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text or other visual elements so that it is easily noticed, read, and understood;

c. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it;

d. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable;

e. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears;

f. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications;

g. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication; and

h. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, "ordinary consumers" includes reasonable members of that group.

6. "Close Proximity" means on the same print page, webpage, or other electronic page, and proximate to the triggering representation, and not accessed or displayed through hyperlinks, pop-ups, interstitials, or other means.

7. "Covered Product" means any dietary supplement, food, or drug, including, but not limited to, Amberen.

8. "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 is 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.

9. "Endorsement" means as defined in 16 C.F.R. § 255.0(b).

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. "Food" and "drug" mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

12. "Material connection" means any relationship that materially affects the weight or credibility of any endorsement and that would not reasonably be expected by consumers.

13. "Person" means a natural person, an organization, or other legal entity, including a corporation, partnership, sole proprietorship, limited liability company, association, cooperative, or any other group or combination acting as an entity.

14. "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.

ORDER

PROHIBITED REPRESENTATIONS: WEIGHT-LOSS AND MENOPAUSE-RELATED CLAIMS

I. IT IS ORDERED that Defendants, Defendants' 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 the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, 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. Causes weight loss;

B. Causes sustained weight loss;

C. Causes loss of belly fat;

D. Boosts metabolism;

E. Relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause; or

F. Cures, mitigates, or treats, any disease;

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 substantiates 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 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 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.

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C. The Commission's agreement to the suspension of part of the judgment is expressly premised upon the truthfulness, accuracy, and completeness of Defendants' sworn financial statements and related documents (collectively, "financial attestations") submitted to the Commission, namely:

1. The Financial Statement of Individual Defendant Donna Kasseinova signed on November 23, 2015;

2. The Financial Statement of Individual Defendant Roman Trunin signed on November 23, 2015;

3. The Financial Statement of Individual Defendant Emil Arutyunov, signed on November 23, 2015; and

4. The Financial Statement of Corporate Defendant Lunada Biomedical, Inc., signed by Roman Trunin, Chief Executive Officer, on December 9, 2015, including the following attachments thereto:

a. Lunada Biomedical 2014 U.S. Income Tax Return for an S Corporation, with attached schedules;

b. Lunada Biomedical Balance Sheet (as of Dec. 31, 2014);

c. Lunada Biomedical Balance Sheet (as of Nov. 30, 2015);

d. Lunada Biomedical Statement of Profit and Loss (Jan. – Dec. 2014);

e. Lunada Biomedical Statement of Profit and Loss (Jan. – Nov. 2015);

f. Lunada Biomedical Statement of Cash Flows (Jan. – Dec. 2014);

g. Lunada Biomedical Statement of Cash Flows (Jan. – Nov. 2015); and

h. Lunada Biomedical Bank of America Combined Statement (Nov. 1, 2015 – Nov. 30, 2015).

D. The suspension of the judgment will be lifted as to any Defendant if, upon motion by the Commission, the Court finds that Defendant failed to disclose any material asset, materially misstated the value of any asset, or made any other material misstatement or omission in the financial attestations identified above.

E. If the suspension of the judgment is lifted, the judgment becomes immediately due as to that Defendant in the amount specified in Subsection A above (which the parties stipulate only for purposes of this Section represents the consumer injury alleged in the Complaint), less any payment previously made pursuant to this Section, plus interest computed from the date of entry of this Order.

F. 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.

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

H. 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 will have collateral estoppel effect for such purposes.

I. Defendants acknowledge that their Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendants previously submitted to the Commission, may be used for collecting and reporting on any delinquent a167 0 cT.3242 TwlinqsJ-1-17

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 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.

CUSTOMER INFORMATION

COMPLIANCE REPORTING

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

A. One hundred twenty days 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 Defendant; (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 goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant (which Individual Defendants must descri

1. Each Defendant must report

RECORDKEEPING

XII. IT IS FURTHER ORDERED that Defendants must create certain records for 10 years after entry of the Order, and retain each such record for 5 years. Specifically, Corporate Defendant in connection with the marketing and sale of any dietary supplement, food, or drug, and each Individual Defendant in connection with the marketing and sale of any dietary supplement, food, or drug 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, that person's: name; addresses; 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, whether received directly or indirectly, such as

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 of the protections set forth in Rule 26(c).

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.

RETENTION OF JURISDICTION

XIV. 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 25th day of May, 2016.

_____

Michael W. Fitzgerald

SO STIPULATED AND AGREED:

FOR PLAINTIFF:

_____ Dated: _____

MICHAEL J. DAVIS
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_____ Dated: _____

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6733 S. Sepulveda Blvd.,
Los Angeles, CA 90045

_____ Dated: _____

ROMAN TRUNIN, individually and
as an officer of LUNADA BIOMEDICAL, INC.
6733 S. Sepulveda Blvd.
Los Angeles, CA 90045

_____ Dated: _____

EMIL ARUTYUNOV, a/k/a EMIL CHIABERI,
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_____ Dated: _____

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