



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m2247n

WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 13, 1998

Dr. Robert C. Blaine, President
Blaine's Research Laboratories
17814 Woodruff Avenue, Suite 2
Bellflower, CA 90706

WL -7-9

Dear Dr. Blaine:

This is in reference to "Tineacide® Antifungal Cream & Nail Revitalizer" which is marketed by your firm. According to the labeling, the product is offered for the treatment of nail fungus, athlete's foot, jock itch, and ringworm. The label of the product lists the active ingredient as clotrimazole, 1%. However, the promotional material claims that other ingredients in the product (tea tree oil, lavender oil, undecylenic acid, and urea) are also intended to treat fungus infections.

Based on the claims listed above, "Tineacide® Antifungal Cream & Nail Revitalizer" is a drug as described in Section 201 (g) of the Federal Food, Drug, and Cosmetic Act (the Act). It is subject to the final regulations covering topical antifungal drug products in Title 21 Code of Federal Regulations (21 CFR) Part 333.201. The active ingredient declared on the label, clotrimazole 1%, is not permitted by regulation as cited in 21 CFR § 333.210. Tea tree oil, lavender oil, and lavender oil, and urea, which are promoted as antifungal ingredients, are not permitted under the final rule.

"Tineacide® Antifungal Cream & Nail Revitalizer" is also subject to the final rule covering topical antifungal drug products offered for the treatment of nail fungus infection. The agency has determined that any OTC drug product that is labeled, represented, or promoted as an antifungal to treat fungal infections of the nails or scalp is regarded as a new drug (Section of 201(p) of the Act).

Based on the above, "Tineacide® Antifungal Cream & Nail Revitalizer" is a "new drug" (Section 201 (p) of the Act) which may not be legally marketed (Section 505(b) of the Act). The product is also misbranded (Section 502(f)(1) of the Act) because its labeling fails to bear adequate directions for use.

This letter is not intended to be an 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. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

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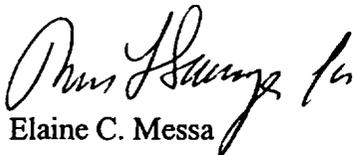
We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in enforcement action being initiated by the Food and Drug Administration without further notice. This action may include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you intend to take to correct these violations, including an explanation of each step being taken to prevent recurrence of similar violations. If corrective actions cannot be completed with 15 working days state the reason for the delay and the time within which corrections will be completed.

Your response should be directed to:

Mary LoVetere
Compliance Officer
U.S. Food & Drug Administration
1990 MacArthur Blvd., Ste. 300
Irvine, CA 92612

Sincerely,



Elaine C. Messa
District Director
Los Angeles District

cc:

