PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF THE ADMINISTRATIVE LAW JUDGES

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**	**DOCKET NO. 9397**

RESPONDENTS' RESPONSE TO CROSS MOTION TO AMEND COMPLAINT

Complaint Counsel's Cross Motion to Amend Complaint should be denied because it is unauthorized and unnecessary and because it seeks to inject issues into this case that are beyond a Part 3 Administrative Proceeding.

I. SUMMARY

Rather than continue a fight that has been ongoing for more than six years, Respondents elected to admit all material facts–an action expressly permitted by 16 C.F.R. § 3.12. Remarkably, Complaint Counsel opposes Respondents' efforts to admit the material facts alleged *in the FTC's Complaint*. To prolong any resolution of this case, Complaint Counsel now seeks to amend the Part 3 Administrative Complaint to allege, among other things, that Respondents violated the Maine Consent Order—an issue that is

exclusively within the jurisdiction of the federal court that issued the Consent Order. For the reasons set forth below, the Cross Motion to Amend the Complaint should be denied.

II. BACKGROUND FACTS

On February 12, 2021, Respondents filed a motion for leave to amend the complaint pursuant to Rule 3.12(b)(2). Rule 3.12(b)(2) provides as follows:

> (2) **If allegations of complaint are admitted.** **If the respondent elects** not to contest **the allegations of fact** set forth in the complaint, the answer shall **consist of a statement that the respondent admits all of the material allegations to be true**. **Such an answer** shall constitute a waiver of hearings as to the facts alleged in the complaint, and together with the complaint will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such an answer, the respondent may, however, reserve the right to submit proposed findings of fact and conclusions of law under § 3.46.

16 C.F.R. § 3.12 (emphasis added). Respondents cited Rule 3.12(b)(2) and tracked the language of the rule in Respondents' proposed Answer. Respondents' proposed Answer includes the "statement" referenced in Rule 3.12(b) that Respondents "admit all of the material allegations to be true." In an effort to nullify Respondents' election under 16 C.F.R. § 3.12 and start this case from square one, Complaint Counsel requests permission to amend the Complaint to add the following new facts and theories:

> 4. The FTC and Respondents HRL and Kramer Duhon signed a Stipulated Final Judgment and Order ("Order") entered by U.S. District Judge Jon D. Levy on January 16, 2018 in *FTC and State of Maine v. Health Research Laboratories, et al.*, 2:17-cv-00467 (Dkt. 15). Section III of the Order prohibits Respondents from making "any representation about the health benefits, safety, performance, or efficacy" of a dietary supplement, food, or drug "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." Section III further provides that "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."

6. Respondents' advertisements for Black Garlic Botanicals, BG18, The Ultimate Heart Formula, and Neupathic included representations that the products would effectively prevent, reduce the risk of, cure, treat, or mitigate cardiovascular disease, atherosclerosis, hypertension, or diabetic neuropathy without adequate substantiation to support the representations.

8. HRL began selling Black Garlic Botanicals in November 2016 and continued to sell it following entry of the Order and after the filing of a contempt motion against Respondents in *FTC and State of Maine v. Health Research Laboratories, LLC, et al.*, 2:17-cv-00467-JDL. HRL continued to sell the product to consumers through at least January 2021, despite the filing of the contempt motion and the Complaint in this administrative proceeding.

9. …HRL also sold the product to consumers in other quantities and at different prices.

12. WBS began selling BG18 in August 2017 *and continued to sell it after entry of the Order and after the filing of a contempt motion against Respondents in FTC and State of Maine v. Health Research Laboratories, LLC, et al., 2:17-cv-00467-JDL in December 2019*. [1]

14. …Following entry of the Order, WBS disseminated or caused to be disseminated more than 400,000 mailers to consumer residences in the United States and Canada. WBS continued to disseminate these mailers as late as June 2019 despite Respondents' awareness that the FTC was investigating whether advertising for BG18 violated the Order.

[1] The italicized part of paragraph 12 includes the new allegations.

16. HRL began selling The Ultimate Heart Formula ("UHF") in November 2008 and continued to sell it following entry of the Order and after the filing of a contempt motion against Respondents in *FTC and State of Maine v. Health Research Laboratories, LLC, et al.*, 2:17-cv-00467-JDL. HRL continued to sell the product to consumers through at least January 2021, despite the filing of the contempt motion and the Complaint in this administrative proceeding.

17. UHF contains Vitamins C, E, and B12 as well as garlic extract (25 mg), Tetrasodium EDTA (40 mg), Ubiquinol (CoEnzyme Q-10) (5 mg), and Nattokinase (10 mg). *The recommended dosage is 20 drops or 1ml, twice per day.* HRL sold a one-month's supply of UHF for $39.95, plus shipping and handling. *HRL also sold the product to consumers in other quantities and at different prices.*

18. HRL disseminated or caused to be disseminated advertisements for UHF, including multipage mailers and company websites. *Following entry of the Order, HRL disseminated or caused to be disseminated more than 200,000 mailers to consumer residences in the United States and Canada.*

20. …HRL continued to sell the product following entry of the Order and after the filing of a contempt motion against Respondents in *FTC and State of Maine v. Health Research Laboratories, LLC, et al.*, 2:17-cv-00467-JDL…. The recommended dosage is two capsules per day. … HRL also sold the product to consumers in other quantities and at different prices.

21. …Following entry of the Order, HRL disseminated or caused to be disseminated more than 400,000 mailers to consumer residences in the United States and Canada. HRL continued to disseminate these mailers as late as June 2019 despite Respondents' awareness that the FTC was investigating whether their advertising for Neupathic violated the Order

23. Respondents did not have competent and reliable scientific evidence to support the representations in their advertisements. Further, they relied in part on advice from consultants and/or advisors who did not have appropriate qualifications or expertise to evaluate substantiation for the representations.

In the Declaration of Jonathan Cohen attached to the Cross Motion to Amend, Jonathan Cohen states the following:

> The allegations in the proposed Amended Complaint derive substantially from limited information that Respondents have disclosed within the past month.

Respondents have no idea why Complaint Counsel would make this statement. It is not true. First, Complaint Counsel Elizabeth J. Averill was involved in all of the proceedings in *FTC and State of Maine v. Health Research Laboratories, LLC, et al.*, 2:17-cv-00467-JDL so none of those allegations were "disclosed within the past month." Second, as Elizabeth J. Averill swore in her February 19, 2021 Declaration, the majority of documents produced by Respondents in this case "had been produced to the FTC as part of the contempt investigation related to *FTC and State of Main v. Health Research Laboratories, LLC, et al.*, Case No. 2:17-cv-00467-JDL (D. Me.)." *See* Ex. D (Declaration of Elizabeth J. Averill), p. 3. Despite the statement from Complaint Counsel, the allegations in the proposed Amended Complaint are not "derive[d] substantially" from information disclosed within the past month.

