UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FEDERAL TRADE COMMISSION, Plaintiff, v. NEORA, LLC, formerly known as NERIUM INTERNATIONAL, LLC, a Texas limited liability company, SIGNUM BIOSCIENCES, INC., a Delaware corporation, SIGNUM NUTRALOGIX, a Delaware corporation and subsidiary of SIGNUM BIOSCIENCES, INC., and JEFFREY OLSON, individually and as Chief Executive Officer of NEORA, LLC, formerly known as NERIUM INTERNATIONAL, LLC, Defendants.	)	Case No. 19-19699

STIPULATED ORDER FOR PERMANENT INJUNCTION AS TO DEFENDANTS SIGNUM BIOSCIENCES, INC., AND SIGNUM NUTRALOGIX

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed its Complaint For Permanent Injunction and Other Equitable Relief ("Complaint"), pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission and Defendants Signum Biosciences, Inc., and Signum Nutralogix (collectively, "Stipulating Defendants"), stipulate to the entry of this Stipulated Order for Permanent Injunction ("Order") to resolve all matters in dispute in this action between them.

THEREFORE, IT IS ORDERED as follows:

FINDINGS

1. This Court has jurisdiction over this matter.

2. The Complaint charges that Stipulating Defendants participated in deceptive acts or practices that violate Section 5 of the FTC Act, 15 U.S.C. § 45(a) by:

a. making false, misleading, or unsubstantiated health claims about eicosanoyl-5-hydroxytryptamide ("EHT") and products containing EHT; and

b. making false claims that scientific studies prove the effects of EHT and products containing EHT.

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

4. Stipulating 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, and agree to bear their own costs and attorney fees.

5. Stipulating Defendants waive all rights to appeal or otherwise challenge or contest the validity of this Order.

DEFINITIONS

For purposes of this Order, the following definitions apply:

1. "**Covered Product**" means any Dietary Supplement, Food, or Drug, and includes Nerium EHT, ME Sports, and EHT or any product purporting to contain EHT.

2. "**Dietary Supplement**" means: (a) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (b) 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.

3. "**Defendants**" means all of the Defendants, individually, collectively, or in any combination.

4. "**Stipulating Defendants**" means Signum Biosciences, Inc., Signum Nutralogix, and their successors and assigns.

5. "**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 subsection (a), (b), or (c); but does not include devices or their components, parts, or accessories.

6. "**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 relevant 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.

7. "**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.

I. PROHIBITED REPRESENTATIONS REGARDING HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

IT IS ORDERED that Stipulating Defendants, Stipulating Defendants' officers, agents, employees, and independent contractors, 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 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 or program name, endorsement, depiction, or illustration, any representation that such product:

A. cures, mitigates, or treats Alzheimer's, Parkinson's disease, or brain injury or

diseases, including Chronic Traumatic Encephalopathy;

B. prevents, lowers the risk of, or treats concussions; or

C. 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 the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II. PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Stipulating Defendants, Stipulating Defendants' officers, agents, employees, and independent contractors, 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 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 or program name, endorsement, depiction, or illustration, any representation, other than representations covered under the section of this Order entitled "Prohibited Representations Regarding Health-Related Claims Requiring Human Clinical Testing for Substantiation," about the health benefits, performance, or efficacy of any Covered Product, including any representation that such product lowers the risk of or prevents Alzheimer's, Parkinson's disease, brain injury or diseases, including Chronic Traumatic Encephalopathy, or any other 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 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 the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. PROHIBITED REPRESENTATIONS REGARDING TESTS, STUDIES, OR OTHER RESEARCH

IT IS FURTHER ORDERED that Stipulating Defendants, Stipulating Defendants' officers, agents, employees, and independent contractors, 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 labeling, advertising, promotion, offering for sale, sale, or distribution of any product are permanently restrained and enjoined from misrepresenting, or assisting others in misrepresenting, expressly or by implication, including through the use of any product name, endorsement, depiction, or illustration:

A. That any Covered Product is scientifically or clinically proven to lower the risk of, prevent, cure, mitigate, or treat any disease, including Alzheimer's, Parkinson's disease, or brain injury or diseases, including Chronic Traumatic Encephalopathy;

B. That any Covered Product is scientifically or clinically proven to lower the risk of, prevent, or treat concussions;

C. That the performance or benefits of any product are scientifically or clinically proven or otherwise established; or

D. The existence, contents, validity, results, conclusions, or interpretations of any

test, study, or other research.

