UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

FEDERAL TRADE COMMISSION, Plaintiff, v. DERMAdoctor, Inc., a corporation, and AUDREY KUNIN, M.D., individually and as an officer of DERMAdoctor, Inc., Defendants.	)	Case No. _____

JOINT MOTION TO ENTER STIPULATED JUDGMENT FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), has filed a Complaint for Permanent Injunction and Other Equitable Relief against defendants DERMAdoctor, Inc., and Audrey Kunin, M.D. (collectively, "defendants"), pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), alleging unfair or deceptive acts or practices and false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

The Commission and defendants, having been represented by counsel and acting by and through such counsel, have consented to the entry of a Stipulated Judgment for Permanent Injunction and Other Equitable Relief in the form of Exhibit 1, attached hereto, without a trial or

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,

JONATHAN NUECHTERLEIN
General Counsel

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[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 Equivalent Product.

For purposes of this Section, "adequate and well-controlled human clinical study" means a human clinical study that is (1) randomized, double-blind, and placebo-controlled; (2) conducted by persons qualified by training and experience to conduct such a study; and (3) as to which, all underlying or supporting data and documents generally accepted by experts in weight loss research 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.

II.

OTHER PROHIBITED REPRESENTATIONS

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 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. Transforms UV light into visible red light that has anti-aging effects on skin;

B. Provides anti-aging results equivalent to those provided by: laser treatments or intense pulsed light treatments provided in a physician's office, in-home visible red light devices, prescription treatments, or a surgical procedure; or

C. Reduces or eliminates cellulite;

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 field, 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

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 under any new drug application approved by the Food and Drug Administration; and

B. 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.

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

3. the additional documentation submitted by letter from Defendants' counsel David A. Zetoony and Joshua A. James to Commission counsel Christine DeLorme, dated July 22, 2014; July 24, 2014; August 8, 2014; August 11, 2014; and August 19, 2014; including all attachments thereto.

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 representations 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.

VI.

ADDITIONAL MONETARY PROVISIONS

IT IS FURTHER ORDERED that:

A. 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 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.

E. 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 amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

VII.

ORDER ACKNOWLEDGMENTS

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

A. Each Defendant, within seven (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 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 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 seven days of entry of this Order for current personnel. To all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Defendant delivered a copy of this Order, that Defendant must obtain, within thirty (30) days, a signed and dated acknowledgment of receipt of this Order.

VIII.

NOTICE TO RETAILERS AND DISTRIBUTORS

IT IS FURTHER ORDERED that:

A. Within thirty (30) days after the date of service of this Order, Defendants shall deliver to the Commission a searchable electronic file containing the name and contact information of all wholesalers, distributors, resellers, or retailers who have purchased: (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 from Defendants. Such file shall: (1) include each wholesaler, distributor, reseller, or retailer's name and address,

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 REPORTING

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

A. Ninety (90) 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 that Defendant; (b) identify all of that Defendant's businesses by all of their names, telephone numbers, and email, Internet, physical, and postal addresses; (c) describe the activities of each business, including the products and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant (which Defendant Kunin must describe if she knows or should know due to her own involvement); (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, 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:

A. Accounting records showing the revenues from all products or services sold, all costs incurred in generating those revenues, and the resulting net profit or loss;

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, 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 advertisement or other marketing material.

XI.

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 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 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.

COMPLIANCE MONITORING

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

A. Within fourteen (14) days of receipt of a written request from a representative of the Commission, each 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 also is 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 through undersigned counsel or other counsel designated by a Defendant or, if Defendant is unrepresented by counsel with regard to this Order, directly with that Defendant. Each Defendant must permit representatives of the Commission to interview any employee or other person affiliated with such 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

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 scientific evidence, we will not make claims in our advertising or promotional materials that our products:

- Transform UV light into visible red light that has anti-aging effects on skin;

- Give users anti-aging results equivalent to those provided by laser or intense pulsed light treatments available in a physician's office, in-home visible red light devices, prescription treatments, or a surgical procedure;

- Cause weight loss or reduce body size, including by up to one inch in two weeks, or reduce or eliminate cellulite; or

- Are clinically proven to work.

This letter has been provided for your files. We have enclosed a copy of the court order in this case, and you can find more information at [URL].

Sincerely,

Audrey Kunin, M.D.
President, DERMAdoctor, Inc.

Enclosure