



WARNING LETTER

AUG 1 8 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William F. Robertson, President
Hobe Laboratories, Inc.
4032 East Broadway Road
Phoenix, AZ 85040

W/L 40-9

Dear Mr. Robertson:

This letter is in reference to your firm's marketing and distribution of the products, Col-S-Rol, Lapacho, and Psoria-Gard Skin Treatment System Steps 1, 2, and 3. Labeling for these products contains therapeutic claims which cause the products to be drugs [section 201(g) of the Federal Food Drug, and Cosmetic Act (the Act)]. Labeling is not limited to the immediate product containers but includes all promotional literature which you distribute in connection with your products.

Examples of the objectionable claims include:

Col-S-Rol	"high blood pressure, caused in part by fatty arterial deposits"
Lapacho	antibiotic properties
Psoria-Gard Skin Treatment System Steps 1, 2, and 3	Psoria-Gard, emulsifies sebum and helps remove scales

These products are "new drugs"[section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [section 505(a) of the Act].

These drugs are also misbranded because their labeling fails to bear adequate directions for the condition for which they are offered [section 502(f)(1) of the Act]. Their labeling

is also false and misleading, since it suggests that the products are safe and effective for their intended uses when this has not been established [section 502(a) of the Act].

Further, claims for the treatment of psoriasis cause the Psoria-Gard Skin Treatment System to be subject to the final monograph, "Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis." This monograph is found in Title 21 Code of Federal Regulations (21 CFR) section 358.701. Neither the formulation nor the labeling for the product conform to this final regulation.

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. 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 actions to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the 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, including 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 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your written reply should be sent to the attention of Thomas L. Sawyer, Director, Compliance Branch, 19900 MacArthur Boulevard, Suite 300, Irvine, CA 92612-2445.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas Sawyer", written in a cursive style.

Acting District Director