FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. LANE LABS-USA, INC., a corporation, and ANDREW J. LANE, an individual, Defendant(s).	Civ. No. 99-5782 (WGB) **O R D E R**

This matter having come before the Court on the motion of plaintiff UNITED STATES OF AMERICA ("Plaintiff") for summary judgment pursuant to Fed. R. Civ. P. 56; and

The Court having heard oral argument on November 13, 2003 and having considered the entire record of this case, including the submissions of the parties filed with the Court both before and subsequent to oral argument; and

The Court having found that BeneFin, MGN-3, and SkinAnswer are unapproved new drugs within the meaning of 21 U.S.C. §§ 321(p), 355(a), and misbranded drugs within the meaning of 21 U.S.C. § 352(f)(1); and

The Court having found that defendants LANE LABS-USA, INC. and ANDREW LANE ("Defendants") are violating and, unless restrained by order of this Court, will continue to violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a), (d) & (k); and

For the reasons set forth in the Opinion issued this day; and

Good cause otherwise appearing;

It is this 9th day of July, 2004 ORDERED that:

1. Plaintiff's motion for summary judgment is **granted** as to liability.

2. This Court has jurisdiction over the subject matter and all parties to this action.

3. The Complaint for injunction states a cause of action against Defendants under 21 U.S.C. §§ 301, *et seq.* ("FDCA").

4. Defendants, and all of their officers, agents, employees, successors, representatives, assigns, and attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Order by personal service or otherwise, are hereby permanently enjoined under 21 U.S.C. § 322(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, labeling, packing, processing, or distributing BeneFin, SkinAnswer, MGN-3, or any drug that is a "new drug" within the meaning of 21 U.S.C. § 321(p), unless and until:

(1) an approved new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug; or

(2) an investigational new drug application filed pursuant to 21 U.S.C. § 355(I) and 21 C.F.R. Part 312 is in effect for such drug and the drug is distributed and used solely for the purpose of conducting clinical investigations in strict accordance with the protocol as authorized as part of the investigational new drug application.

B. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, labeling, packing, processing, or distributing any drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1).

C. While Defendants are marketing any product containing, or purporting to contain, shark cartilage, a glycoalkaloid, arabinoxylane, or rice bran hemicellulose with Shiitake mushroom enzymes, promoting, advertising, or representing in any media that shark cartilage, a glycoalkaloid, arabinoxylane, or rice bran hemicellulose with Shiitake mushroom enzymes is:

(1) the same as, similar to, as or more effective than, or intended for the same uses as BeneFin, SkinAnswer, or MGN-3; or

(2) safe and/or effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, unless and until an approved new drug application authorizing such representations for such product(s) is in effect for such

product(s).

5. Nothing in this Order shall be construed as prohibiting Defendants from making any lawful health claim under 21 U.S.C. §§ 343(r)(1)(B), 343(r)(5)(D); 21 C.F.R. § 101.70.

6. On the first day of each month, Defendants shall submit to the United States Food and Drug Administration ("FDA"), at the address specified in paragraph 16 of this Order, one copy of all promotional materials that were distributed or disseminated during the preceding month by Defendants, or on their behalf, that relate to any of Defendants' products that contain, or purport to contain, shark cartilage, glycoalkaloid, arabinoxylane, and/or rice bran hemicellulose with Shiitake mushroom enzymes.

7. Duly authorized representatives of the FDA are authorized, as when the FDA deems necessary and without prior notice, to make inspections of Defendants' facilities, and all equipment, finished and unfinished materials and products, containers, labeling, and other promotional material therein; to take photographs; to take samples of Defendants' finished and unfinished materials and products, containers, labeling, and other promotional material; and to examine and copy all records relating to the manufacturing, packing, processing, labeling, promoting, holding, and distributing of any and all of Defendants' products in order to ensure continuing compliance with the terms of this Order. The inspections shall be permitted

upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is apart from, and in addition to, the authority to make inspections under 21 U.S.C. § 374. In addition, in order to ensure Defendants' compliance with this Order, Plaintiff and the FDA are authorized to monitor Defendants' compliance with this Order by all lawful means, including but not limited to using representatives posing as consumers to contact Defendants' websites, employees, and representatives, and/or any other person or entity managed or controlled in whole or in part by Defendants, without the necessity of identification or prior notice.

