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.

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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;

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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 REDtnistratiopwS0 TD.00V. FDA

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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.

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; test; source documents 30jc-.0002 .saints v

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 fro

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

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 prescri