III. ARGUMENT

A. Affirmative defenses do not justify an amendment.

Complaint Counsel contends that two specific affirmative defenses, that the action is not in the public interest and mootness, raise issues of material facts that justify amending the Complaint. In particular, Complaint Counsel argues:

> Regardless of how the ALJ resolves Respondents' pending motion, the parties will litigate **the public interest at stake, alleged mootness**, and the scope of relief—including facts that support the broad relief Complaint Counsel seeks. Accordingly, Complaint Counsel seeks leave to file an Amended Complaint, which adds factual allegations related to these issues.

Cross-Motion to Amend, p. 7. (emphasis added). The defenses of mootness and lack of a public interest were asserted in the Original Answer and have been on file for almost three months. Complaint Counsel does not explain why these affirmative defenses now require an amendment to the Complaint or how any of the new facts relate to these affirmative defenses.

The three issues raised by Complaint Counsel (i.e., lack of public interest, mootness, and scope of relief) do not justify the proposed amendments. The scope of relief provided by the FTC Act is a pure question of law, not a factual issue that needs to be alleged. *See United States v. Williams*, 733 F.3d 448, 452 (2d Cir. 2013) ("Interpretations of statutes are pure questions of law, and we therefore review [them] de novo...."); *see also In re Zale Corp.*, 77 F.T.C. 1635, 1970 WL 117293 (June 17, 1970) (noting that the scope of the remedy is not governed by the allegations in the complaint).

With regard to the affirmative defenses of mootness and lack of public interest, Respondents waived these two affirmative defenses. *See* Ex. C (Waiver filed on February 25, 2021). To the extent there is any confusion regarding this waiver, Respondents again affirm that the affirmative defense of mootness and lack of public interest are hereby waived and will not be asserted in the Amended Answer.

In summary, there are no outstanding factual issues that justify the proposed amendments.

B. A motion for discovery is not before the Court.

Complaint Counsel includes one paragraph requesting that the Court "should permit discovery to continue concerning all remaining issues." The scope and extent of any future discovery is not before the Court. The current issue before the Court is whether to allow Respondents to elect to not contest the allegations in the [Original] Complaint and whether to allow Complaint Counsel to add new facts and theories through a proposed Amended Complaint. Respondents request the opportunity to address any issues regarding discovery if and when those issues are properly before the Court.

C. The proposed amendments are not "appropriate" amendments.

"In contrast to Federal Rule 15, FTC Rule 3.15(a), which requires that leave to amend be freely granted, FTC Rule 3.15(a) provides that 'appropriate' amendments 'may' be allowed, upon such conditions as will avoid prejudice to the parties and the public interest, if the amendments will facilitate a determination on the merits." *In re Matter of Daniel Chapter One*, Dkt. No. 9329, 2009 WL 871702 (Mar. 9, 2009) (citing 16 C.F.R § 3.15(a)(1). 16 C.F.R. § 3.15(a)(1) provides:

> (a) *Amendments*—(1) By leave. If and whenever determination of a controversy on the merits will be facilitated thereby, the Administrative Law Judge may, upon such conditions as are necessary to avoid prejudicing the public interest and the rights of the parties, allow appropriate amendments to pleadings or notice of hearing: **Provided, however, That a motion for amendment of a complaint or notice may be allowed by the Administrative Law Judge only if the amendment is reasonably within the scope of the original complaint or notice.** Motions for other amendments of complaints or notices shall be certified to the Commission.

16 C.F.R. § 3.15(a) (emphasis added). Complaint Counsel does not explain how the amendment is "necessary" to avoid "prejudicing the public interest" or to avoid prejudicing "rights of the parties." More importantly, Complaint Counsel does not explain how the proposed amendments will "facilitate a determination on the merits." In other words, how will the new allegations "facilitate" a determination on the merits? What determination, if any, will be made based on these new facts and legal theories? These critical questions are not addressed in Complaint Counsel's motion to amend.

D. The proposed amendments are futile and will hinder, not facilitate, a determination on the merits.

Rule 3.15(a) requires that the proposed amendment "facilitate a determination on the merits." However, even under the federal rules' liberal amendment policy, the federal courts exercise discretion to deny leave to amend where an amendment would be futile. *See In re Matter of Daniel Chapter One*, Dkt. No. 9329, 2009 WL 871702 (Mar. 9, 2009) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). In this case, the proposed amendments will not facilitate a determination on the merits, but would be futile and, therefore, should be denied. *See In the Matter of LabMD, Inc.*, Dkt. 9357, 2015 WL 5453096 (July 24, 2015) (noting that the court should deny proposed amendments that are futile); *See Great Western Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 174 (3d Cir. 2010) ("futility of amendment is a sufficient basis to deny leave to amend")(quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

Pursuant to Rule 3.12(b)(2), Respondents have admitted all material facts in the Complaint. The amendment is futile because none of the new facts are necessary to

obtain a cease-and-desist order—which is the *only* relief that can be awarded in a Part III Administrative Action. This Court should be guided by what facts are necessary to award the relief provided by Sections 5 and 12 of the FTC Act. Permitting the FTC to inject unnecessary facts into this proceeding—so the FTC can attempt to use those facts in other proceedings—is an abuse of the FTC Act. Finally, by injecting unnecessary and inflammatory facts, Complaint Counsel hinders or delays a determination on the merits by making it impossible for Respondents to "elect" not to contest the material facts. Forcing a private citizen to continue a fight against the government even when the citizen seeks to admit all material facts in the Complaint is an abuse of process.

E. The ALJ lacks authority to permit the amended complaint.

"ALJ lacks authority to permit modifications where the effect is an alteration of the underlying theory behind the complaint." *In the Matter of Century 21 Commodore Plaza, Inc.*, 89 F.T.C. 238, 1977 WL 188998 (Apr. 20, 1977). Complaint Counsel's original theory was that Respondents violated Section 5 and 12 of the FTC Act by making representations that "were not substantiated at the time the representations were made." *See* Complaint, p. 11 and 12. Complaint Counsel's new theory is that Respondents knowingly violated a Court Order (a finding that the federal court rejected), and that this conduct was allegedly done based on reliance from unqualified "consultants and/or advisors."

The new facts are reasonably within the scope of the Original Complaint. In fact, Complaint Counsel admits that the amendment seeks to expand the scope of relief.[2] Alleging new facts and theories and seeking an expanded scope of relief are clearly matters that must be approved by the Commission. Allowing this case to proceed under a new Complaint that has not been authorized by the Commission will only lead to other legal challenges later.

F. Statements about the Maine Consent Order are improper.

Most of the new allegations relate to Consent Judgment in *FTC and State of Maine v. Health Research Laboratories, et al.*, 2:17-cv-00467. The ALJ should not re-litigate or interpret the Consent Judgment, especially after the federal judge that signed the Consent Judgment has already interpreted it within the last six months. Furthermore, at the request of the FTC, Judge Levy retained jurisdiction "for the purposes of construction, modification, and enforcement of this Order." *See* Ex. B, p. 31 (Consent Judgment). Complaint Counsel cites no statute, law, or regulation that grants the ALJ or the Commission the authority to construe or interpret the Consent Judgment, and there is no reason to make the Consent Judgment a part of the FTC's claims against Respondents. Furthermore, had Respondents known that the Consent Judgment could be interpreted by the Commission and the ALJ—rather than a federal district judge—Respondents would have never agreed to the entry of the Consent Judgment.

