IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Federal Trade Commission, Plaintiff, vs. TriVita, Inc., et al., Defendants.	No. CV-14-01557-PHX-SPL **ORDER ON STIPULATION FOR PERMANENT INJUNCTION, OTHER EQUITABLE RELIEF, AND MONETARY JUDGMENT**

Before the Court is the parties' Stipulation (Doc. 2). On July 10, 2014, Plaintiff Federal Trade Commission ("Commission" or "FTC") filed a Complaint (Doc. 1), seeking permanent injunction and other equitable relief pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). In their Stipulation, the parties jointly move for entry of their proposed stipulated order which resolves all matters in this action. Upon consideration of the parties' stipulation,

IT IS ORDERED that the Stipulation (Doc. 2) is **GRANTED**.

IT IS FURTHER ORDERED that the parties' proposed stipulated order (Doc. 2-1) is **adopted**, and the Court orders as follows:

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,

in the advertising, marketing, and sale of a product, which purports to relieve pain, improve breathing, and treat other health conditions.

3. 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, Defendants admit the facts necessary to establish jurisdiction.

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

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

DEFINITIONS

6. "Adequate and well-controlled human clinical study" means a human clinical study that is randomized, double-blind, placebo-controlled, and conducted by persons qualified by training and experience to conduct such study.

7. "Corporate Defendants" means TriVita, Inc. ("TriVita") and Ellison Media Company ("Ellison Media), and their successors and assigns.

8. "Covered Product" means any food, drug, or dietary supplement, including but not limited to, Nopalea, Nopalea Daily Cleanse, and any other food, drug, or dietary supplement containing Nopal cactus or its components.

9. "Defendants" means all of the Individual Defendants and the Corporate Defendants, individually, collectively, or in any combination.

10. "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.

11. "Individual Defendants" means Michael R. Ellison and Susan R. Ellison.

12. "Reliably Reported," for a human clinical test or study ("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.

PERMANENT INJUCTION AND OTHER EQUITABLE RELIEF

I. PROHIBITED REPRESENTATIONS

Defendants, Defendants' officers, agents, servants, employees, and attorneys, 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, in or affecting commerce, are hereby **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 that such product:

A. Significantly reduces or eliminates the effects of inflammation on the body;

B. Provides significant relief from pain, including but not limited to, chronic pain, joint pain, back pain, nerve pain, phantom pain, and pain from inflammation, arthritis, fibromyalgia, surgical procedures, or other conditions;

C. Significantly reduces or relieves swelling of joints and muscles;

D. Significantly improves breathing or provides significant relief from respiratory conditions, including, but not limited to, sinus infections; or

E. Provides significant relief from skin conditions, including, but not limited to, psoriasis;

unless the representation is non-misleading and, at the time of making such representation, Defendants possess and rely upon competent and reliable scientific evidence to substantiate 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 field, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing shall: (1) be randomized, double-blind, and placebo-controlled; and (2) be 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 relevant 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. Defendants shall have the burden of proving that a product satisfies the definition of an Essentially Equivalent Product.

II. PROHIBITED REPRESENTATIONS REGARDING OTHER HEALTH-RELATED CLAIMS

Defendants, Defendants' officers, agents, servants, employees, and attorneys, 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, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation, other than representations covered under Section I of this Order, about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, Defendants possess and rely

upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, 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 qualified persons; (2) that are generally accepted in the profession to yield accurate and reliable results; and (3) as to which, when they 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 are available for inspection and production to the Commission.

III. PROHIBITED REPRESENTATIONS REGARDING TESTS OR STUDIES

Defendants and Defendants' officers, agents, servants, employees, and attorneys, 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, promoting, offering for sale, or sale of any Covered Product, in or affecting commerce, are hereby **permanently restrained and enjoined** from misrepresenting, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration:

A. The existence, contents, validity, results, conclusions, or interpretations of any test or study, in connection with any representations covered by Sections I and II of this Order; or

B. That the benefits of the product are scientifically proven.

IV. PROHIBITED REPRESENTATIONS REGARDING ENDORSEMENTS

Defendants and Defendants' officers, agents, servants, employees, and attorneys, 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, promoting, offering for sale, or sale of any Covered Product, are **permanently restrained and enjoined** from making, or assisting others in making, directly or indirectly, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation about any user or endorser of any Covered Product unless they disclose, clearly and prominently, any material connection between such user or endorser and any Defendant, and any material connection between such user or endorser and any other individual or entity manufacturing, advertising, promoting, offering for sale, selling, or distributing such product. For purposes of this Section, a "material connection" shall mean any relationship that materially affects the weight or credibility of the user testimonial or endorsement and that would not reasonably be expected by consumers, including, but not limited to, monetary payments and the provision of goods, services, or other benefits to anyone providing a user testimonial or endorsement.

