

Complaint

IN THE MATTER OF

**HEALTH RESEARCH LABORATORIES, LLC,
WHOLE BODY SUPPLEMENTS, LLC,
AND
KRAMER DUHON**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT

*Docket No. 9397; File No. X180007
Complaint, November 13, 2020 – Decision, June 24, 2022*

This consent order addresses Health Research Laboratories, LLC and Whole Body Supplements, LLC's advertising for Black Garlic Botanicals, BG18, The Ultimate Heart Formula, and Neupathic. The complaint alleges that 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. The consent order bans Respondents from advertising, marketing, promoting, or offering for sale any dietary supplements and from making any disease prevention, reduction of risk, cure, mitigation, or treatment claim when advertising, marketing, promoting, or offering for sale any product.

Participants

For the *Commission*: Elizabeth J. Averill and Philip Z. Brown.

For the *Respondents*: Joel W. Reese and Joshua Russ, Reese Marketos LLP.

COMPLAINT

The Federal Trade Commission, having reason to believe that Health Research Laboratories ("HRL"), a limited liability company, Whole Body Supplements ("WBS"), a limited liability company, and Kramer Duhon, individually and as an owner and officer of HRL and WBS (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent HRL is a Nevada limited liability company with its principal office or place of business at 16250 Knoll Trail Drive, Dallas, TX 75248.
2. Respondent WBS is a Nevada limited liability company with its principal office or place of business at 16250 Knoll Trail Drive, Dallas, TX 75248.
3. Respondent Kramer Duhon is the Chief Operating Officer and managing member of HRL and the Chief Operating Officer and managing member of WBS. Individually or in concert with others, he controlled or had the authority to control the acts and practices of HRL and WBS, including the acts and practices alleged in this complaint. His principal office or place of business is 16250 Knoll Trail Drive, Dallas, TX 75248.

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4. Respondents have advertised, labeled, offered for sale, sold, and distributed, or caused to be distributed a number of dietary supplement products to consumers. HRL sold, among other products, Black Garlic Botanicals, The Ultimate Heart Formula, and Neupathic. WBS sold BG18, among other products. Black Garlic Botanicals, BG18, The Ultimate Heart Formula, and Neupathic are “food” and/or “drugs” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

5. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

Black Garlic Botanicals

6. HRL began selling Black Garlic Botanicals in November 2016. Each capsule contains 600 mg of the active ingredient black garlic, and the recommended dosage is two capsules a day. HRL sells a one-month supply of Black Garlic Botanicals for \$39.95, plus shipping and handling.

7. HRL has disseminated or has caused to be disseminated advertising and promotional materials for Black Garlic Botanicals in multi-page mailers sent to consumer residences and on company websites. The Black Garlic Botanicals mailer attached as Exhibit A opens with the following representations and depictions:

Every 90 seconds, someone dies from heart disease in the U.S. — are you next?

1 in 7 people die from heart disease.

Only 10% of people survive cardiac arrest if treated by emergency medical services. What are you waiting for?

GOOD NEWS: Everything you need to know about your heart health is in this issue!

In This Heart Health Breaking News Issue:

Cardiovascular disease — #1 cause of death in the world!	2
Diabetes & venous insufficiency are additional risks	6
Overweight? Belly fat creates new risk factors	7
Why don't people suffer from high cholesterol in Japan?	8
One Man's Personal Journey Created an Empire of Good Health . . . 10	
Black Garlic all over the news!	12

PRODUCT NOW AVAILABLE

HEALTH RESEARCH LABS — Breaking News Cardiovascular Issue

Exhibit A (Black Garlic Botanicals mailer)

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This front-page content is followed by additional descriptions of the dangers of cardiovascular disease. For example, the second and third pages display a banner across the top, which states, “Cardiovascular Disease: #1 cause of Death in the world, especially the U.S.!” A banner at the bottom states, “There’s a miraculous natural solution that can help – find out what it is!!”