[2] In footnote 3, Complaint Counsel states that the amendment "adds facts related to the scope of relief" and that Complaint Counsel seeks to ban Respondents from the supplements industry.

G. Amendment is prejudicial.

The FTC issued its Part III Administrative Complaint on November 13, 2020. Because the Complaint sought a cease-and-desist order for acts or practices that had ceased more than a year prior to the Complaint, Respondents relied on the allegations in the Complaint to not conduct any discovery. *See* Ex. A (Declaration of Joel W. Reese); *see also* Respondents' Answer, p. 2. Respondents have prepared their case based on the pleadings that were on file from the beginning of the case, not a new complaint filed on the eve of trial. *See id.* In other words, if the FTC was seeking a cease-and-desist order regarding acts or practices that had already ceased long before the administrative complaint was filed and the only available relief is a cease-and-desist order, then there was no reason to incur the cost and expense of hiring experts and conducting discovery to fight an irrelevant cease-and-desist order. Furthermore, pursuant to the Court's Scheduling Order and based on the allegations on file at the time, Respondents identified fact witnesses on January 29, 2021 and elected not to designate expert witnesses on February 26, 2021. *See id.*

In summary, changing the material facts, theories, and allegations in a case that is set for trial on a very tight schedule is prejudicial and should not be permitted.

CONCLUSION

For the reasons set forth herein, the ALJ should deny Complaint Counsel's Cross Motion to Amend the Complaint.

PUBLIC

Dated: February 26, 2021

Respectfully submitted,

REESE MARKETOS LLP

By: */s/ Joel W. Reese*

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ATTORNEYS FOR RESPONDENTS

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CERTIFICATE OF SERVICE

I hereby certify that on February 26, 2021, I filed the foregoing document electronically using the FTC's E-Filing system, which will send notification to:

April J. Tabor
Acting Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580
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The Honorable D. Michael Chappell
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COMPLAINT COUNSEL

/s/ Joel W. Reese
Joel W. Reese

EXHIBIT A

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF THE ADMINISTRATIVE LAW JUDGES

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	DOCKET NO. 9397

DECLARATION OF JOEL W. REESE

I, Joel W. Reese, hereby declare:

1. My name is Joel W. Reese. I am counsel for the Respondents, Health Research Laboratories, LLC, Whole Body Supplements, LLC and Kramer Duhon. I make this declaration based on personal knowledge of the facts set forth herein.

2. In the Declaration of Jonathan Cohen attached to the Cross Motion to Amend, Jonathan Cohen states:

> The allegations in the proposed Amended Complaint derive substantially from limited information that Respondents have disclosed within the past month.

3. I am familiar with all information disclosed by Respondents. I am also familiar with the allegations in the proposed Amended Complaint. After carefully reviewing the new allegations in the proposed Amended Complaint and the information that has been disclosed by Respondents, I am not aware of "[t]he allegations in the

proposed Amended Complaint" that would "derive substantially" from information Respondents have "disclosed within the past month."

4. The Commission filed this Administrative Complaint alleging that Respondents have "disseminated or [have] caused to be disseminated advertising and promotional materials"[1] for four supplements that the Commission contends were "not substantiated at the time the representations were made."[2] Respondents relied on the allegations in the Complaint to not conduct any discovery. Respondents have prepared their case based on the pleadings that were on file from the beginning of the case. In other words, if the FTC was seeking a cease-and-desist order regarding acts or practices that had already ceased long before the administrative complaint was filed and the only available relief is a cease-and-desist order, then there was no reason to incur the cost and expense of hiring experts and conducting discovery to fight an irrelevant cease-and-desist order.

5. Pursuant to the Court's Scheduling Order and based on the allegations in the Complaint, Respondents identified fact witnesses on January 29, 2021 and elected not to designate expert witnesses on February 26, 2021. Changing the allegations or the scope of relief could affect Respondents' decisions on fact witnesses or expert witnesses, depending on what new allegations and scope of relief are permitted.

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[1] *See* Complaint, ¶¶ 7, 9, 11 and 13.

[2] *See* Complaint, ¶¶ 15, 17, 19, and 21.

Pursuant to 28 U.S. C. § 1746, I declare under penalty of perjury that the foregoing is true and correct based on my personal knowledge.

JOEL W. REESE

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EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

FEDERAL TRADE COMMISSION and STATE OF MAINE, Plaintiffs, v. HEALTH RESEARCH LABORATORIES, LLC, a limited liability company, and KRAMER DUHON, individually and as an owner and officer of HEALTH RESEARCH LABORATORIES, LLC, Defendants.	Case No. 2:17-cv-00467-JDL **STIPULATED FINAL JUDGMENT AND ORDER FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF**

Plaintiffs, the Federal Trade Commission ("FTC" or "Commission") and the State of Maine, as represented in this matter by the Office of the Attorney General of Maine ("Maine AG") (collectively, "Plaintiffs"), filed a Complaint for Permanent Injunction and Other Equitable Relief against Defendants pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), pursuant to Section 4(a) of the Telemarketing and Consumer Fraud and Abuse Prevention Act ("Telemarketing Act"), 15 U.S.C. § 6103(a), and pursuant to Section 209 of the Maine Unfair Trade Practices Act ("Maine UTPA"), 5 M.R.S.A. § 209, to obtain permanent injunctive relief, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for Defendants' acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, the Telemarketing Act, 15 U.S.C. §§ 6101-6108, the FTC's Trade Regulation Rule entitled "Telemarketing Sales Rule" ("TSR"), 16 C.F.R. Part 310, the Electronic Fund Transfer Act

("EFTA"), 15 U.S.C. §§ 1693-1693r, and its implementing Regulation E, 12 C.F.R. § 1005.10, and Section 207 of the Maine UTPA, 5 M.R.S.A. § 207, in connection with the labeling, advertising, marketing, distribution, and sale of products purported to cause weight loss, treat arthritis and relieve joint and back pain, and prevent or mitigate cognitive decline.

The Commission, the State of Maine, and Defendants Health Research Laboratories, LLC and Kramer Duhon (hereafter collectively, "Defendants"), stipulate to the entry of this Final Judgment and Order for Permanent Injunction and Other Equitable Relief to resolve all matters in dispute in this action between them, including the allegations in the Complaint.

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(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, the Telemarketing Act, 15 U.S.C. §§ 6101-6108, the TSR, 16 C.F.R. Part 310, the EFTA, 15 U.S.C. §§ 1693-1693r, and its implementing Regulation E, 12 C.F.R. § 1005.10, and Section 207 of the Maine UTPA, 5 M.R.S.A. § 207, in connection with the labeling, advertising, marketing, distribution, and sale of products purported to cause weight loss, treat arthritis and relieve joint and back pain, and prevent or mitigate cognitive decline.

