

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

 v.

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

 Defendants.

:
: Hon.
:
: Civil Action No.

:
:
: STIPULATED FINAL ORDER FOR
 PERMANENT INJUNCTION
 AS TO CARTILAGE CONSULTANTS,
 INC., AND I. WILLIAM LANE

Plaintiff, the Federal Trade Commission (“FTC” or “Commission”), filed a Complaint for permanent injunction and other relief against Cartilage Consultants, Inc. and I. William 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. Cartilage Consultants, Inc. ("Cartilage Consultants"), its divisions and subsidiaries, its successors and assigns, and its officers, agents, representatives and employees;
 - B. I. William Lane, individually and in his capacity as a director or officer of Cartilage Consultants; 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.

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. Cartilage Consultants, 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 Cartilage Consultants shall send by certified mail, return receipt requested, a notice, in the form shown on Appendix A, to each distributor with whom Cartilage Consultants has done business since January 1, 1995, to the extent that such distributor is known to

Cartilage Consultants 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.

VIII.

IT IS FURTHER ORDERED that defendant 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 by Lane Labs-USA for use in the National Cancer Institute - Lane Labs Benefin Clinical Trial (Clinical Trials Agreement #0299) , whether in the form of profits, loans, or otherwise.

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 Cartilage Consultants 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 I. William 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 defendants I. William 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 I. William Lane, individually and on behalf of defendant Cartilage Consultants, 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.

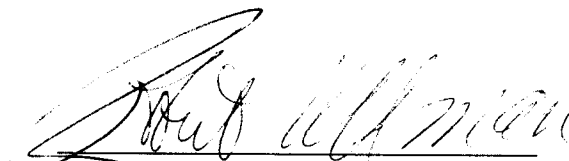
SO STIPULATED:


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



I. WILLIAM LANE, Individually,
and on behalf of Cartilage
Consultants 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
CARTILAGE CONSULTANTS,
INC. AND I. WILLIAM LANE

SO ORDERED

DATED: _____

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 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]

APPENDIX B

[To be printed on defendants' letterhead]

[date]

Dear [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.

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

Thank you very much for your assistance,

[Defendant's signature]

APPENDIX C

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

FEDERAL TRADE COMMISSION,

Plaintiff

v.

LANE LABS-USA, INC. et al.,

Defendants.

:

:

:

:

:

:

CIVIL ACTION
NO.

AFFIDAVIT OF [DEFENDANT]

[Defendant], being duly sworn, hereby states and affirms:

1. My name is _____. I am a citizen of the United States and am over the age of eighteen. I have personal knowledge of the matters discussed in this declaration, and if called as a witness, I could and would competently testify as to the matters stated herein. I am a defendant in the above captioned action.

2. On (date) _____, I received a copy of the Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief, which was signed by the Honorable _____, United States District Court Judge for the District of New Jersey.

A true and correct copy of the Order that I received is appended to this Affidavit.

I hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date) _____, at (city, state) _____, _____.

(Name of Defendant)

STATE OF _____

COUNTY OF _____

BEFORE ME this day personally appeared _____, who being first duly sworn, deposes and says that s/he has read and understands the foregoing statement and that s/he has executed the same for the purposes contained therein.

SUBSCRIBED AND SWORN TO before me this _____ day of _____, 200_, by _____. S/he is personally known to me or has presented (state identification) _____ as identification.

Print Name

NOTARY PUBLIC,
STATE OF _____

Commission Number
Affix Seal