

adjudication of any issue of law or fact. Wherefore, the parties request the Court to enter a Stipulated Judgment for Permanent Injunction and Other Equitable Relief in the form of Exhibit 1. A proposed order will be submitted by email.

Respectfully submitted,

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ATTORNEYS FOR DEFENDANTS

^{1/} Licensed to practice law in the Commonwealth of Virginia and the District of Columbia. Not licensed to practice law in the State of Colorado and not a member of the United States District Court for the Western District of Missouri. Application to appear *pro hac vice* before this Court will be filed contemporaneously with this Motion.

EXHIBIT 1

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 labeling, advertising, marketing, distribution, and sale of: Photodynamic Therapy Liquid Red Light Anti-Aging Lotion with Broad Spectrum SPF 30; Photodynamic Therapy Liquid Red Light Eye Lift Lotion; and Shrinking Beauty Firming, Sculpting & Toning Lotion with Lobster Weight Loss Inspired Technology.
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. The parties waive all rights to appeal or otherwise challenge or contest the validity of this Order.

DEFINITIONS

For the purpose of this Order:

1. “Advertising” and “promotion” mean any written or verbal statement, illustration, or depiction designed to effect a sale or create interest in the purchasing of products or services, whether it appears in a brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, free standing insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable

television, audio program transmitted over a telephone system, program-length commercial (“infomercial”), the Internet, email, press release, video news release, or in any other medium.

2. “Commerce” means as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

3. “Corporate Defendant” means DERMAdoctor, Inc., and its successors and assigns.

4. “Cosmetic” and “drug” mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

5. “Covered Product” means any cosmetic or drug. Covered Product does not include any products discussed between Defendant Kunin and individual patients in the course of her professional medical practice, so long as such products are not manufactured or marketed to the general public by any Defendant or an entity that is majority owned or controlled by any Defendant.

6. “Defendants” means the Individual Defendant and the Corporate Defendant, individually, collectively, or in any combination.

7. “Endorsement” means as defined in 16 C.F.R. § 255.0(b).

8. “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.

9. “Individual Defendant” means Audrey Kunin, M.D.

10. “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.

11. “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.

12. The term “including” in this Order means “including without limitation.”

13. The terms “and” and “or” in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

ORDER

I.

PROHIBITED REPRESENTATIONS: WEIGHT-LOSS CLAIMS

IT IS ORDERED that 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 that such product:

- A. Causes weight loss; or
- B. Reduces body size;

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 at least two adequate and well-controlled human clinical studies of the Covered Product, or of an Essentially Equivalent Product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true. Defendants shall have the burden of proving that a product satisfies the definition of Essentially

any Covered Product, are permanently restrained and enjoined from making, or assisting others

III.

PROHIBITED REPRESENTATIONS REGARDING TESTS OR STUDIES

IT IS FURTHER ORDERED that 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 misrepresenting, or assisting others in misrepresenting, in any manner, expressly or by implication, including through the use of any product name, endorsement, depiction, or illustration:

- A. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or research; or
- B. That the benefits of such product are scientifically proven.

IV.

FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order shall prohibit Defendants from:

- A. Making any representation for any drug that is permitted in labeling for such drug under any tentative or final monograph promulgated by the Food and Drug Administration, or

V.

MONETARY JUDGMENT

IT IS FURTHER ORDERED that:

A. Judgment in the amount of EIGHT HUNDRED FORTY-THREE THOUSAND, NINE HUNDRED AND NINETY-SIX DOLLARS (\$843,996) is entered in favor of the Commission against Defendants, jointly and severally, as equitable monetary relief.

B. Defendants are ordered to pay to the Commission TWELVE THOUSAND, SIX HUNDRED AND SEVENTY-FIVE DOLLARS (\$12,675), which, as Defendants stipulate, their undersigned counsel holds in escrow for no purpose other than payment to the Commission. Such payment must be made within ten (10) days of entry of this Order by electronic fund transfer in accordance with instructions previously provided by a representative of the Commission. Upon such payment, the remainder of the judgment is suspended, subject to the Subsections below.