V. FDA-APPROVED CLAIMS

A. Nothing in this Order shall prohibit Defendants from making any representation for any product that is specifically permitted 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; and

B. Nothing in this Order shall prohibit Defendants from making any representation for any drug that is permitted in the 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.

VI. MONETARY JUDGMENT AND CONSUMER REDRESS

A. **Judgment in the amount of $3,500,000 is entered in favor of the Commission against Defendants, jointly and severally, as equitable monetary relief.**

B. Defendants shall pay to the Commission $3,500,000, which, as Defendants stipulate, their counsel shall hold in escrow for no purpose other than payment to the

Commission. Such payment must be made within **seven (7) days** of entry of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

C. 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.

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

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

F. Defendants acknowledge that their Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendants must submit to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

G. 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 Commission may apply any remaining money for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Defendants' practices alleged in the Complaint. Any money not used for such equitable relief shall be deposited to the U.S. Treasury as disgorgement. Defendants shall

have no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

VII. CUSTOMER INFORMATION

Defendants, Defendants' officers, agents, servants, employees, and attorneys, 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 and indirectly, 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.

VIII. PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

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, but not necessarily limited to:

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, but not limited to, 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 contracts and communications between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement shall not apply to a Reliably Reported test, unless the test was conducted, controlled, or sponsored, in whole or in part (1) by any Defendant, or any person or entity affiliated with or acting on behalf of any Defendant, including officers, agents, representatives, and employees, or by any other person or entity in active concert or participation with any Defendant ("Defendant's affiliates"), (2) by the supplier or manufacturer of the product at issue, or (3) by a supplier to any Defendant, to Defendant's affiliates, or to the product's manufacturer of any ingredient contained in such product.

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 shall be documented in writing and shall contain administrative, technical, and physical safeguards appropriate to Defendants' size and complexity, the nature and scope of Defendants' activities, and the sensitivity of the personal information collected from or about the participants.

IX. ORDER ACKNOWLEDGMENTS

Defendants shall acknowledge receipt of this Order as follows:

A. Each 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 **5 years** after entry of this Order, each Individual Defendant for any business that such Defendant, individually or collectively with any other Defendant, is the majority owner or controls directly or indirectly, and each Corporate Defendant, must

deliver a copy of this Order to: (1) all principals, officers, directors, and corporation managers and members; (2) all employees, agents, distributors, and representatives who participate in the marketing, distribution, offering for sale, or sale of any Covered Product; 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.

X. COMPLIANCE REPORTING

Defendants shall make timely submissions to the Commission as follows:

A. **One year** 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 representatives of the Commission may use to communicate with Defendants; (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 products offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant ; (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 the Commission;
2. Additionally, each 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 **20 years** following 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; or (b) the structure of any Corporate Defendant or any entity that 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.
2. Additionally, each Individual Defendant must report any change in: (a) name, including aliases or fictitious name, or residence address; or (b) title or role 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 Internet address of the business or entity.
3. Each Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or any similar proceeding by or against such Defendant within **14 days** of its filing.
4. 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.

5. 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. TriVita, Inc. et al.*, File No. 1223185.

XI. RECORDKEEPING

Defendants shall create certain records for **twenty (20) years** after entry of the Order, and retain each such record for **five (5) years**. Specifically, TriVita and each Individual Defendant for any business in which that Defendant, individually or collectively with any other Defendants, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. Accounting records showing the revenues from all products sold;

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

C. Records of all consumer complaints and refund requests concerning the subject matter of this Order, 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.

XII. COMPLIANCE MONITORING

For the purpose of monitoring Defendants' compliance with this Order and any failure to transfer any assets as required by this Order:

A. Within **14 days** of receipt of a written request from a representative of the

Commission, each Defendant shall: 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.

B. For matters concerning this Order, the Commission is authorized to communicate directly with each Defendant. Defendant must permit representatives of the Commission 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. The Commission may use all other lawful means, including posing, through its 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.

XIII. RETENTION OF JURISDICTION

This Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

IT IS FURTHER ORDERED that the Clerk of Court shall enter judgment accordingly and terminate this action.

Dated this 11th day of July, 2014.

Honorable Steven P. Logan
United States District Judge