The mailer continues with the following statements about the efficacy of black garlic in reducing arterial plaque, blood pressure, and cholesterol:

- **BLACK GARLIC WORKS WITH YOUR BODY**
 - Cholesterol: Black Garlic helps maintain healthy cholesterol levels.
 - Clotting: Black Garlic supports healthy platelet aggregation, which can help to keep blood circulating and works against clotting.
 - Supports and helps maintain healthy blood pressure levels to combat risks.
- **Healthy Arteries**
 Plaque build-up in arteries can lead to unhealthy heart conditions. Black Garlic helps keep blood vessels barrier-free to create smooth flow, which could address symptoms of fatigue. It may also inhibit calcium binding, which is responsible for arterial plaque formation.
- **Want Healthy Blood Pressure & Cholesterol? Black Garlic helps maintain healthy blood pressure, cholesterol and triglyceride levels.**
- **BLACK GARLIC
A BREAKTHROUGH FOR**
 - ✓ Cholesterol
 - ✓ Blood Sugar
 - ✓ Blood Pressure
 - ✓ The Heart
 - ✓ The Brain
- “I made the switch to Black Garlic Botanicals and within the span of 3 months my LDL levels have reduced from 300 to 150. This product works!” ~ Gerald W.
- “I now have my blood pressure under control with Black Garlic Botanicals. This is a quality product!” ~ Rolf M.

BG18

8. WBS began selling BG18 in August 2017. The product has identical ingredients to Black Garlic Botanicals. Each capsule contains 600 mg of the active ingredient black garlic, and the recommended dosage is two capsules a day. WBS sells a one-month supply of BG18 for \$44.95, plus shipping and handling.

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9. WBS has disseminated or has caused to be disseminated advertising and promotional materials for BG18, including multi-page mailers and content on company websites. An example of a mailer for BG18 is attached as Exhibit B.

The front page of the attached BG18 mailer features an image of a caduceus and, a photograph of a doctor in a white coat, and states “Black Garlic has shown an amazing power to improve heart and cardiovascular health, maintain normal cholesterol levels, boost your immune system. And MUCH MORE!” The mailer continues with the following representations:

- Black Garlic is a proven miracle for . . . Cholesterol . . . Hypertension . . . Your Heart.
- [Black Garlic] can help reverse plaque build-up in arteries – not just slow it down. Black Garlic keeps blood vessels barrier-free to create a smooth blood flow and alleviates symptoms of fatigue. It also strongly inhibits calcium binding, which is responsible for plaque build-up.
- Reduces Blood Pressure and Cholesterol. . . Black Garlic helps reduce high blood pressure and lowers high levels of bad cholesterol and triglycerides.
- “My blood pressure has also been lowered. I recommend this product because IT WORKS!” ~ Lorraine T.
- On the following page, the brochure poses this question and answer:

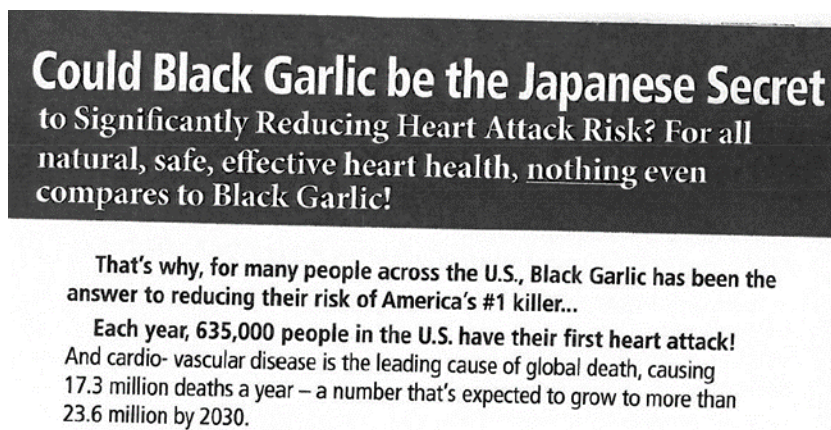


Exhibit B (BG18 mailer).

- Yes, Black Garlic is a true miracle for cardiovascular health! Just 1 capsule knocks down cholesterol and high blood pressure within days. It can also unblock, clean, and strengthen your arteries.
- The cardio-protective effect of black garlic. . . Black garlic can also improve your lipid profile, an important factor in protecting against cardiovascular problems.

