UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Lina M. Khan, Chair

Noah Joshua Phillips Rebecca Kelly Slaughter Christine S. Wilson Alvaro M. Bedoya

In the Matter of

HEALTH RESEARCH LABORATORIES, LLC, a limited liability company,

WHOLE BODY SUPPLEMENTS, LLC, a limited liability company, and

KRAMER DUHON, individually and as an officer of HEALTH RESEARCH LABORATORIES, LLC and WHOLE BODY SUPPLEMENTS, LLC. **DECISION AND ORDER**

DOCKET NO. 9397

DECISION

The Federal Trade Commission ("Commission") issued a Complaint challenging certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") filed the Complaint, which charged the Respondents with violating Sections 5(a) and 12 of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) a statement by Respondents that only for purposes of this action, they admit the facts necessary to establish jurisdiction, and 2) waivers and other provisions as required by the Commission's Rules.

This matter was subsequently withdrawn from adjudication in accordance with Section 3.25 of the Commission's Rules, 16 C.F.R. § 3.25.

The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section

2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 3.25(f), the Commission makes the following Findings and issues the following Order:

FINDINGS

- 1. The Respondents are:
 - a. Respondent Health Research Laboratories, LLC, a Nevada limited liability company with its principal office or place of business at 16250 Knoll Trail Drive, Dallas, TX 75248.
 - b. Respondent Whole Body Supplements, LLC, a Nevada limited liability company with its principal office or place of business at 16250 Knoll Trail Drive, Dallas, TX 75248.
 - c. Respondent Kramer Duhon, an officer and managing member of Health Research Laboratories, LLC, and an officer and managing member of Whole Body Supplements, LLC. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of Health Research Laboratories, LLC and Whole Body Supplements, LLC. His principal office or place of business is the same as that of Health Research Laboratories, LLC and Whole Body Supplements, LLC.
- 2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

- A. "Covered Product" means any Food or Drug.
- B. "Corporate Respondent" means Health Research Laboratories, LLC, and Whole Body Supplements, LLC.
- 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: (a) 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; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and (d) articles intended for use as a component of any article specified in (a), (b), or (c); 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., inactive 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 are unlikely to impede or inhibit the effectiveness of the ingredients in the essentially equivalent product.
- F. "Food" means: (a) any article used for food or drink for humans or other animals; (b) chewing gum; and (c) any article used for components of any such article.
- G. "Individual Respondent" means Kramer Duhon.
- H. "Negative Option Feature" means, in an offer or agreement to sell any good of service, a provision under which the consumer's silence or failure to take affirmative action to reject a good or service or to cancel the agreement is interpreted by the seller or provider as acceptance or continuing acceptance of the offer.
- I. "Respondents" means Health Research Laboratories, LLC, Whole Body Supplements, LLC, and Kramer Duhon, individually, collectively, or in any combination.

Provisions

I.

IT IS ORDERED that Respondents must not advertise, market, promote, or offer for sale any Dietary Supplement or assist others in the advertising, marketing, promoting, or offering for sale of any Dietary Supplement.

II.

IT IS FURTHER ORDERED that Respondents, whether acting directly or indirectly, in connection with the advertising, marketing, promoting, or offering for sale of any product, must

not make any representation, expressly or by implication, that a product cures, treats, mitigates, prevents, or reduces the risk of any disease.

III.

IT IS FURTHER ORDERED that subject to the prohibitions in Parts I and II of this Order, Respondents, Respondents' officers, agents, and employees, 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, must not make any representation expressly or by implication, about the health benefits, safety, performance, or efficacy 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 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 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 Part V of this Order must be available for inspection and production to the Commission. Respondents have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

IV.

IT IS FURTHER ORDERED that subject to the prohibitions in Parts I and II of this Order, Respondents, Respondents' officers, agents, employees, 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 advertising, marketing, promoting, offering for sale, sale, or distribution of any Covered Product must not make any misrepresentations expressly or by implication:

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

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim not banned by Parts I or II, but covered by Part III, Respondents 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) any Respondent; (2) any Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Respondent; (4) any person or entity affiliated with or acting on behalf of any 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 Respondents, Respondents 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 Corporate Respondents' size and complexity, the nature and

scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

VI.

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

- A. Respondents must identify all consumers who purchased Black Garlic Botanicals, BG18, The Ultimate Heart Formula, and Neupathic on or after January 17, 2018 ("Eligible Customers").
 - 1. Such Eligible Customers, and their contact information, must be identified to the extent such information is in Respondents' possession, custody or control;
 - 2. Eligible Customers include those identified at any time through the eligibility period, which runs for 1 year after the issuance date of the Order.
- B. Respondents must mail all Eligible Customers the letter in the form shown in Attachment A. Each such mailing must comply with the following:
 - 1. The envelope containing the letter must be in the form shown in Attachment B.
 - 2. The mailing of the notification letter must not include any other enclosures other than a copy of this Order.
 - 3. The mailing must be sent by first-class mail, postage prepaid, address correction service requested with forwarding and return postage guaranteed. For any mailings returned as undeliverable, Respondents must use standard address search methodologies such as re-checking Respondents' records and the Postal Service's National Change of Address database and re-mailing to the corrected address within 8 days.
 - 4. Each such notice must be mailed within 120 days after the effective date of this Order.
- C. Respondents must report on their notification program under penalty of perjury as follows:
 - 1. Respondents must submit a report at the conclusion of the program, but in no event later than 180 days after the effective date of this Order, detailing its compliance with this Provision.
 - 2. If a representative of the Commission requests any information regarding the program, including any of the underlying customer data, Respondents must submit the requested information within 10 days of the request.

