

DEBRA A. VALENTINE  
General Counsel

DARREN A. BOWIE  
SARAH L. KNAPP  
Federal Trade Commission  
600 Pennsylvania Ave., NW, Rm S-4002  
Washington, DC 20580  
(202) 326-2018, - 2619  
(202) 326-3259 (facsimile)  
DAB-1003  
SLK-6862

Local Counsel  
MICHAEL A. CHAGARES  
Chief, Civil Division  
United States Attorney, District of New Jersey  
970 Broad Street, Suite 700  
Newark, NJ 07102  
(973) 645-2839  
MC-5483

Attorneys for Plaintiff

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

FEDERAL TRADE COMMISSION,

~~Plaintiff~~

Hon. *WGB*

Civil Action No. *003174*

v.

LANE LABS-USA, INC.,  
CARTILAGE CONSULTANTS, INC.,  
I. WILLIAM LANE, AND ANDREW J. LANE,

STIPULATED FINAL ORDER FOR  
PERMANENT INJUNCTION AND  
SETTLEMENT OF CLAIMS FOR  
MONETARY RELIEF AS TO  
LANE LABS-USA, INC. AND  
ANDREW J. LANE

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), filed a Complaint for permanent injunction and other relief against Lane Labs-USA, Inc. and Andrew J. Lane, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). Defendants deny the allegations in the Complaint, except jurisdictional facts, but are willing to agree to the entry of the following Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief ("Order").

The Commission and defendants have stipulated to the entry of the following Order in settlement of the Commission's Complaint against defendants. The Court, being advised in the premises, finds:

#### FINDINGS

1. This Court has jurisdiction over the subject matter of this case and jurisdiction over all parties. Venue in the District of New Jersey is proper.
2. The Complaint states a claim upon which relief can be granted, and the Commission has authority to seek the relief it has requested.
3. The activities of defendants are in or affecting commerce, as defined in 15 U.S.C. § 44.
4. Defendants waive all rights to seek judicial review or otherwise challenge or contest the validity of this Order. Defendants also waive any claim that they may have held under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action to the date of this Order.
5. This action and the relief awarded herein are in addition to, and not in lieu of, other remedies as may be provided by law.

6. Each party shall bear its own costs and attorneys' fees.
7. Entry of this Order is in the public interest.
8. Pursuant to Federal Rule of Civil Procedure 65(d), the provisions of this Order are binding upon defendants, and their officers, agents, servants, employees and all other persons or entities in active concert or participation with them, who receive actual notice of this Order by personal service or otherwise.

### **DEFINITIONS**

For the purposes of this Order, the following definitions shall apply:

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
2. "Cancer" shall mean any malignant growth or tumor, or any disease or condition characterized by such growths.
3. Unless otherwise specified, "defendants" shall mean:
  - A. Lane Labs USA-Inc. ("Lane Labs"), its divisions and subsidiaries, including CompassioNet, its successors and assigns, and its officers, agents, representatives and employees; and
  - B. Andrew J. Lane, individually and in his capacity as a director or officer of Lane Labs; and
  - C. Each of the foregoing, and any combination of the foregoing.

4. "Distributor" shall mean any purchaser or other transferee of any product covered by this Order who acquires such product from defendants, with or without valuable consideration, and who is known by defendants to have sold or offered to sell such product to other sellers or to consumers, including but not limited to individuals, retail stores, or catalogs.

5. "Food" and "drug" shall mean "food" and "drug" as defined in Section 15 of the FTC Act, 15 U.S.C. § 55(b)-(c).

6. "Glycoalkaloid product" shall mean any product containing glycoalkaloids from any source, chemical or natural, or containing an extract of any plant from the Solanum or nightshade family.

7. "Metatag" shall mean any word or words embedded in the source code of an Internet web site that may be used by an Internet search engine in indexing web sites for the purpose of selecting sites in response to an Internet user's search request.

8. "Shark cartilage product" shall mean any product containing shark cartilage in any form.

9. "Skin cancer" shall mean any benign or malignant tumorous skin lesions, or any disease or condition characterized by such lesions, including melanoma, basal cell and squamous cell carcinoma, keratosis and keratoacanthoma.

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10. "Employment" shall mean any affiliation with any business, non-profit, or government entity, including the performance of services as an officer, owner, manager, supervisor, employee, consultant, or independent contractor; and "Employer" shall mean any and all individuals or entities for whom any defendant performs services as an employee, consultant, or independent contractor.

11. A requirement that any defendant "notify the Commission" shall mean that the defendant shall send the necessary information via first-class mail, costs prepaid, to the Associate Director for Advertising Practices, Federal Trade Commission, 600 Pennsylvania Ave., N.W., Washington, D.C. 20580. Attn: FTC v. Lane Labs-USA, Inc. et al., (D.N.J.).

