mailing or emailing each a notice as shown in Attachment B:

1. The heading of the notice and the subject line for any email must read "Important Notice about Whole Leaf Organics Court Settlement," and the email must be sent to each recipient individually from an address with the wholeleaforganics.com domain.

2. The Whole Leaf Organics name and return address, for any mailing, must appear on the front of the envelope, the customer's name and address must be printed on the front of the envelope or be visible through a window in the envelope, and the words "Important Notice about Whole Leaf Organics Court Settlement" must be printed in easily noticed text near the customer's name and address.

3. The notice must not include any other materials or message about Respondent, or otherwise concern his goods or services.

VII. Notice to Resellers

IT IS FURTHER ORDERED that within 30 days of the effective date of this Order, Respondent must notify all retailers or resellers by sending each by first-class mail, postage paid and return receipt requested, or by courier service with signature proof of delivery, the

notification letter attached as Attachment C. Respondent must include a copy of this Order, but no other document or enclosure.

VIII. Acknowledgments of the Order

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

A. Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 20 years after the issuance date of this Order, Respondent for any business that

E. A copy of each unique advertisement or other marketing material making a representation subject to this Order;

F. For 5 years from the date of the last dissemination of any representation covered by this Order:

1. all materials that were relied upon in making the representation; and

2. all tests, studies, analysis, other research or other such evidence in Respondent's possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations;

G. For 5 years from the date received, copies of all subpoenas and other communications with law enforcement, if such communication relate to Respondent's compliance with this Order; and

H. For 5 years from the date created or received, all records, whether prepared by or on behalf of Respondent, that demonstrate non-compliance or tend to show any lack of compliance by Respondent with this Order.

XI. Compliance Monitoring

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

A. Within 10 days of receipt of a written request from a representative of the Commission, Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with Respondent. Respondent must permit representatives of the Commission to interview anyone affiliated with Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondent or any individual or entity affiliated with Respondent, 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.

XII. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate October 16th, 2040, or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Chopra dissenting, Commissioner Slaughter not participating.

April J. Tabor

ATTACHMENT A: Notice to Thrive Purchasers

Dear Whole Leaf Organics Customer:

We're writing to let you know that some of the things we said in our advertising about Thrive aren't true. Scientific studies have **not** shown that Thrive reduces the risk of, prevents, or treats COVID-19.

Thrive has no known benefit related to the novel coronavirus or the disease it causes, COVID-19. Thrive won't reduce your chances of getting COVID-19. It won't prevent you from getting COVID-19. It won't treat COVID-19 or its symptoms.

If you're sick and think you may have COVID-19, contact your healthcare provider immediately. The same goes for anyone living with you. Learn more about coronavirus (COVID-19) at cdc.gov/coronavirus.

Things that may seem safe – like vitamins and herbal extracts – may interfere with other medicines and cause serious health risks. Before you take any alternative treatment for a disease, talk to your doctor.

ATTACHMENT B: Notice to CBD-EX, CBD-RX, and/or CBD-Max Purchasers

Dear Whole Leaf Organics Customer:

We're writing to let you know that some of the things we said in our advertising about CBD-EX, CBD-RX, and CBD-Max aren't true. Scientific studies have **not** shown that CBD-EX, CBD-RX, and CBD-Max, alone or in combination, treat or prevent cancer.

These products are not effective for treating or preventing cancer. In fact, taking CBD-EX, CBD-RX, or CBD-Max could interfere with effective cancer treatments.

Things that may seem safe – like oil extracts – may interfere with other medicines and cause serious health risks. Before you take any alternative treatment for a disease, talk to your doctor.

ATTACHMENT C

[On Whole Leaf Organics letterhead]

[on envelope]

GOVERNMENT-ORDERED DISCLOSURE

[content of letter, 16-point font]

[Insert Date]

Dear [Recipient]:

We're writing because you may have bought our products Thrive, CBD-EX, CBD-RX, and CBD-Max. The Federal Trade Commission (FTC) sued us for making deceptive health claims in our advertising for these products.

Contrary to our advertising claims, scientific studies have **not** shown that Thrive reduces the risk of, prevents, or treats COVID-19.

Contrary to our advertising claims, scientific studies have **not** shown that CBD-EX, CBD-RX, and CBD-Max, alone or in combination, treat or prevent cancer. These products are not effective for treating or preventing cancer. In fact, taking CBD-EX, CBD-RX, or CBD-Max could interfere with effective cancer treatments.

The enclosed order requires us to:

1) stop claiming that Thrive reduces the risk of, prevents, or treats COVID-19
2) stop claiming that CBD-EX, CBD-RX, and CBD-Max, alone or in combination, treat or prevent cancer
3) tell our customers about the FTC's lawsuit

Learn more about the FTC's lawsuit at [URL].

Sincerely,

[Whole Leaf Organics signatory]

Enclosure [Enclosed Order]