8. Defendants shall reimburse the FDA for the costs of all FDA inspections, investigations, supervision, analyses, and document reviews that the FDA deems necessary to evaluate Defendants' compliance with any part of this Order at the standard rates prevailing at the time the activities are accomplished. As of the date of entry of this Order, these rates are: $69.37 per hour and fraction thereof per representative for inspection and investigation work, $83.15 per hour or fraction thereof per representative for analytical work, $0.385 per mile for travel expenses by automobile, government rate or the equivalent for travel by air, and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day per representative for

subsistence expenses, where necessary. In the event that the standard rates applicable to the FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court. In addition, if Defendants violate this Order and are found in civil or criminal contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys fees, investigational expenses, and court costs relating to any contempt proceedings.

9. Within ten (10) business days of the date of entry of this Order, Defendants shall provide a copy thereof, by personal service or certified mail (restricted delivery, return receipt requested), to each of their officers, agents, employees, successors, assigns, representatives, and attorneys, and any and all persons in active concert or participation with any of them (including, but not limited to, I. William Lane, Ph.D. and Mamdooh Ghoneum, Ph.D., and other individuals, directors, corporations, subsidiaries, affiliates, and partnerships) (hereafter, collectively referred to as “associated persons”). In the event that Defendants becomes associated, at any time after entry of this Order, with any additional associated person(s), Defendants immediately shall provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to such associated person(s). Each time Defendants become associated with any such

additional associated person pursuant to this paragraph, and within ten (10) business days of doing so, Defendants also shall provide to the District Director, FDA New Jersey District Office, an affidavit stating the fact and manner of his or their compliance with this paragraph, identifying the names, addresses, and positions of all associated persons notified pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) business days of receiving a request from the FDA for any information or documentation that the FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to the FDA.

10. A. If, based on the results of any inspection, investigation, analysis of a sample or samples, or other information, the FDA determines that Defendants have failed to comply fully with or have violated the FDCA, applicable regulations, or this Order, the FDA may, as and when it deems necessary, direct Defendants to take one or more of the following actions:

(1) Cease manufacturing, labeling, processing, packing, holding, and/or distributing any article or articles;

(2) Recall an article(s) in accordance with procedures identified by FDA; or

(3) Take any other corrective actions(s) as the FDA, in its discretion, deems necessary to bring Defendants and

their products into compliance with the FDCA, applicable regulations, and this Order.

B. Unless a different time frame is specified by the FDA in its directive, within five (5) business days after receiving the directive pursuant to subparagraph A, Defendants shall notify the FDA in writing either that:

(1) Defendants are undertaking or have undertaken the actions(s) specified in the FDA's directive; or

(2) Defendants do not agree with the FDA's diretive. If Defendants notify FDA that they do not agree with the FDA's directive, Defendants shall explain in writing the basis for their disagreement. In so doing, Defendants also may propose specific alternative actions and specific time frames for achieving the FDA's objectives.

C. If Defendants notify the FDA that they do not agree with the FDA's directive, the FDA will review Defendants' objections to the Notice and thereafter, in writing, affirm, modify, or withdraw its directive, as the FDA deems appropriate.

D. If the FDA affirms or modifies its directive, Defendants shall, within five (5) business days of receipt of the FDA's directive, implement the directive (as modified, if applicable) or, if they so choose, bring the matter before this Court on an expedited basis.

E. Any matter brought before this Court shall be based exclusively on the record before the FDA at the time the

directive in dispute was issued pursuant to subparagraph D. No discovery shall be taken by either party.

11. Within thirty (30) days of entry of this Order, Defendants shall, under FDA supervision, destroy all BeneFin, SkinAnswer, and MGN-3 in Defendants' possession, custody, and/or control. However, Defendants may retain a quantity of BeneFin necessary to complete the clinical trials for which an investigational new drug application filed pursuant to 21 U.S.C. § 355(I) and 21 C.F.R. Part 312 is in effect, provided that Defendants' obtain FDA's written approval of the quantity of BeneFin they wish to retain and provided further that Defendants strictly comply with all requirements in 21 C.F.R. Part 312. Defendants shall reimburse FDA for the supervision of the destruction of BeneFin, SkinAnswer, and MGN-3 at the rates set forth in paragraph 8 of this Order. Defendants shall not dispose of any drug products in a manner contrary to the provisions of the FDCA, any other federal law, or the laws of the State or Territory (as defined in the FDCA) in which the drug products are destroyed.