12. The term "including" in this Order shall mean "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.

## CONDUCT PROHIBITIONS

### I.

IT IS HEREBY ORDERED that defendants, directly or through any corporation, subsidiary, division, or other device, and their officers, agents, servants, employees and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of BeneFin or any other shark cartilage product shall not represent in any manner, including by means of metatags, expressly or ~~by implication, that such product prevents, treats or cures cancer unless, at the time the~~ representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that defendants, directly or through any corporation, subsidiary, division, or other device, and their officers, agents, servants, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of SkinAnswer or any other glycoalkaloid product shall not represent, in any manner, including by means of metatags, expressly or by implication, that such product prevents, treats or cures skin cancer unless, at the time the representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that defendants, directly or through any corporation, subsidiary, division, or other device, and their officers, agents, servants, employees and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, dietary supplement, or drug, shall not make any representation, in any manner, including by means of metatags, expressly or by implication, about the effect of such product on any disease or disorder, or the effect of such product on the structure or function of the human body, or about any other health benefits of such product, unless, at the time the representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV.

IT IS FURTHER ORDERED that defendants, directly or through any corporation, subsidiary, division, or other device, and their officers, agents, servants, employees and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, dietary supplement, or drug, shall not, in any manner, expressly or by implication, misrepresent the existence, contents, validity, results, conclusions, or interpretations of any test, study or research.

V.

IT IS FURTHER ORDERED that defendants, directly or through any corporation, subsidiary, division, or other device, and their officers, agents, servants, employees and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, dietary supplement, or drug, shall not use the name of any government agency or health organization in such a manner as to state or imply that such agency or organization has evaluated the efficacy or safety of that food, dietary supplement, or drug, unless such is the case.

VI.

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 standard

promulgated by the Food and Drug Administration or under any new drug application approved by the Food and Drug Administration. Nothing in this Order shall prohibit defendants from making any representation for any product that is specifically permitted in the labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990. Nothing in this Order shall prohibit the use of a publication, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, dietary supplement, or drug, including an article, a chapter of a book, or an official abstract of a peer-reviewed scientific publication that appears as an article and was prepared by the author or editors of the publication, when its use is not false, deceptive or misleading pursuant to Sections 5(a) and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a) and 52.

VII.

IT IS FURTHER ORDERED that:

- A. Defendants shall not disseminate to any distributor any material containing any representation prohibited by this Order.
- B. Defendants shall not, directly or indirectly, authorize any distributor to make any representation prohibited by this Order.
- C. Within thirty (30) days after entry of this Order, defendant Lane Labs shall send by certified mail, return receipt requested, a notice, in the form shown on Appendix A, to each distributor with whom Lane Labs has done business since January 1, 1995, to the extent that such distributor is known to Lane Labs through



a diligent search of their records, including but not limited to computer files, sales records, and inventory lists. The mailing shall not include any other documents.

- D. For a period of three (3) years following entry of this Order, defendants shall send by certified mail, return receipt requested, a notice, in the form shown on Appendix A, to each distributor with whom defendants do business after the date of entry of this Order who has not previously received the notice. Such notice shall be sent within one (1) week from the first shipment of defendants' product to said distributor. The mailing shall not include any other documents.
- E. In the event that defendants receive any information that subsequent to receipt of the letter attached to this Order as Appendix A, any distributor is using or disseminating any advertisement or promotional material or making any oral statement that contains any representation related to BeneFin or any other shark cartilage product, or SkinAnswer or any other glycoalkaloid product, that is prohibited by Sections I and II of this Order, defendants shall promptly investigate such information and upon verification shall immediately terminate said distributor's right to market such products, and shall not reinstate such right without the express prior consent of the Commission.
- ~~F. In the event that defendants receive any information that subsequent to receipt of the letter attached to this Order as Appendix A, any distributor is using or disseminating any advertisement or promotional material or making any oral statement that contains any representation other than a representation covered under subparagraph E, above, that is prohibited by this Order, defendants shall~~

promptly investigate such information and upon verification shall immediately terminate said distributor's right to market defendants' products, and shall not reinstate such right unless said distributor provides written confirmation of permanent discontinuance of the prohibited practice and written assurance that it shall not be resumed.