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The Ultimate Heart Formula

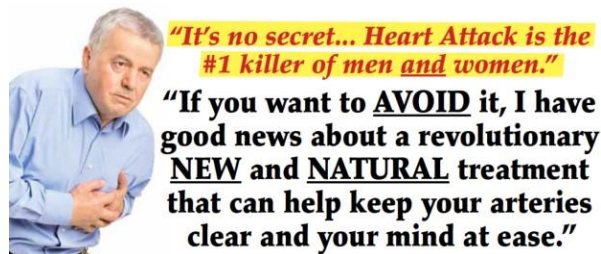
10. HRL has been selling The Ultimate Heart Formula (“UHF”) since November 2008. UHF contains Vitamins C, E, and B12 as well as garlic extract (25 mg), Tetrasodium EDTA (40 mg), Ubiquinol (CoEnzyme Q-10) (5 mg), and Nattokinase (10 mg). HRL sold a one-month’s supply of UHF for \$39.95, plus shipping and handling. The recommended dosage is 20 drops or 1ml, twice per day.

11. HRL disseminated or caused to be disseminated advertisements for UHF, including multipage mailers and company websites. An example of a mailer is attached as Exhibit C, which contains the following statements and depictions on its first and second pages:

The advertisement is a multi-page mailer. The top section features a portrait of Dr. Richard Cohen, M.D., Scientific Advisor, on the left. To his right, the text reads: **“When it comes to a sudden heart attack... What You Don’t Know CAN Hurt You!”**. Below this, a blue banner asks: **Do you KNOW what YOUR arteries look like right now?**. The middle section shows a woman with white hair looking concerned, with a diagram of a heart and arteries overlaid. The diagram has three levels: **All Clear!** (red circle with green arteries), **Uh Oh!** (red circle with yellow arteries), and **DANGER!** (red circle with red arteries). The bottom section features a close-up of a liquid drop being dispensed from a bottle. The text reads: **Keeping your risk low and your HEART healthy is all about keeping your arteries CLEAR! See inside for help from a revolutionary, new, heart-helping liquid drop formula...** Below this, a red banner says: **SEE INSIDE to discover a natural nutrient that is up to 95% EFFECTIVE at maintaining clear arteries and reducing risk of a heart problem!** A red arrow points to the right.

Exhibit C (The Ultimate Heart Formula mailer).

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Avoiding a heart attack is all about keeping your arteries clear, your cholesterol in check, your blood pressure low and your risk of a blood clot low... so accumulated plaque does not close off an artery or break off and cause a stroke.



Now there's a new, improved twist on our most effective natural, heart-helping treatment.

Exhibit C (The Ultimate Heart Formula mailer, p.2)

These depictions and representations are followed by a number of additional claims, including:

- Instead, right before you is a simple, safe, inexpensive, non-painful and preventative option that could help you say goodbye to your heart surgeon and avoid an angioplasty.
- Our Ultimate Heart Formula can help support a healthy heart, healthy cholesterol and healthy blood pressure. As blockages in your veins and arteries become clear, you can experience better blood circulation – resulting in more energy, better sleep, sharper mental clarity and better health.
- The Ultimate Heart Formula also contains a powerful, clot-busting agent!
- The Ultimate Heart Formula is an all-natural combination of 19 powerful herbs and essential nutrients that counter the causes of poor cardio health. The Ultimate Heart Formula's unique "Senior Formula" is made with ingredients specifically shown to help improve the effects of a weakened heart, clogged arteries, high blood pressure and high cholesterol for older people!
- With our Ultimate Heart Formula ...You get it ALL ... Amazing heart and artery protection ... without side effects!

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- Yes, with the Ultimate Heart Formula, a lifetime of plaque build up could disappear before you know it! The artery-flushing power of this formula does not even require a doctor's visit or stay in the hospital!