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

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. The parties agree to bear their own costs and attorney fees.

5. Defendants and Plaintiffs 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:

1. "**Charge**" or "**Charged**" means any attempt to collect money or other consideration from a consumer, including but not limited to causing billing information to be submitted for payment, including against the consumer's credit card, debit card, bank account, telephone bill, or other account.

2. "**Clear(ly) and Conspicuous(ly)**" means that a required disclosure is difficult to miss (*i.e.*, easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:

A. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure is made in only one means;

B. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood;

C. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it;

D. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable;

E. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears;

F. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications;

G. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication; and

H. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, "ordinary consumers" includes reasonable members of that group.

3. "**Close Proximity**" means that the disclosure is very near the triggering representation. For example, a disclosure made through a hyperlink, pop-up, interstitial, or other similar technique is not in close proximity to the triggering representation.

4. "**Corporate Defendant**" means Health Research Laboratories, LLC, and its successors and assigns.

5. "**Covered Product**" means any Dietary Supplement, Food, or Drug, including BioTherapex and NeuroPlus.

6. "**Defendants**" means the Individual Defendant and the Corporate Defendant, individually, collectively, or in any combination.

7. "**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.

8. "**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.

9. "**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.

10. "**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.

11. "**Including**" means including but not limited to.

12. "**Individual Defendant**" means Kramer Duhon.

13. "**Negative Option Feature**" means, in an offer or agreement to sell or provide any good, program, or service, a provision under which the consumer's silence or failure to take an affirmative action to reject a good, program, or service, or to cancel the agreement, is interpreted by the seller or provider as acceptance or continuing acceptance of the offer.

14. "**Person**" means a natural person, an organization, or other legal entity, including a corporation, partnership, sole proprietorship, limited liability company, association, cooperative, or any other group or combination acting as an entity.

15. "**Preauthorized Electronic Fund Transfer**" as defined by the Electronic Fund Transfer Act, 15 U.S.C. § 1693a(10), means an electronic fund transfer authorized in advance to recur at substantially regular intervals.

I.

BANNED WEIGHT-LOSS CLAIMS

IT IS HEREBY ORDERED that Defendants, Defendants' 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 the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Dietary Supplement, over-the-counter Drug, patch, cream, wrap, or other product worn on the body or rubbed into the skin, are permanently restrained and enjoined from representing, or assisting others in representing, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product:

A. Causes weight loss of two pounds or more a week for a month or more without dieting or exercise;

B. Causes substantial weight loss no matter what or how much the consumer eats;

C. Causes permanent weight loss;

D. Blocks the absorption of fat or calories to enable consumers to lose substantial weight;

E. Safely enables consumers to lose more than three pounds per week for more than four weeks;

F. Causes substantial weight loss for all users; or

G. Causes substantial weight loss by wearing a product on the body or rubbing it into the skin.

II.

PROHIBITED REPRESENTATIONS: OTHER WEIGHT-LOSS CLAIMS, JOINT-RELATED DISEASE CLAIMS, AND ALZHEIMER'S DISEASE, MEMORY, AND COGNITIVE PERFORMANCE CLAIMS

IT IS FURTHER ORDERED that Defendants, Defendants' 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 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, including through the use of a product name, endorsement, depiction, or illustration, any representation, other than representations covered under the Section of this Order entitled Banned Weight-Loss Claims, that, in humans, such product:

A. Causes or assists in causing weight loss, including any specific amount of weight loss;

B. Causes or assists in causing fat loss, including any specific amount of fat loss;

C. Treats or cures rheumatism, arthritis, or osteoarthritis;

D. Relieves joint pain, back pain, or muscle pain;

E. Protects the brain against Alzheimer's disease or dementia;

F. Reverses memory loss;

G. Improves memory, concentration, or cognitive performance; or

H. 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 shall 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 Plaintiffs. 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 Defendants, Defendants' 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, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation about the health benefits, safety, performance, or efficacy of any Covered Product, other than representations covered under the Sections of this Order entitled Banned Weight-Loss Claims and Prohibited Representations: Other Weight-Loss Claims, Joint-Related Disease Claims, and Alzheimer's Disease, Memory, and Cognitive Performance Claims, 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 Plaintiffs. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

IV.

PROHIBITED REPRESENTATIONS REGARDING TESTS, STUDIES, OR OTHER RESEARCH

IT IS FURTHER ORDERED that Defendants, Defendants' 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 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, including through the use of any product name, endorsement, depiction, or illustration:

A. That any Covered Product is scientifically proven to protect the brain against Alzheimer's disease or dementia, reverse memory loss, or improve memory, concentration, or cognitive performance;

B. That the performance or benefits of any Covered Product are scientifically or clinically proven or otherwise established; or

C. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

V.

FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Defendants, Defendants' officers, agents, employees, 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, or under any new drug application approved by the Food and Drug Administration; 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.

VI.

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 Defendants rely to substantiate any claim covered by this Order, Defendants shall 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 Defendant; (2) any Defendant's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Defendant; (4) any person or entity affiliated with or acting on behalf of any 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.

For any test conducted, controlled, or sponsored, in whole or in part, by Defendants, Defendants 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 Defendant's size and complexity, the nature and scope of Defendants' activities, and the sensitivity of the personal information collected from or about the participants.

VII.

PROHIBITED REPRESENTATIONS RELATED TO ENDORSEMENTS

IT IS FURTHER ORDERED that Defendants, Defendants' 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 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, including through the use of any good or service name, endorsement, depiction, or illustration, that:

A. Any person is an expert with respect to the endorsement message provided by that person;

B. Purported consumers who appear in advertising obtained a reported result through use of those goods or services; and

C. Experts are providing their objective, independent opinions regarding the efficacy of any good or service.

VIII.

OTHER PROHIBITED MISREPRESENTATIONS

IT IS FURTHER ORDERED that Defendants, Defendants' 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 the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, are permanently restrained and enjoined from misrepresenting, or assisting others in misrepresenting, expressly or by implication:

A. That consumers are receiving a money-back guarantee, a free trial offer, a risk-free trial offer, a free gift, or a bonus;

B. The total cost to purchase, receive, or use the good or service, including shipping, handling, processing, and any additional financial obligations that may be incurred as a result of accepting the free product, service, or offer;

C. The timing or manner of any Charge or bill;

D. Any material restrictions, limitations, or conditions to purchase, receive, or use the good or service;

E. Any material aspect of the performance, efficacy, nature, or central characteristics of the good or service;

F. To the extent applicable, that customs duties or taxes may be assessed by the relevant taxing authority; and

G. Any material aspect of the nature or terms of a refund, return, cancellation, exchange, or repurchase policy for the good or service, including the deadline (by date or frequency) by which the consumer must act.

IX.