### MONETARY RELIEF

#### VIII.

IT IS FURTHER ORDERED that judgment against defendant Lane Labs is hereby entered in the amount of ONE MILLION DOLLARS (\$1,000,000.00). This judgment shall be satisfied as follows:

- A. Within ten (10) days after entry of this Order, defendant Lane Labs shall transfer to the Commission the sum of FIVE HUNDRED FIFTY THOUSAND DOLLARS (\$550,000.00).
- B. Defendant Lane Labs shall use the balance of the 1,000,000 judgment set forth above, FOUR HUNDRED FIFTY THOUSAND DOLLARS (\$450,000.00), to pay for shark cartilage and placebo to be used in the National Cancer Institute - ~~Lane Labs Benefin Clinical Trial (Clinical Trials Agreement #0299)~~ ("NCI study"), or for any other expense required by the National Cancer Institute in connection with the NCI study. Defendant Andrew Lane and I. William Lane shall not receive, directly or indirectly, any funds or other assets resulting from or related to the purchase of shark cartilage and placebo for the NCI study, whether

in the form of profits, loans, or otherwise. Any funds designated in this subparagraph for the NCI study that have not been used to purchase shark cartilage, placebo or other expense required by the National Cancer Institute as set forth herein, shall be transferred to the Commission within ten (10) days of the conclusion of the NCI study.

C. In the event that the NCI study is canceled by any party other than Lane Labs, the Commission may, at its sole discretion, approve the use of the funds designated in subparagraph B for another comparable study.

D. All funds collected by the Commission pursuant to this Section shall be deposited into an account to be maintained by the Commission or its agent. Upon final disposition of this action, such funds shall be either (1) used to provide consumer redress and any administrative costs associated with providing such redress, or (2) paid to the United States Treasury as equitable disgorgement, if the Commission in its sole discretion deems that consumer redress is impractical. If the Commission in its sole discretion determines that consumer redress is practical, it shall submit a plan for the disbursement of funds to the Court for review and approval.

~~E. Defendants agree that the facts as alleged in the Commission's complaint in this~~  
action shall be taken as true solely in the event of any subsequent litigation to collect amounts due pursuant to this Order, including but not limited to a nondischargeability complaint in any bankruptcy proceeding.

## RECORD KEEPING

### IX.

IT IS FURTHER ORDERED that defendants, for a period of five (5) years after the last date of dissemination of any representation covered by this Order, shall maintain and upon request make available to the Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession, custody, or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

## MONITORING

### X.

IT IS FURTHER ORDERED that defendants, for a period of five (5) years after the date of entry of this Order, shall deliver a copy of this Order to all current and future principals, ~~officers, directors, and managers, and shall secure from each such person a signed and dated~~ statement acknowledging receipt of the Order. Defendants shall deliver this Order to current principals, officers, directors, and managers within thirty (30) days after the date of service of this Order, and to future principals, officers, directors, and managers within thirty (30) days after the person assumes such position or responsibilities. Defendants shall maintain and upon request

make available to the Commission for inspection and copying each such signed and dated statement for a period of five (5) years.

IT IS FURTHER ORDERED that defendants, for a period of five (5) years after the date of entry of this Order, shall provide a letter in the form shown on Appendix B to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this Order. Defendants shall deliver such letter to current personnel within thirty (30) days after the date of service of this Order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Defendants shall create, maintain, and upon request make available to the Commission for inspection and copying records reflecting the delivery of such letter to each such person for a period of five (5) years.

XI.

IT IS FURTHER ORDERED that defendant Lane Labs shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this Order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices ~~subject to this Order, the proposed filing of a bankruptcy petition; or a change in the corporate~~ name or address. Provided, however, that, with respect to any proposed change in the corporation about which defendants learn less than thirty (30) days prior to the date such action is to take place, defendants shall notify the Commission as soon as is practicable after obtaining such knowledge.

XII.

IT IS FURTHER ORDERED that defendant Andrew J. Lane, within five (5) days of receipt of notice of entry of this Order, shall notify the Commission of (1) his residence address and mailing address; (2) the name and address of his employer; (3) the full names of his employer's principals; (4) if applicable, the names of his supervisors, and (5) a description of his employer's activities, and his duties and responsibilities.

XIII.

IT IS FURTHER ORDERED that defendant Andrew J. Lane for a period of five (5) years after the date of entry of this Order, shall notify the Commission of (1) any changes in his residence or mailing address; (2) the discontinuance of his current business or employment; and (3) his affiliation with any new business or employment where such business or employment relates to the manufacturing, advertising, promotion, offering for sale, sale or distribution of any food, drug, or dietary supplement. Notice of affiliation with any such new business shall include: (1) the new business or employer's name and address; (2) the full names of the new business or employer's principals; (3) if applicable, the names of defendant's supervisors, and (4) a description of the new business or employer's activities, and defendant's duties and responsibilities.