Neupathic

12. Beginning in August 2016, HRL also sold a dietary supplement called Neupathic. Neupathic contains the following active ingredients: Vitamins E (30 IU), B1 (33.3 mg), B6 (33.3 mg), B12 (16.7 mcg), and folate (266.7 mcg), and Evening Primrose Oil (666.7 mg). HRL sold a one-month's supply of Neupathic for \$39.95, plus shipping and handling. The recommended dosage is two capsules per day.

13. HRL has disseminated or caused to be disseminated advertising and promotional materials for Neupathic, including multi-page mailers and content on company websites. An example of a mailer is attached as Exhibit D, which contains the following depictions and statements on the first page:

This “Perfect” Nerve Pain easing pill combines special nutrients to restore circulation and soothe nerve pain associated with diabetes!
See inside how it can help you...

OPEN NOW to Ease These Issues:

- ✓ Burning
- ✓ Itching
- ✓ Tingling
- ✓ Numbness
- ✓ Constant cold
- ✓ Swelling and heaviness
- ✓ Cramps and restlessness...

And SO MUCH MORE!

Exhibit D (Neupathic mailer).

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The mailer continues inside with additional claims:

- If you have diabetic nerve pain, you could suffer with any or all of the symptoms below.
 - ✓ Shooting pain
 - ✓ Burning
 - ✓ Pins and needles
 - ✓ Electric shock-like pain
 - ✓ Extra sensitivity
 - ✓ Numbness
 - ✓ Throbbing
 - ✓ Tingling
 - ✓ Stinging
 - ✓ Stabbing
 - ✓ Radiating

Neupathic was specifically formulated with 6 distinct nutrients to help address ALL these issues and more.

- A “perfect” nerve pain supplement that was formulated from the ground up to improve your circulation and ease the numbness, tingling, itching, burning and swelling from excess fluid trapped in your legs.
- Take this easy step towards normal, pain free legs and feet again! Non- drug ... proven ingredients.

It can also help address the direct cause of nerve pain and neuropathy, damaged nerves, excess fluid — and poor circulation.

Allowing you to:

- ...Increase** your mobility
- ...Relieve** nerve pain
- ...Reduce** swelling and tightness
- ...Gain back** your freedom to move easily and enjoy your favorite activities again

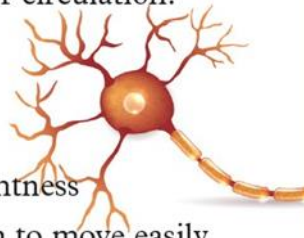


Exhibit D (Neupathic mailer, p. 11).

- Respond now if your nerve pain is driving you crazy! You’ll get completely natural, real relief from your discomfort. All natural Neupathic is 100% effective and safe to use every day! Remember, it has [sic] shown to help reverse damaged nerves to help you feel great all day and all night.
- “Great reduction of pain. No more nerve pain in my feet. I also hardly notice any leg cramps. This product is great!” — Ruth J.

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- “Neupathic is a great ‘miracle-like product’ which starts working the very first day you use it. Then it continues to control your pain every day. My feet have began [*sic*] to feel normal. Neupathic has improved my life. My nerve pain is gone and I will continue to take Neupathic until my numbness is gone too!” — Gloria R. *Id.*

Count I**Respondents’ Unsubstantiated Claims Related to Black Garlic Botanicals
(HRL and Duhon)**

14. In connection with the advertising, promotion, offering for sale, or sale of Black Garlic Botanicals, HRL and Kramer Duhon have represented, directly or indirectly, expressly or by implication, that Black Garlic Botanicals:

- a. Prevents or reduces the risk of cardiovascular disease including by lowering blood pressure, improving blood flow, reducing cholesterol, or decreasing arterial plaque;
- b. Treats cardiovascular disease including by lowering blood pressure, improving blood flow, reducing cholesterol, or decreasing arterial plaque;
- c. Prevents or reduces the risk of atherosclerosis including by reducing cholesterol or decreasing arterial plaque;
- d. Treats atherosclerosis including by reducing cholesterol or decreasing arterial plaque; and
- e. Cures, treats, or mitigates hypertension including by decreasing arterial plaque or lowering blood pressure.