IV. 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 Stipulating Defendants rely to substantiate any claim covered by this Order, Stipulating 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 Stipulating Defendant; (2) any Stipulating Defendant's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Stipulating Defendant; (4) any person or entity affiliated with or acting on behalf of any Stipulating 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 Stipulating Defendants, Stipulating 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 Stipulating Defendants' size and complexity, the nature and scope of Stipulating Defendants' activities, and the sensitivity of the personal information collected from or about the participants.

V. FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Stipulating Defendants, Stipulating Defendants' officers, agents, employees, and independent contractors, 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. COOPERATION

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

VII. ORDER ACKNOWLEDGMENTS

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

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

B. For 3 years after entry of this Order, each Stipulating Defendant, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, independent contractors, and representatives who participate in conduct related to the subject matter of the Order; 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 Stipulating Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

VIII. COMPLIANCE REPORTING

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

A. One year after entry of this Order, Stipulating Defendants must submit a compliance report, sworn under penalty of perjury: each Stipulating Defendant must: (1) 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 Stipulating

Defendant; (2) identify all of that Stipulating Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (3) 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 Defendant; (4) describe in detail whether and how that Stipulating Defendant is in compliance with each Section of this Order; and (5) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

B. For 10 years after entry of this Order, each Stipulating Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following: (1) any designated point of contact; or (2) the structure of any Stipulating Defendant or any entity that Stipulating Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

C. Each Stipulating Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Stipulating Defendant 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: *FTC v. Neora, LLC, formerly known as Nerium International, LLC*, Matter No. 1623099.

IX. RECORDKEEPING

IT IS FURTHER ORDERED that Stipulating Defendants must create certain records for 10 years after entry of the Order, and retain each such record for 5 years. Specifically, Stipulating Defendants for any business that such Defendant, individually or collectively with any other Defendant, 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;

B. personnel records showing, for each person providing services, whether as an employee or otherwise, including that person's: name; addresses; telephone numbers; job title or position; dates of service; amounts paid to or paid by such person; and (if applicable) the reason for termination;

C. 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.

X. COMPLIANCE MONITORING

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

A. Within 14 days of receipt of a written request from a representative of the Commission, each Stipulating 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. The Commission is 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, provided that Defendants, after attempting to resolve a dispute without court action, and for good cause shown, may file a motion with this Court seeking an order for one or more protections set forth in Rule 26(c).

B. For matters concerning this Order, the Commission is authorized to communicate directly with each Stipulating Defendant. Stipulating Defendants must permit representatives of the Commission to interview any employee or other person affiliated with any Stipulating Defendant who has agreed to such an interview. The person interviewed 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 Stipulating Defendants or any individual or entity affiliated with Stipulating 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.

XI. RETENTION OF JURISDICTION

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

SO ORDERED this _____ day of _____, 2019.

_____
UNITED STATES DISTRICT JUDGE

SO STIPULATED AND AGREED:

FOR PLAINTIFF:

ALDEN F. ABBOTT
General Counsel

_____ Dated: October 29, 2019
DAVID A. O'TOOLE
KATHARINE ROLLER
GUY G. WARD
Federal Trade Commission, Midwest Region
230 South Dearborn St., Room 3030
Chicago, Illinois 60604
(312) 960-5634
dotoole@ftc.gov
kroller@ftc.gov
gward@ftc.gov

Attorneys for Plaintiff
FEDERAL TRADE COMMISSION

FOR STIPULATING DEFENDANTS:

DEFENDANT SIGNUM BIOSCIENCES, INC.

By: _____ Dated: October 16th, 2019
MAXWELL STOCK, as President and Chief Executive Officer of
SIGNUM BIOSCIENCES, INC.

DEFENDANT SIGNUM NUTRALOGIX

By: _____ Dated: October 16th, 2019
MAXWELL STOCK, as Shareholder of
SIGNUM NUTRALOGIX

COUNSEL FOR STIPULATING DEFENDANTS SIGNUM BIOSCIENCES, INC. AND SIGNUM NUTRALOGIX

_____ Dated: Oct. 17, 2019

J. Kathleen ("Katie") Bond
Jennifer M. Adams
Amin Talati Wasserman, LLP
1101 30th Street, N.W.
Suite 500
Washington, D.C. 20007
(202) 496-4966
katie@amintalati.com
jennifer@amintalati.com