Analysis of Proposed Consent Order to Aid Public Comment
***In the Matter of Health Research Laboratories, LLC, et al.*, Docket No. 9397**

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from Health Research Laboratories, LLC, Whole Body Supplements, LLC and their Managing Member and officer, Kramer Duhon ("Respondents").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter involves the Respondents' advertising for Black Garlic Botanicals, BG18, The Ultimate Heart Formula, and Neupathic. The complaint alleges Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) Black Garlic Botanicals, BG18, and The Ultimate Heart Formula will prevent, reduce the risk of, cure, mitigate, or treat cardiovascular disease, atherosclerosis, and/or hypertension; and (2) Neupathic will cure, treat, or mitigate diabetic neuropathy. Respondents Kramer Duhon and Health Research Laboratories are also parties to a previous federal court order in *FTC and State of Maine v. Health Research Laboratories, LLC, et al.*, 2:17-cv-00467-JDL (D. Me. Jan. 16, 2018).

The proposed consent order includes injunctive relief that addresses these alleged violations and contains provisions designed to prevent Respondents from engaging in similar acts and practices in the future.

Part I would ban Respondents from advertising, marketing, promoting, or offering for sale any dietary supplements.

Part II would ban Respondents from making any disease prevention, reduction of risk, cure, mitigation, or treatment claim when advertising, marketing, promoting, or offering for sale any product.

Part III prohibits Respondents from making any representation about the health benefits, safety, performance, or efficacy of any food or drug, unless the representation is non-misleading, and at the time such representation is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this provision, "competent and reliable scientific evidence" means 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) are generally accepted by such experts to yield accurate and reliable results; and (3) are randomized, double-blind, and placebo-controlled human clinical testing of the product or of an essentially equivalent product, when experts would generally require such human clinical testing to substantiate that the representation is true. In addition, this provision requires that when such tests or studies are human clinical

tests or studies, all underlying or supporting data and documents generally accepted by experts as relevant to an assessment of such testing must be available for inspection and production to the Commission.

Part IV prohibits Respondents from making misrepresentations: (1) that the performance or benefits of any food or drug are scientifically or clinically proven or otherwise established; or (2) about the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

Part V requires Respondents to preserve supporting data and documents relevant to assessing human clinical tests that they rely on to support claims within the scope of Part III of the proposed order.

Part VI requires Respondents to send notices to consumers who purchased Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic informing them about this matter and the Commission's order.

Part VII prohibits Respondents and their officers, agents, and employees from disclosing, using, or receiving any benefit from customer information that Respondents obtained in connection with sales of Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic.

Part VIII requires Respondents to cancel any subscription plan with a negative option feature related to Black Garlic Botanicals, BG18, The Ultimate Heart Formula, or Neupathic.

Parts IX through **XII** of the proposed order relate to compliance reporting and monitoring. Part IX is an order acknowledgment and distribution provision requiring Respondents to acknowledge the order, to provide the order to current and future owners, managers, business partners, certain employees, and to obtain an acknowledgement from each such person that they received a copy of the order. Part X requires Respondents to submit a compliance report one year after the order is entered, and to promptly notify the Commission of corporate changes that may affect compliance obligations. Part XI requires Respondents to maintain, and upon request make available, certain compliance-related records. Part XII requires Respondents to provide additional information or compliance reports, as requested.

Part XIII states that the proposed order will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.