15. The representations set forth in Paragraph 14 were not substantiated at the time the representations were made.

Count II**Respondents’ Unsubstantiated Claims Related to BG18
(WBS and Duhon)**

16. In connection with the advertising, promotion, offering for sale, or sale of BG18, WBS and Kramer Duhon have represented, directly or indirectly, expressly or by implication, that BG18:

- a. Prevents or reduces the risk of cardiovascular disease including by lowering blood pressure, improving blood flow, reducing cholesterol, or decreasing arterial plaque;
- b. Treats cardiovascular disease including by lowering blood pressure, improving blood flow, reducing cholesterol, or decreasing arterial plaque.

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- c. Prevents or reduces the risk of atherosclerosis including by reducing cholesterol or decreasing arterial plaque;
- d. Treats atherosclerosis including by reducing cholesterol or decreasing arterial plaque; and
- e. Cures, treats, or mitigates hypertension including by decreasing arterial plaque or lowering blood pressure.

17. The representations set forth in Paragraph 16 were not substantiated at the time the representations were made.

Count III
Respondents' Unsubstantiated Claims Related to UHF
(HRL and Duhon)

18. In connection with the advertising, promotion, offering for sale, or sale of UHF, HRL and Kramer Duhon have represented, directly or indirectly, expressly or by implication, that UHF

- a. Prevents or reduces the risk of cardiovascular disease including by lowering blood pressure, improving blood flow, reducing cholesterol, or decreasing arterial plaque;
- b. Treats cardiovascular disease including by lowering blood pressure, improving blood flow, reducing cholesterol, or decreasing arterial plaque.
- c. Prevents or reduces the risk of atherosclerosis including by reducing cholesterol or decreasing arterial plaque;
- d. Treats atherosclerosis including by reducing cholesterol or decreasing arterial plaque; and
- e. Cures, treats, or mitigates hypertension including by decreasing arterial plaque or lowering blood pressure.

19. The representations set forth in Paragraph 18 were not substantiated at the time the representations were made.

Count IV
Respondents' Unsubstantiated Claims Related to Neupathic
(HRL and Duhon)

20. In connection with the advertising, promotion, offering for sale, or sale of Neupathic, HRL and Kramer Duhon have represented, directly or indirectly, expressly or by implication, that Neupathic:

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- a. Cures, treats, or mitigates diabetic neuropathy including by improving blood circulation, or eliminating or alleviating diabetic nerve pain and discomfort.

21. The representations set forth in Paragraph 20 were not substantiated at the time the representations were made.

Violations of Sections 5 and 12

22. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

NOTICE

You are notified that on July 13, 2021, at 10:00 a.m., at the Federal Trade Commission offices, 600 Pennsylvania Avenue, NW, Room 532-H, Washington, DC 20580, an Administrative Law Judge of the Federal Trade Commission will hold a hearing on the charges set forth in this Complaint. At that time and place, you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in this Complaint.

You are notified that you are afforded the opportunity to file with the Federal Trade Commission (“Commission”) an answer to this Complaint on or before the 14th day after service of the Complaint upon you. An answer in which the allegations of the Complaint are contested must contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the Complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the Complaint not thus answered will be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the Complaint, the answer should consist of a statement that you admit all of the material facts to be true. Such an answer will 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 may issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings of fact and conclusions of law under FTC Rule § 3.46.

Failure to answer timely will be deemed to constitute a waiver of your right to appear and contest the allegations of the Complaint. It will also authorize the Commission, without further notice to you, to find the facts to be as alleged in the Complaint and to enter a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding.

The Administrative Law Judge will hold an initial prehearing scheduling conference not later than 10 days after the answer is filed by the last answering Respondent. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will

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take place at the Federal Trade Commission, 600 Pennsylvania Avenue, NW, Room 532-H, Washington, DC 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, but in any event no later than 5 days after the answer is filed by the last answering Respondent. Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a Respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the Complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers. Such relief could be in the form of restitution for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for such relief on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

a. NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that Respondents have violated or are violating Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including but not limited to:

1. A prohibition on any representation that Respondents' products cure, treat, mitigate, prevent, or reduce the risk of any disease.
2. A prohibition on representations about the health benefits, safety, efficacy, or the performance of Respondents' products unless those representations are supported by competent and reliable scientific evidence.
3. A prohibition on misrepresentations regarding tests, studies, or other research.
4. A requirement that Respondents preserve records relating to competent and reliable clinical tests or studies.
5. A requirement that Respondents send appropriate notification of the order to all affected customers.
6. A requirement that Respondents cancel any automatically recurring orders for Black Garlic Botanicals, BG18, UHF, or Neupathic for any existing customer who was first charged before the issuance of the Complaint.
7. A requirement that Respondents will not use, sell, rent, lease, or transfer any identifying information related to any customer who paid money to any Respondent for Black Garlic Botanicals, BG18, UHF, or Neupathic prior to the issuance of the Complaint.

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8. A requirement that, for a period of time, Respondents send acknowledgments of the order to the Commission.
9. A requirement that, for a period of time, Respondents create and preserve certain records demonstrating compliance with the order.
10. A requirement that, for a period of time, Respondents provide notice of all new business activity to the Commission.
11. A requirement that Respondents file periodic compliance reports with the Commission.
12. A requirement that Respondents' compliance with the order be monitored for a term to be determined by the Commission.
13. Any other relief appropriate to correct or remedy the effects of Respondents' deceptive practices or of any or all of the conduct alleged in the complaint.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed at Washington, DC, this 13th day of November 2020.

By the Commission.

DECISION

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

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

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

The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The

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Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 3.25(f), the Commission makes the following Findings and issues the following Order:

FINDINGS

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

ORDER**Definitions**

For purposes of this Order, the following definitions apply:

- A. “Covered Product” means any Food or Drug.
- B. “Corporate Respondent” means Health Research Laboratories, LLC, and Whole Body Supplements, LLC.
- C. “Dietary Supplement” means:
 1. any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or
 2. any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a

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concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

- D. “Drug” means: (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and (d) articles intended for use as a component of any article specified in (a), (b), or (c); but does not include devices or their components, parts, or accessories.
- E. “Essentially Equivalent Product” means a product that contains the identical ingredients, except for inactive ingredients (e.g., inactive binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients are unlikely to impede or inhibit the effectiveness of the ingredients in the essentially equivalent product.
- F. “Food” means: (a) any article used for food or drink for humans or other animals; (b) chewing gum; and (c) any article used for components of any such article.
- G. “Individual Respondent” means Kramer Duhon.
- H. “Negative Option Feature” means, in an offer or agreement to sell any good or service, a provision under which the consumer’s silence or failure to take affirmative action to reject a good or service or to cancel the agreement is interpreted by the seller or provider as acceptance or continuing acceptance of the offer.
- I. “Respondents” means Health Research Laboratories, LLC, Whole Body Supplements, LLC, and Kramer Duhon, individually, collectively, or in any combination.

Provisions**I.**

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

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II.

IT IS FURTHER ORDERED that Respondents, whether acting directly or indirectly, in connection with the advertising, marketing, promoting, or offering for sale of any product, must not make any representation, expressly or by implication, that a product cures, treats, mitigates, prevents, or reduces the risk of any disease.

III.

IT IS FURTHER ORDERED that subject to the prohibitions in Parts I and II of this Order, Respondents, Respondents' officers, agents, and employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make any representation expressly or by implication, about the health benefits, safety, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant condition or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant condition or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in Part V of this Order must be available for inspection and production to the Commission. Respondents have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

IV.

IT IS FURTHER ORDERED that subject to the prohibitions in Parts I and II of this Order, Respondents, Respondents' officers, agents, employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with advertising, marketing, promoting, offering for sale, sale, or distribution of any Covered Product must not make any misrepresentations expressly or by implication:

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

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- B. About the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

V.

IT IS FURTHER ORDERED that, with regard to any human clinical test or study (“test”) upon which Respondents rely to substantiate any claim not banned by Parts I or II, but covered by Part III, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

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

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Respondent; (2) any Respondent’s officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Respondent; (4) any person or entity affiliated with or acting on behalf of any Respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product’s manufacturer; or (6) the supplier or manufacturer of such product.