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 representations") submitted to the Commission, namely:

1. the Financial Statement of Individual Defendant Audrey Kunin signed on August 8, 2014, including the attachments;
2. the Financial Statement of Corporate Defendant DERMAdoctor, Inc., signed by Audrey Kunin, President, on August 8, 2014, including the attachments; and

money not used for such equitable relief is to be deposited to the U.S. Treasury as disgorgement. Defendants have no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

B. 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.

C. 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, including in a proceeding to enforce its rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

D. 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.

B. For five years after entry of this Order, the Individual Defendant, or any business that such Defendant, individually or collectively with the Corporate Defendant, is the majority owner or directly or indirectly controls, and where such business engages in the conduct related to the subject matter of the Order, and the Corporate Defendant must deliver a copy of this Order to: (1) all principals, officers, directors, and managers; (2) all employees, agents, and representatives who have managerial responsibilities with respect to the subject matter of the

and, if available, the telephone number and email address; and (2) be accompanied by a sworn affidavit attesting to its accuracy.

B. Within forty-five (45) days after the date of service of this Order, Defendants shall send by first-class mail, postage paid and return receipt requested, or by courier service with signature proof of delivery, an exact copy of the notice attached as Attachment A, showing the date of mailing, to all wholesalers, distributors, resellers, or retailers identified pursuant to Section IX.A. The notice required by this Section shall include a copy of this Order, but shall not include any other document or enclosure, and shall be sent to the principal place of business of each wholesaler, distributor, reseller, or retailer.

IX.

COMPLIANCE REPO

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, Defendant Kunin must: (a) identify all telephone numbers and all email, Internet, physical, and postal addresses, including all residences; (b) identify all titles and roles in all business activities, including any business for which Defendant Kunin performs services whether as an employee or otherwise and any entity in which Defendant Kunin has any ownership interest; and (c) describe in detail her involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For ten (10) years following entry of this Order, each Defendant must submit a compliance notice, sworn under penalty of perjury, within fourteen 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 the Corporate Defendant or any entity that Defendant has any ownership interest in or directly or indirectly controls that may affect compliance obligations arising under this Order, including: the 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, Defendant Kunin 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 Defendant Kunin performs services, whether as an employee or otherwise, and any entity in which Defendant Kunin has: (i) any ownership interest; and (ii) of which Defendants have direct or indirect control; and identify its name, physical address, and Internet address, if any.

C. 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 fourteen (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, D.C. 20580. The subject line must begin: FTC v. DERMAdoctor, Inc., et al. **[insert X number]**.

X.

RECORDKEEPING PROVISIONS

IT IS FURTHER ORDERED that Defendants must create certain records for ten (10) years after entry of the Order, and retain each such record for five (5) years. Specifically, the Corporate Defendant; and Defendant Kunin for any business, excluding any private medical practice owned by Defendant Kunin, in which Defendant Kunin, individually or collectively with the Corporate Defendant, is a majority owner or directly or indirectly controls; must maintain the following records:

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 by: (1) any Defendant; (2) any Defendant's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Defendant; (4) any person or entity affiliated with or acting on behalf of any 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 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.

XII.

XIII.

RETENTION OF JURISDICTION

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

ATTACHMENT A
[To be printed on DERMAdoctor, Inc.'s letterhead]

[Date]

[Notice recipient's name]

[Notice recipient's address]

Dear Seller of DERMAdoctor products:

DERMAdoctor recently settled a civil dispute with the Federal Trade Commission (FTC) involving advertising claims for our (1) Photodynamic Therapy Liquid Red Light Anti-Aging Lotion with Broad Spectrum SPF 30; (2) Photodynamic Therapy Liquid Red Light Eye Lift Lotion; and (3) Shrinking Beauty Firming, Sculpting & Toning Lotion with Lobster Weight Loss Inspired Technology. Although we neither admit nor deny that the FTC's allegations are true, we have agreed to notify our distributors as part of the settlement.

Pursuant to the settlement, we have agreed that, unless we have competent and reliable