



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Mid-Atlantic Region

457

Telephone (201) 331-2904

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

September 24, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Andrew Lane, President
Lane Labs USA, Inc.
110 Commerce Drive
Allendale, New Jersey 07401

RELEASE

REVIEWED BY AL
C.O.

9/29/97
DATE

FILE NO.: 97-NWJ-50

Dear Mr. Lane:

This letter is in reference to the promotion, marketing and distribution of the products "BeneFin" and SkinAnswer."

Reference is made to a letter dated June 13, 1997, from Dr. Tracy L. Acker of the Division of Drug Marketing, Advertising, and Communications regarding Dr. William Lane's commercialization of [REDACTED] in his promotional presentations for "BeneFin."

Based on the claims made for these products and their intended uses, "BeneFin" and "SkinAnswer" are neither cosmetics nor dietary supplements. Under Section 201 (g) of the Food, Drug, and Cosmetics Act (the Act) [Section 201(g)], they are drugs. They are also unapproved new drugs [Section 201 (p) of the Act] and may not be legally marketed in the United States without approved New Drug Applications (§ 505).

These drugs are also misbranded (§ 502(f)(1)) because the labeling fails to bear adequate directions for use and because the labeling is false and misleading as it suggests that the products are safe and effective for their intended uses when this has not been established [502 (a)]. "

In your statements to the Agency, you stated that Lane Labs makes no drug claims for these products. However, there are drug claims in the labeling of Lane Labs' "BeneFin" and "SkinAnswer." For example, claims made for "BeneFin" include the treatment of arthritis, psoriasis, and cancer as well as, more specifically, breast cancer, prostate cancer and Karposi's sarcoma. "SkinAnswer" is promoted as an "all-natural glycoalkaloid cream for skin cancer."

Moreover, statements made by Dr. I. William Lane, who you describe as a paid consultant, provide evidence that "BeneFin" and "SkinAnswer" are intended to be used in the treatment and prevention of disease thereby making these products, by definition, drugs, new drugs, and misbranded drugs. The following are examples of such statements:

- Dr. Lane's brochure for the product "SkinAnswer" specifically claims the product is "Dr. Lane's next cancer breakthrough: all-natural glycoalkaloid cream for skin cancer";
- the booklet "16 Questions Most Often Asked of Dr. I. William Lane" specifically promotes "BeneFin" as a treatment for cancer;
- magazine advertisements (such as one in the March/April 1997 issue of "Christian American") that bear pictures of Lane "Labs' "BeneFin" and Dr. Lane's claim that "BeneFin helps fight arthritis, psoriasis, and cancer"; and
- the webpage for Lane Labs contains explicit instructions "For information on Shark Cartilage please visit www.DrLane.com. Here you will find cutting edge information on research and use of shark cartilage." Dr. Lane's website specifically promotes Lane Labs' product "BeneFin" for the above-mentioned disease claims.

This letter is not intended to be all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reasons for the delay and the time within which the corrections will be implemented.

Lane Labs USA, Inc.
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Your reply should be sent to the Food and Drug Administration,
New Jersey District Office, 10 Waterview Blvd., Third Floor,
Parsippany, New Jersey 07054, Attention: Andrew Ciaccia,
Compliance Officer.

Very truly yours,

A handwritten signature in cursive script, appearing to read "Douglas I. Ellsworth for".

Douglas I. Ellsworth
District Director
New Jersey District Office

AC: slw