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

For any test conducted, controlled, or sponsored, in whole or in part, by Respondents, Respondents must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards

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appropriate to Corporate Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

VI.

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

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

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

VII.

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

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

VIII.

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

IX.

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

- A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.
- B. For 20 years after the issuance date of this Order, the Individual Respondent, for any business that such Respondent, individually or collectively with any other Respondent, is the majority owner or controls directly or indirectly, and each Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for the manufacturing, labeling, advertising, marketing, distribution, or sale of any Covered Product, and all agents and representatives who participate in manufacturing, labeling, advertising, marketing, distribution, or sale of any Covered Product; and (3) any business entity resulting from any change in structure as set forth in Part X. Delivery must occur within 10 days after the

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effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

- C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

X.

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

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

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including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, the Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity, including (i) any business for which such Respondent performs services whether as an employee or otherwise and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.
- C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.
- D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: “I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____” and supplying the date, signatory’s full name, title (if applicable), and signature.
- E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Health Research Laboratories, Dkt. 9397.

XI.

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

- A. Accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;
- B. Personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person’s: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

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- C. Copies or records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;
- D. All records necessary to demonstrate full compliance with each Provision of this Order, including all submissions to the Commission; and
- E. A copy of each unique advertisement or other marketing material making a representation subject to this Order.
- F. For 5 years from the date of the last dissemination of any representation covered by this Order:
 - 1. All materials that were relied upon in making the representation; and
 - 2. All tests, studies, analysis, other research or other such evidence in Respondents' possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.
- G. For 5 years from the date created or received, all records, whether prepared by or on behalf of Respondents, that tend to show any lack of compliance by Respondents with this Order.

XII.

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

- A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce documents for inspection and copying. Respondents will answer interrogatories and sit for investigational hearings within 30 days of a written request from Commission staff.
- B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.
- C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the

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Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

XIII.

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

- A. Any Provision in this Order that terminates in less than 20 years;
- B. This Order's application to any Respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

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

By the Commission.

ATTACHMENT A

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

[Date]

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

[Mailing address of customer Including zip code]

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Dear [Name of customer]:

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

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

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

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

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

Sincerely,

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

Enclosure [Enclosed Order]

ATTACHMENT B

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

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

FORWARDING AND RETURN POSTAGE GUARANTEED ADDRESS CORRECTION
SERVICE REQUESTED

Analysis to Aid Public Comment

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

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

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

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.

Analysis to Aid Public Comment

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.

Analysis to Aid Public Comment

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.

Complaint

IN THE MATTER OF

**MEDTRONIC PLC,
MEDTRONIC, INC.,
AND
INTERSECT ENT, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4763; File No. 211 0184
Complaint, May 7, 2022 – Decision, June 27, 2022*

This consent order addresses the \$1.1 billion acquisition by Medtronic, Inc. of certain assets of Intersect ENT, Inc. The complaint alleges that the Acquisition violated Section 7 of the Clayton Act and that the Acquisition agreement constitutes a violation of Section 5 of the Federal Trade Commission Act by substantially lessening competition markets for balloon sinus dilation products and ear, nose, and throat (“ENT”) navigation systems in the United States. The consent order requires Respondents to divest the assets and business of Intersect’s subsidiary Fiagon AG Medical Technologies to Hemostasis, LLC.

Participants

For the *Commission*: Charles Dickinson, and Stephanie A. Wilkinson.

For the *Respondents*: Mike McFalls and Jonathan Klarfeld, Ropes & Gray LLP; Jackie Grise, Cooley LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Medtronic plc, through its subsidiary Respondent Medtronic, Inc., has entered into an agreement to acquire Respondent Intersect ENT, Inc., that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that a proceeding in respect thereof would be in the public interest, hereby issues this complaint, stating its charges as follows.

I. RESPONDENTS

1. Respondent Medtronic plc is a public limited company organized, existing, and doing business under and by virtue of the laws of Ireland, with its executive offices and principal place of business located at 20 Lower Hatch Street, Dublin 2, and its United States address for service of process is 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

2. Respondent Medtronic, Inc. (“Medtronic”), is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Minnesota, with its executive