3. Failure to provide required notices or any requested information will be treated as a continuing failure to obey this Order.

VII.

IT IS FURTHER ORDERED that Respondents and their 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, must not disclose, use, or receive any benefit from customer information including the name, address, telephone number, e-mail address, social security number, or other identifying information or any data that enables access to a customer's account (including a credit card, bank account or other financial account) that any Respondent obtained prior to the issuance of this Order in connection with sales of Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic. Respondents must also preserve such identifying information together with records of the product(s) individual customers purchased and the date and amount of payments made to Respondents until receipt of written notice from Commission staff to destroy the information. Once Commission staff notify Respondents to destroy such customer information, Respondents will have five days to comply.

Provided, however, that Respondents may disclose such customer information to the FTC or any law enforcement agency, or as required by any law, regulation, or court order.

VIII.

IT IS FURTHER ORDERED that, consistent with Part VII, Respondents must immediately cancel any subscription plan with a Negative Option Feature related to Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic.

IX.

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

- A. Each 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, the Individual Respondent, for any business that such Respondent, individually or collectively with any other Respondent, is the majority owner or controls directly or indirectly, and each Corporate Respondent, 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 the manufacturing, labeling, advertising, marketing, distribution, or sale of any Covered Product, and all agents and representatives who participate in manufacturing, labeling, advertising, marketing, distribution, or sale of any Covered Product; and (3) any business entity resulting from any change in structure as set forth in Part X. Delivery must occur within 10 days after the effective date 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 a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

X.

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

- A. One year after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:
 - 1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Respondent; (b) identify all of that Respondent'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, and the involvement of any other Respondent (which Individual Respondent must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Part of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.
 - 2. Additionally, the Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email, and Internet addresses, including all residences; (b) identify all his business activities, including any business for which such Respondent performs services whether as an employee or otherwise and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.
- B. Each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:
 - 1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of any Corporate Respondent or any entity that Respondent 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, the Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in

any business activity, including (i) any business for which such Respondent performs services whether as an employee or otherwise and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.

- C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent 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: In re Health Research Laboratories, Dkt. 9397.

XI.

IT IS FURTHER ORDERED that Respondents must create certain records for 20 years after the issuance date of the Order, and retain each such record for 5 years, unless otherwise specified below. Specifically, the Corporate Respondents and Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is a majority owner or controls directly or indirectly, must create and retain the following records:

- A. Accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;
- B. Personnel records showing, for each person providing services in relation to any aspect of the Order, 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. Copies or 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 Provision of this Order, including all submissions to the Commission; and

- 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 Respondents' 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 created or received, all records, whether prepared by or on behalf of Respondents, that tend to show any lack of compliance by Respondents with this Order.

XII.

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

- A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce documents for inspection and copying. Respondents will answer interrogatories and sit for investigational hearings within 30 days of a written request from Commission staff.
- B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any 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 Respondents or any individual or entity affiliated with Respondents, 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.

XIII.

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (www.ftc.gov) as a final order. This Order will terminate on June 24, 2042, 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 any 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.

April J. Tabor Secretary

SEAL:

ISSUED: June 24, 2022

ATTACHMENT A

[To be printed on Health Research Laboratories, LLC or Whole Body Supplements, LLC letterhead and sent via First Class mail]

[Date]

Subject: [Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic]

[Name of customer] [Mailing address of customer Including zip code]

Dear [Name of customer]:

Our records show that you bought [Black Garlic Botanicals, The Ultimate Heart Formula, or Neupathic from Health Research Laboratories] [BG18 from Whole Body Supplements].

The Federal Trade Commission sued us for making misleading claims our products would prevent, reduce the risk of, treat or cure serious diseases and health conditions such as cardiovascular disease, high blood pressure, and diabetic nerve pain without having scientific evidence to support those claims.

The enclosed FTC order requires us to stop selling dietary supplements and claiming that our products cure, treat, mitigate, prevent, or reduce the risk of any disease.

Some products, like vitamins and herbal extracts, may interfere with other treatments recommended by your doctor and cause serious health risks. Before you take any alternative treatment for a disease, talk to your doctor.

Learn more about the lawsuit against Health Research Laboratories and Whole Body Supplements at https://www.ftc.gov/news-events/press-releases/2020/11/ftc-approves-administrative-complaint-against-supplement-marketer.

Sincerely,

Kramer Duhon Health Research Laboratories, LLC Whole Body Supplements, LLC

Enclosure [Enclosed Order]

ATTACHMENT B

The envelope for the notification letter must be in the following form, with the underlined text completed as directed:

[HEALTH RESEARCH LABORATORIES, LLC OR WHOLE BODY SUPPLEMENTS, LLC Street Address City, State and Zip Code]

FORWARDING AND RETURN POSTAGE GUARANTEED ADDRESS CORRECTION SERVICE REQUESTED

[name and mailing address of customer, including zip code]

ABOUT YOUR PURCHASE OF [BLACK GARLIC BOTANICALS/BG18/THE ULTIMATE HEART FORMULA, OR NEUPATHIC]