REQUIRED DISCLOSURES

IT IS FURTHER ORDERED that, in connection with the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, Defendants and their 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, are permanently restrained and enjoined from:

A. Failing to Clearly and Conspicuously disclose, or assisting others in failing to Clearly and Conspicuously disclose, before consumers are asked to reveal billing information such as account number or to consent to any purchase in connection with any claim that a good or service is offered on a "free," "risk-free," "trial," "no obligation," "reduced," discounted basis, or words of similar import, the following material terms and conditions of any offer:

1. In Close Proximity to such claim, the total cost to purchase, or receive, or use any good or service that is the subject of the sales offer, including shipping, handling, and processing;
2. The amount, timing, and manner of payment of all fees, Charges, or other amounts that a consumer will be Charged or billed, and any additional financial obligations that may be incurred as a result of accepting the free product, service, or offer; and
3. The terms and conditions of any refund, cancellation, exchange, or purchase policy or policies, including the specific steps and means by which such requests must be submitted, and the telephone number, email address, web address, or street address to which such requests must be

directed, including the deadline (by date or frequency) by which the consumer must act, and, if there is a policy of not making refunds, cancellations, exchanges, or repurchases, a statement regarding this policy; and

B. Obtaining, or assisting others in obtaining, billing information such as account number from a consumer for any transaction involving a good or service that includes a Negative Option Feature, without first disclosing Clearly and Conspicuously, and in Close Proximity to where a consumer provides billing information:

1. The extent to which the consumer must take affirmative action(s) to avoid any Charges: a) for the offered good or service, b) of an increased amount after any trial or promotional period ends, and c) on a recurring basis;
2. The total cost (or range of costs) the consumer will be Charged (including shipping, handling, and processing), the date the initial Charge will be submitted for payment, and, if applicable, the frequency of such Charges unless the consumer timely takes affirmative steps to prevent or stop such Charges;
3. The deadline(s) (by date or frequency) by which the consumer must affirmatively act in order to stop all recurring Charges, whether such recurring charges are refundable and, if so, the terms and conditions of any refund policy;
4. The name of the seller or provider of the good or service and, if the name of the seller or provider will not appear on billing statements, the billing descriptor that will appear on such statements;

5. A description of the good or service;

6. Any Charge or cost for which the consumer is responsible in connection with the cancellation of an order or the return of a good; and

7. The mechanism to stop any recurring Charges.

In addition, for any transaction involving a sale of a good or service to a consumer through a Negative Option Feature, within 10 days after the date of the sale, Defendants must send the consumer written confirmation of the transaction, either by email or first class mail, according to the consumer's preference, which is identified as a written confirmation in the email subject line or on the outside of the envelope. Such written confirmation must include Clear and Conspicuous disclosure of all the information required by this Subsection IX.B(1)-(7) above, and must specify the procedures by which consumers can cancel or obtain a refund if a refund is offered.

X.

EXPRESS INFORMED CONSENT

IT IS FURTHER ORDERED that Defendants, Defendants' 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 the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, are permanently restrained and enjoined from using billing information to obtain payment from a consumer, unless, prior to using such billing information to obtain payment, they obtain the express informed consent of the consumer.

A. For all written offers with a Negative Option Feature (including over the Internet or other web-based applications or services), a consumer's express informed consent must be

obtained, prior to Defendants' obtaining any billing information from consumers, through a check box, signature, or other substantially similar method, that consumers must affirmatively select or sign to accept the Negative Option Feature. Immediately adjacent to such check box, signature, or substantially similar method, Defendants must disclose all costs associated with the Negative Option Feature, including shipping, handling, and processing, that the consumer is agreeing to pay such costs, the length of any trial period, and the date by which consumers must cancel to avoid being Charged. This disclosure must contain no additional information and must be Clear and Conspicuous in relation to any other information provided on the page relating to costs, risks, or obligations associated with any Negative Option Feature, including any terms referring to "free," "trial," and "processing fee."

B. For all oral offers including a Negative Option Feature, Defendants must, in addition to disclosing the information identified in the Section entitled Required Disclosures, and prior to obtaining any billing information such as account number from a consumer, obtain affirmative and unambiguous oral confirmation that the consumer:

1. Consents to authorizing payment for any goods or services, including shipping, handling, and processing;
2. Understands that the transaction includes a Negative Option Feature; and
3. Understands the specific affirmative steps the consumer must take to prevent further Charges.

Defendants must maintain for 3 years from the date of each transaction an unedited voice recording of the entire transaction, including the prescribed statements set out in the Section entitled Required Disclosures. Each recording must be retrievable by date and by the

consumer's name, telephone number, or billing information and must be provided upon request and without Charge to the consumer, the consumer's bank, or any law enforcement entity.

XI.

PROHIBITIONS CONCERNING REFUNDS AND CANCELLATIONS

IT IS FURTHER ORDERED that Defendants, Defendants' 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 the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, are permanently restrained and enjoined from:

A. Failing to honor a refund, return, or cancellation request that complies with any policy to make refunds or allow returns or cancellations; and

B. Failing to provide a simple mechanism for a consumer to immediately stop any recurring Charge for such good or service, at least one of which is as simple and easy to use as the mechanism the consumer used to initiate the Charges.

1. For consumers who entered into the agreement to purchase a good or service including a Negative Option Feature over the Internet or through other web-based applications or services, Defendants must provide a mechanism for consumers to stop the recurring Charge over the Internet or through such other web-based application or service.

2. For consumers who entered into the agreement to purchase a good or service including a Negative Option Feature through an oral offer and acceptance, Defendants must maintain a telephone number through which the consumer can easily cancel the good or service, seek a refund for past

Charges where such refund is offered, and immediately stop all further Charges. Defendants must answer all calls to this telephone number during normal business hours.

XII.

COMPLIANCE WITH THE ELECTRONIC FUND TRANSFER ACT

IT IS FURTHER ORDERED that Defendants, Defendants' 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 the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, are permanently restrained and enjoined, in connection with any person who purchases any good or service subsequent to the date of this Order, and who uses a debit card or other means of electronic fund transfer, from:

A. Failing to obtain written authorization for Preauthorized Electronic Fund Transfers from a consumer's account before initiating any Preauthorized Electronic Fund Transfer, as required by Section 907(a) of the Electronic Fund Transfer Act, 15 U.S.C. § 1693e(a), and Section 1005.10(b) of Regulation E, 12 C.F.R. § 1005.10(b), as more fully set out in Section 1005.10 of the Consumer Financial Protection Bureau's Official Staff Commentary to Regulation E, 12 C.F.R. § 1005, Supp. I; and

B. Failing to maintain procedures reasonably adapted to avoid an unintentional failure to obtain written authorization for a Preauthorized Electronic Fund Transfer, as required in Section 1005.10 of the Consumer Financial Protection Bureau's Official Staff Commentary to Regulation E, 12 C.F.R. § 1005, Supp. I.

XIII.

MONETARY JUDGMENT AND CONSUMER REDRESS

IT IS FURTHER ORDERED that:

A. Judgment in the amount of $3,700,514 is hereby entered in favor of the Commission against Defendants, jointly and severally, as equitable monetary relief.

B. Defendants are ordered to pay to the Commission $800,000. Defendants stipulate that they have posted $450,000 into the escrow account of their undersigned counsel for no purpose other than payment to the Commission. Defendants will remit the balance of $350,000 to the escrow account of their undersigned counsel prior to submission of this Order to the Court for approval. The escrowed funds shall be paid to the Commission within 7 days of the Court's entry of this Order and shall be transferred in accordance with the wire transfer instructions previously provided to counsel by a representative of the Commission.

C. Upon satisfaction of the obligations described in Subsection B above, the remainder of the judgment as to the Defendants shall be suspended subject to Subsections E and F below.

D. In the event of default of any obligation to make payments under this Order, including, but not limited to, failure to pay $800,000 to the Commission pursuant to Section B, above, interest shall accrue as computed pursuant to 28 U.S.C. § 1961(a) from the date of default to the date of payment. In the event such default continues for 10 calendar days beyond the date any payments are due, the entire judgment amount of $3,700,514 shall immediately become due and payable.

E. Plaintiffs' agreement to the suspension of part of the judgment is expressly premised upon the truthfulness, accuracy, and completeness of Defendants' sworn financial

statements and related documents (collectively, "financial representations") submitted to Plaintiffs, namely the following:

1. the Financial Statement of Individual Defendant Kramer Duhon signed on December 19, 2016, including the attachments (HRL003490-3504; HRL004034);

2. the Financial Statement of Corporate Defendant Health Research Laboratories, LLC, signed by Kramer Duhon, President, on December 18, 2016, including the attachments (HRL003474-3489); and

3. the additional documentation and information submitted by letter from Defendants' counsel Andrew Lustigman to Commission counsel Elizabeth Nach, dated December 22, 2016; January 13, 2017; February 8, 2017; February 17, 2017; February 28, 2017; March 31, 2017; and April 20, 2017; including all attachments thereto (bates-stamped HRL003227-4894 and 117 un-stamped JP Morgan investment account statements).

F. The suspension of the judgment will be lifted as to any Defendant if, upon motion by either of Plaintiffs, the Court finds that such Defendant failed to disclose any material asset, materially misstated the value of any asset, or made any other material misstatement or omission in the financial representations identified in Subsection E above.

G. If the suspension of the judgment is lifted, the judgment becomes immediately due as to the Defendant or Defendants causing the suspension to be lifted in the amount specified in Subsection A above (which the parties stipulate only for purposes of this Section represents the consumer injury alleged in the Complaint), less any payment previously made pursuant to this Section, plus interest computed from the date of entry of this Order.

H. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for equitable relief, including

consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the money shall be divided with the State of Maine. Any money not transferred to the State of Maine or not used by the Commission for equitable relief, including consumer information remedies, is to be deposited to the U.S. Treasury as disgorgement. Defendants have no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

I. All money paid to the State of Maine pursuant to this Order must be deposited into the Attorney General's other special revenue account and used for consumer education, consumer protection, antitrust enforcement, or for any lawful purpose at the sole discretion of the Attorney General.

J. Defendants relinquish 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.

K. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of either of Plaintiffs, in a proceeding to enforce their rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

L. The facts alleged in the Complaint establish all elements necessary to sustain an action by either of Plaintiffs pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

M. Defendants acknowledge that their Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendants previously submitted

to Plaintiffs, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

XIV.

COOPERATION WITH FTC AND MAINE

IT IS FURTHER ORDERED that Defendants must fully cooperate with representatives of the Commission, the Maine AG, and any of their representatives in this case and in any investigation related to or associated with the transactions or the occurrences that are the subject of the Complaint. Defendants must provide truthful and complete information, evidence, and testimony. Individual Defendant must appear and Corporate Defendant must cause its officers, employees, representatives, or agents to appear for interviews, discovery, hearings, trials, and any other proceedings that a representative of the Commission or the Maine AG may reasonably request upon 5 days' written notice, or other reasonable notice, at such places and times as a Commission or Maine AG representative may designate, without the service of a subpoena. Defendants may have counsel present.

XV.

CUSTOMER INFORMATION

IT IS FURTHER ORDERED that Defendants' officers, agents, and employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, are permanently restrained and enjoined from directly or indirectly:

A. Failing to provide sufficient customer information to enable the Commission to efficiently administer consumer redress. If a representative of the Commission requests in writing any information related to redress, Defendants must provide it, in the form prescribed by the Commission, within 14 days.

B. Disclosing, using, or benefitting from customer information, including the name, address, telephone number, email address, Social Security number, 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 Defendant obtained prior to entry of this Order in connection with the labeling, advertising, marketing, distribution, or sale of any formulation of BioTherapex or NeuroPlus; and

C. Failing to destroy such customer information in all forms in their possession, custody, or control within 30 days after receipt of written direction to do so from representatives of both the Commission and the Maine AG.

Provided, however, that customer information need not be destroyed, and may be disclosed, to the extent requested by a government agency or required by law, regulation, or court order.

XVI.

ORDER ACKNOWLEDGMENTS

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

A. Each Defendant, within 7 days of entry of this Order, must submit to the Commission and the Maine AG an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 10 years after entry of this Order, the Individual Defendant for any business involved in the sale or marketing of any Covered Product that such Defendant, individually or collectively with the Corporate Defendant, is the majority owner or controls directly or indirectly, and the Corporate Defendant, must deliver a copy of this Order to:

1. All principals, officers, directors, and LLC managers and members;
2. All employees, agents, and representatives with managerial responsibility who participate in the manufacturing, labeling, advertising, marketing, distribution, or sale of any Covered Product or service; 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 a Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

XVII.

COMPLIANCE REPORTING

IT IS FURTHER ORDERED that Defendants make timely submissions to the Commission and to the Maine AG:

A. Sixty days after entry of this Order, each Defendant must submit a compliance report, sworn under penalty of perjury:

1. Each Defendant must: (a) identify the primary physical, postal, and email address and telephone number as designated points of contact, which Plaintiffs' representatives may use to communicate with Defendant; (b) identify all of that 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, and the involvement of the other Defendant (which Individual Defendant must describe if he knows or should know due to his own involvement); (d) describe in detail whether and how that 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 Plaintiffs.

2. Additionally, the Individual 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 such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest; and (c) describe in detail such 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, each Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Defendant must report any change in: (a) any designated point of contact; (b) the structure of the Corporate Defendant or any entity that Defendants have any ownership interest in or control 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 Defendant must report any change in:

(a) names, including aliases or fictitious names, or residence addresses; or

(b) titles or roles in any business activity, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest, and identify the name, physical address, and any Internet address of the business or entity.

C. For a period of 20 years, each Defendant must submit to the Commission and the Maine AG notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Defendant within 14 days of its filing.

D. Any submission to the Commission or the Maine AG 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, N.W., Washington, D.C. 20580. The subject line must begin: *FTC v. Health Research Laboratories, LLC, et al.*, and the number X180007.

F. Unless otherwise directed by a Maine AG representative in writing, all submissions to the Maine AG pursuant to this Order must be sent by overnight courier (not the U.S. Postal Service) to: Office of the Attorney General of Maine, Consumer Protection Division, 111 Sewall Street, 6th Floor, Augusta, ME 04330. The subject line must begin: *Order in re State of Maine v. Health Research Laboratories, LLC, et al.,* and must identify the Court and docket number of this Order as ordered by the Court.

XVIII.

RECORDKEEPING

IT IS FURTHER ORDERED that in connection with the sale of any Covered Product, Defendants must create certain records for 10 years after entry of the Order, and retain each such record for 8 years. Specifically, the Corporate Defendant and the Individual Defendant for any business that such Defendants, individually or collectively, 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, all costs incurred in generating those revenues, and the resulting net profit or loss;

B. Personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; address; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. Complaints and full or partial 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 the Maine AG; and

E. A copy of each unique advertisement or other marketing material.

XIX.

COMPLIANCE MONITORING

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

A. Within 14 days of receipt of a written request from a representative of the Commission or the Maine AG, each 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. Plaintiffs 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, Plaintiffs are authorized to communicate directly with each Defendant. Defendants must permit Plaintiffs' representatives to interview any employee or other person affiliated with any Defendant who has agreed to such an interview. The person interviewed may have counsel present.

C. Plaintiffs may use all other lawful means, including posing, through their representatives, as consumers, suppliers, or other individuals or entities, to Defendants or any individual or entity affiliated with Defendants, 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. Nothing in this Order limits the Maine AG's lawful use of compulsory process, pursuant to section 211 of the Maine UTPA, 5 M.R.S.A. § 211. Defendants hereby consent to the disclosure by the Maine AG to any law enforcement agency and any representative of the State of Maine of any material or

information produced by Defendants pursuant to section 211 of the Maine UTPA, whether produced before or after the date of this Order.

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

XX.

RETENTION OF JURISDICTION

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

IT IS SO ORDERED this 16th day of January, 2018.

/s/ Jon D. Levy
U.S. DISTRICT JUDGE

IT IS SO STIPULATED this 30th day of November, 2017.

DAVID C. SHONKA
Acting General Counsel

/s/ Elizabeth K. Nach
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Attorneys for Plaintiff
FEDERAL TRADE COMMISSION

IT IS SO STIPULATED this 30th day of November, 2017.

JANET T. MILLS
Attorney General, State of Maine

/s/ Brendan F.X. O'Neil
Brendan F.X. O'Neil
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IT IS SO STIPULATED this 30th day of November, 2017.

HEALTH RESEARCH LABORATORIES, LLC
By:

/s/ Kramer Duhon
KRAMER DUHON, individually, and as an owner and officer of HEALTH RESEARCH LABORATORIES, LLC

IT IS SO STIPULATED this 30th day of November, 2017.

ATTORNEYS FOR DEFENDANTS HEALTH RESEARCH LABORATORIES, LLC AND KRAMER DUHON

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/s/ David J. Marchese
Appearing on behalf of Defendants Health Research Laboratories, LLC and Kramer Duhon

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EXHIBIT C

PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF THE ADMINISTRATIVE LAW JUDGES

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**	**DOCKET NO. 9397**

RESPONDENTS' WAIVER OF AFFIRMATIVE DEFENSES OF MOOTNESS AND LACK OF PUBLIC INTEREST

Respondents hereby unconditionally waive the following affirmative defenses and agree not to assert these particular affirmative defenses in any future answer:

1. **Mootness and Lack of Statutory Authority**: The causes of action alleged in the Complaint are barred by mootness because all alleged conduct (i.e., marketing and advertising) referenced in the Complaint ceased more than a year prior to the filing of the Complaint and will not reoccur in the future. The FTC has alleged no facts regarding a likelihood of reoccurrence. Further, the FTC Act does not grant the FTC the authority to seek a cease and desist order under these circumstances.

2. **Not in the public interest**: Neither the filing of the administrative action nor the contemplated relief is in the public interest as required by 15 U.S.C. § 45.

/s/ Joel W. Reese
Joel W. Reese

PUBLIC

CERTIFICATE OF SERVICE

I hereby certify that on February 25, 2021, I filed the foregoing document electronically using the FTC's E-Filing system, which will send notification to:

April J. Tabor
Acting Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580
ElectronicFilings@ftc.gov

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

Elizabeth Averill
eaverill@ftc.gov

Jonathan Cohen
jcohen2@ftc.gov

COMPLAINT COUNSEL

/s/ Joel W. Reese
Joel W. Reese

PUBLIC

EXHIBIT D

PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

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.**	**DOCKET NO. 9397**

DECLARATION OF ELIZABETH J. AVERILL

I, Elizabeth J. Averill, hereby state that I have personal knowledge of the facts set forth below. I submit this declaration in support of Complaint Counsel's Motion to Compel Respondents to Produce Documents. If called as a witness, I could and would testify as follows:

1. I am a United States citizen and am over eighteen years of age. I am employed by the Federal Trade Commission ("FTC") as an attorney in the Division of Enforcement, Bureau of Consumer Protection. I am acting as Complaint Counsel in the above-captioned matter. I also worked as an attorney representing the Federal Trade Commission in *FTC and State of Maine v. Health Research Laboratories, LLC, et al.*, Case No. 2:17-cv-00467-JDL (D. Me.).

2. On December 9, 2020, I served Complaint Counsel's Initial Disclosures on Respondents' counsel via email. A true and correct copy of those Initial Disclosures are attached as CCX-A1.

3. On December 10, 2020, I received Respondents' Initial Disclosures from Respondents' counsel, Joel Reese. A true and correct copy of these Initial Disclosures are attached as CCX-A2. They appeared to have been largely copied from Complaint Counsel's Initial Disclosures, and they do not provide any information about where Respondents are storing potentially relevant documents. Respondents also did not list categories of relevant documents one would expect to be in their custody such as emails, documents related to work performed by non-attorney consultants and copywriters related to the challenged ads, or business records related to advertising or marketing strategy for Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic.

4. On December 22, 2020, I served Complaint Counsel's First Requests for Production to Respondents ("RFPs") by email to their counsel, Joel Reese and Joshua Russ. A true and correct copy of the RFPs are attached as CCX-A3.

5. On January 6, 2021, my co-counsel, Jonathan Cohen, and I had a telephone conference with Joel Reese to discuss questions related to the RFPs and Respondents' request that Complaint Counsel provide search terms. During that conference, I asked Mr. Reese for specific information about the Respondents' document collection efforts, the custodians searched, how and where ESI was stored, as well as the volume and format of stored ESI. Mr. Reese did not provide any specific information about Respondents' collection efforts or any information relevant to assessing burden. On January 11, 2021, I sent a letter to Mr. Reese following up about some of these unanswered questions. A true and correct copy of this letter is attached as CCX-A4. I never received any information from Mr. Reese in response to these questions.