XIV.

IT IS FURTHER ORDERED that defendants shall, within sixty (60) days after the date of entry of this Order, and at such other times as the Commission may reasonably require, file

with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

XV.

IT IS FURTHER ORDERED that the Commission is authorized to monitor the compliance of defendants with this Order by all lawful means, including but not limited to the following means:

- A. The Commission is authorized, without further leave of court, to obtain discovery from any person in the manner provided by Chapter V of the Federal Rules of Civil Procedure, Fed. R. Civ. P. 26-37, including but not limited to the use of compulsory process pursuant to Fed. R. Civ. P. 45, for the purpose of monitoring and investigating the compliance of defendants with this Order.
- B. Nothing in this Order shall limit 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, to investigate whether defendants have violated any provision of this Order or Sections 5 or 12 of the FTC Act, 15 U.S.C. §§ 45, 55.

~~ACKNOWLEDGMENT OF RECEIPT OF ORDER~~

XVI.

IT IS FURTHER ORDERED that within fifteen (15) business days from the receipt of notice of entry of this Order, defendant Andrew J. Lane, individually and on behalf of defendant

Lane Labs-USA, Inc., shall submit to the Commission a truthful sworn statement, in the form shown on Appendix C, that shall acknowledge receipt of this Order.

**RETENTION OF JURISDICTION**

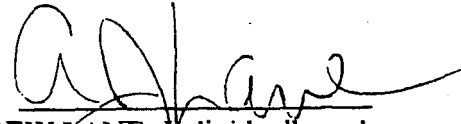
XVII.

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

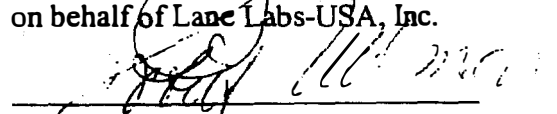
**SO STIPULATED:**



DARREN A. BOWIE  
SARAH L. KNAPP  
Federal Trade Commission  
600 Pennsylvania Ave., N.W., Rm. S-4002  
Washington, D.C. 20580  
(202) 326-2018, -2619  
(202) 326-3259 (facsimile)  
Attorneys for Plaintiff  
FEDERAL TRADE COMMISSION



ANDREW LANE, Individually and  
on behalf of Lane Labs-USA, Inc.

  
ROBERT ULLMAN  
Ullman, Shapiro & Ullman LLP  
299 Broadway, Suite 1700  
New York, NY 10007  
(212) 571-0068  
(212) 571-9424 (facsimile)  
Attorney for Defendants  
LANE LABS-USA, INC. and  
ANDREW LANE

**SO ORDERED**

DATED: September 26, 2000



UNITED STATES DISTRICT JUDGE



APPENDIX A

FIRST CLASS MAIL

[To be printed on defendants' letterhead]

[date]

Dear [distributor's name]:

[Defendant] has settled a civil dispute with the Federal Trade Commission (FTC) involving advertising claims for two products called BeneFin and SkinAnswer. As a part of the settlement, we must make sure that you comply with the settlement order, which was entered by the United States District Court for the New Jersey on \_\_\_\_\_ (date).

Among other things, the settlement with the FTC prohibits us from, among other things, making unsubstantiated claims for any food, dietary supplement, or drug, including, but not limited to, claims that such products are effective in the prevention, treatment, or cure of cancer or skin cancer.

We request your assistance by asking you NOT to use, rely on or distribute any advertising or promotional materials containing unsubstantiated claims and NOT to make unsubstantiated oral representations. Please also notify any of your retail or wholesale customers to do the same. If you or your retail or wholesale customers continue to use such materials or make such representations, we are required by the settlement to stop doing business with you.

Although we deny the FTC's allegations, we have agreed to send this letter as a part of our settlement with the FTC.

Thank you very much for your assistance,

[Defendant's signature]



**CERTIFICATE OF SERVICE**

I, Keith R. Fentonmiller, hereby certify that a copy of Notice of Re-Filing of Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief as to Lane Labs-USA, Inc. and Andrew J. Lane was served on the following via first-class mail on September 21, 2000:

ROBERT ULLMAN  
Ullman, Shapiro & Ullman LLP  
299 Broadway, Suite 1700  
New York, NY 10007

Attorney for Defendants

MICHAEL A. CHAGARES  
Chief, Civil Division  
United States Attorney, District of New Jersey  
970 Broad Street, Suite 700  
Newark, NJ 07102

Local Counsel for Plaintiff



Keith R. Fentonmiller

Certified as a true copy on  
This Date: 4/16/02  
By: Leroy Banks  
( ) Clerk  
(X) Deputy