12. Defendants shall notify the FDA District Director, New Jersey District, in writing at least twenty (20) days before any change in ownership, character, or name of any of their businesses, including incorporation, reorganization, bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation, or any other change in the structure or

identity of Lane Labs (or any of its divisions, including, but not limited to, CompassioNet, Lane Medical, LaneLabs International, Lane Malignancy Testing, Lane Anti-Aging Physician), or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Order. Defendants shall serve a copy of this Order on any prospective successor or assign at least ten (10) days prior to such sale or change in business, and shall furnish Plaintiff with an affidavit of compliance with this paragraph within fifteen (15) days of such sale or change in business. As noted in paragraph 4, this Order shall apply to all of Defendants' successors and assigns.

13. Defendants shall post a copy of this Order on a bulletin board in a common area at 110 Commerce Drive, Allendale, New Jersey 07401 and at any other location at which Defendants conduct business, within ten (10) days of the entry of this Order, and shall ensure that the Order remains posted for a period of twelve (12) months at each location.

14. A. In accordance with the procedures described in subparagraphs A - E of this paragraph, Defendants shall make restitution to all purchasers of BeneFin, MGN-3, and SkinAnswer since September 22, 1999, whether such purchaser obtained the drugs directly from Defendants or through one of Defendants' distributors or resellers. Restitution shall include the full amount paid by the purchaser, including any shipping and handling

costs.

B. The Court denies without prejudice Plaintiff's application for disgorgement of profits and reserves the right to revisit this issue upon completion of restitution payments and pending Defendants' compliance with the terms of this Order.

C. Within thirty (30) days of the entry of this Order, Defendants shall promptly provide to a special master, to be designated by this Court, all records necessary to determine:

(1) The identities, addresses, and phone numbers of the individuals and entities who purchased BeneFin, MGN-3, and/or SkinAnswer products from September 22, 1999 to the date of this Order;

(2) The dates and amounts of products ordered and price paid for such products, including any costs of shipping paid by the purchasers (less any refunds already paid by Defendants to such purchasers);

(3) Defendants' cost of manufacturing such products; and

(4) The profits realized by Defendants from the sale of such products.

The records shall include, but not be limited to, state and federal tax returns; bank records; shipping records; sales invoices; accounting records; truthfully and fully executed copies of Department of Justice Forms OBD-500 and OBD-500C (copies attached); and such other records as the Special Master

may request to effectuate the restitution and disgorgement required by this Order.

D. Within forty-five (45) days of the entry of this Order, or a date otherwise mutually agreed upon, the parties shall meet with the Court to formulate a plan to effectuate the restitution payments.

E. Upon entry of this Order, Defendants shall immediately refrain from disposing of or transferring any assets that may interfere with implementation of restitution payments.

F. Within thirty (30) days of entry of this Order, or no less than fifteen (15) days before the date scheduled to come before this Court pursuant to subparagraph D of this section, the parties shall submit a proposed plan for Defendants to effectuate restitution payments. If the parties are unable to agree on a proposal, they shall submit separate proposals to the Court. The parties shall include in the proposed plan the name of an independent contractor to effectuate restitution payments along with the proposed terms of engagement.

G. Where necessary to implement the requirements of and ensure compliance with this paragraph, attorneys for Plaintiff may conduct discovery on any issue related to this paragraph, notwithstanding paragraphs 10.E. and 15.

15. Any of the FDA's decisions requiring review under this Order shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Except as

provided above, no discovery may be had by either party, and all FDA decisions shall be reviewed solely based upon the written record that was before the FDA at the time it made its decision.

16. All correspondence with FDA pursuant to this Order shall be sent to the FDA District Director, New Jersey District, Waterview Corporate Center, 10 Waterview Boulevard, 3d Floor, Parsippany, New Jersey 07054.

17. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may be hereafter necessary or appropriate.

18. Defendants shall bear their own costs, including attorneys fees, of this action and for compliance with this Order.

/s/ WILLIAM G. BASSLER
UNITED States District Judge