6. On January 21, 2021, I received Respondents' Objections and Responses to Complaint Counsel's First Requests for Production ("Responses"). A true and correct copy of the Responses are attached as CCX-A5.

7. A vendor working with Respondents' counsel produced documents on January 25, 2021 ("January 25 Production"). This is the only document production Complaint Counsel has received in response to the RFPs. It included 492 documents.

8. On January 25, 2021, Respondents' counsel stated he planned to review and produce additional responsive documents to Complaint Counsel within two weeks. A true and correct copy of this email is attached as CCX-A6.

9. I personally reviewed all of the documents in the January 25 Production. During my review, I noticed the majority of the documents had previously been produced to the FTC as part of the contempt investigation related to *FTC and State of Maine v. Health Research Laboratories, LLC, et al.*, Case No. 2:17-cv-00467-JDL (D. Me.).

10. Furthermore, the January 25 Production includes multiple copies of the same articles, random website content, and excerpted sections of alternative health books related to individual ingredients in the four challenged products. For example, six copies of an article entitled "Aged Garlic Extract Reduces Low Attenuation Plaque in Coronary Arteries of Patients with Metabolic Syndrome in a Prospective Randomized Double-Blind Study" authored by Matsumoto et al. were produced with Bates numbers of HRLAC_00186 to 00191; HRLAC_00720 to 00725; HRLAC_01444 to 01449; HRLAC_01991 to 01996; HRLAC_02566 to 02571; and HRLAC_03113 to 03118. Six copies of an article entitled "Garlic Shows Promise for Improving Some Cardiovascular Risk Factors" authored by Ackermann et al. were produced with Bates numbers of HRLAC_00672 to 00683; HRLAC_00684 to 00695; HRLAC_01943 to

001954; HRLAC_01955 to 01966; HRLAC_03065 to 03076; and HRLAC_03077 to 03088. Three copies of an abstract related to an article entitled "Inhibiting progression of coronary calcification using Aged Garlic Extract in patients receiving statin therapy: a preliminary study" authored by Budoff et al. were produced with Bates numbers of HRLAC_00016 to 00017; HRLAC_01262 to 01263; and HRLAC_02384 to 02385. There are three copies of a website article entitled "14 Biggest Myths About Type 2 Diabetes" apparently downloaded from http://community.ihealthlabs.com that was produced with Bates numbers HRLAC_01426 to 01431; HRLAC_00168 to 00173; and HRLAC_02548 to 02553. Respondents produced three copies of an article entitled "Applicable People fermented black garlic; green natural org" apparently downloaded from http://www.iblackgarlic.com and produced with Bates numbers HRLAC_01305 to 01306; HRLAC_00059 to 00060; and HRLAC_02427 to 02428. Respondents produced three copies of an excerpt entitled "Chelation Therapy" from a book entitled "Alternative Medicine: the definitive guide" with Bates numbers HRLAC_01832 to 01842; HRLAC_00561 to 00571; and HRLAC_02954 to 02964. This is just a very small sample of the extensive amount of duplicative materials in the January 25 Production.

11. Based on my review, the January 25 Production did not include any documents related to the development, analysis, review, or approval of the challenged advertisements other than a few statements of ad approval apparently signed by Richard Cohen. The production did not include any communications or documents clearly related to work done by individuals or entities who assisted the Respondents on projects related to advertising and substantiation such as documents involving Inna Yegerova, Inna Consulting, Curtis Walcker, Dietary Supplement Experts, LLC, or Stephen Kimball. The production did not include documents or any communications related to either Respondents' advertising and marketing strategy or product

development for Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic. Respondents have not produced any contemporaneous emails, notes, or correspondence. Respondents have not produced any documents clearly authored by, or addressed to, either Kramer Duhon or Kyle Duhon. The January 25 Production does not include any documents related to Respondents' alleged defense that Kramer Duhon was not responsible for the conduct of the corporate Respondents.

12. Respondents have not produced a privilege log.

13. On January 27, 2021, I sent an email to Respondents' counsel asking to schedule a time to meet and confer about issues related to Respondents' Initial Disclosures, the Responses, as well as Respondents' Objections and Answers to the First Set of Interrogatories. Respondents' counsel advised that the earliest date he was available for such a conference was February 1, 2021. A true and correct copy of an email string between counsel related to scheduling the time to meet and confer is attached as CCX-A7.

14. On February 1, a few hours prior to the scheduled time for counsel to meet and confer about discovery issues, Respondents' counsel, Joel Reese, sent an email indicating Respondents would agree to all relief requested in the Notice of Contemplated Relief without any conditions. Mr. Reese further indicated he believed, as a result, the scheduled meet and confer was not necessary. I responded by advising him it was important for us to meet and confer as scheduled to try to resolve issues related to Respondents' Initial Disclosures, the Responses, and Respondents' Objections and Answers to the First Set of Interrogatories. A true and correct copy of an email string reflecting this exchange between counsel is attached as CCX-A8.

15. On February 1, 2021 starting at 4:30 PM (Eastern), Jonathan Cohen and I spoke by telephone with Joel Reese in an effort to discuss and resolve the issues raised in the Motion to Compel Respondents to Produce Documents as well other issues related to their Objections and Answers to the First Set of Interrogatories. A FTC paralegal, Celia Garrett, also listened to the call. I repeatedly tried to focus the conversation on specific questions and issues related to document production, the Responses, and Respondents' Objections and Answers to the First Set of Interrogatories in an effort to determine if issues could be narrowed by agreement. Mr. Reese was generally unwilling to engage in a detailed discussion about specific discovery issues and instead insisted that all of those issues were irrelevant because Respondents would not participate further in discovery in the administrative action because of cost. During the conference, Mr. Reese stated Respondents were willing to admit to all allegations in the Complaint. He stated that Respondents intended to terminate the administrative proceeding either by settlement, withdrawing their answer, filing a motion to amend their answer to admit allegations in the Complaint, or by declining to participate further in discovery and eventually incurring what he referred to as "death penalty" sanctions from the Court that would terminate the administrative proceeding. During the conference, Mr. Reese also stated Respondents would not review or produce additional documents, produce a privilege log, or otherwise supplement their discovery responses. I did not note the exact time when the conference concluded, but estimate that we spoke for a total of approximately 75 minutes.

16. Following the conference on February 1, counsel for the parties had a discussion related to settlement that was ultimately not successful.

17. During the conversation on February 1 and during a subsequent telephone call on February 11, 2021, Mr. Reese advised us Respondents' position is that attorney-client privilege

and/or the work product doctrine applies to documents related to unidentified non-attorney consultants who were involved in reviewing the challenged advertisements and evaluating substantiation. He told us the law firm of Olshan Frome Wolosky LLP referred Respondents to those consultants, and that such documents would not be produced to Complaint Counsel on the grounds they are protected by the attorney-client privilege or the work product doctrine.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on: February 19, 2021 /s/ Elizabeth J. Averill

Alexandria, VA