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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION**

**NEW YORK DISTRICT
850 THIRD AVENUE
BROOKLYN, NY 11232
TEL. (718) 965-5300**

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

December 26, 1996

M. Gregory Minuto
President
Olan Laboratories, Inc.
20 Newton Place
Hauppauge, NY 11788

Ref: 25-NYK-07

Dear Mr. Minuto:

This letter is in reference to "Synergine Antifungal Solution" and "Synergine Fungus 3 Wash" which are manufactured by your firm. "Synergine Antifungal Solution" is offered for sale "for treatment of Athletes' Foot (tinea pedis)" and "Synergine Fungus 3 Wash" is offered for the treatment of superficial fungal skin infections. Based on these claims, the products are drugs within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act), subject to a Final Rule which covers over-the-counter topical antifungal drug products as set forth in Title 21, Code of Federal Regulations (21 CFR), Part 333. A drug subject to a Final Rule (regulation) must meet the requirements of the regulation unless it has an Approved New Drug Application (NDA).

"Synergine Antifungal Solution" and "Synergine Fungus 3 Wash" labeling and product formulations fail to meet the requirements of the Final Rule. The concentrations of the active ingredient, undecylenic acid, 7.5 percent for "Synergine Antifungal Solution" and 3.8 percent for "Synergine Fungus 3 Wash", are not within the specified concentration range required, i.e., 10 to 25 percent (21 CFR 333.210(f)). Further, the required labeling for the statement of identity, directions and warnings for each product do not comply with the regulations (21 CFR 333.250 (a), (c), and (d)). Therefore, "Synergine Antifungal Solution" and "Synergine Fungus 3 Wash" are "new drugs" (Section 201 (p) of the Act), and may not be marketed in the absence of approved NDAs.

The products are also misbranded (Section 502 (f)(1) of the Act) because the labeling fails to bear adequate directions for use, and are also misbranded (Section 502 (f)(2) of the Act) because the labeling fails to bear the required warnings. Additionally, "Synergine

Antifungal Solution[®] is misbranded (Section 502 [©] of the Act) because the outer carton fails to bear all the required labeling information.

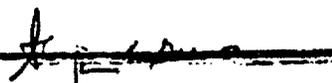
The above list of violations is not intended to be an all inclusive list of deficiencies at your firm. It is your responsibility to ensure that the drug products you distribute meet all requirements of the Act and its implementing regulations. Federal agencies are advised on the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. This action may include seizure and/or injunction.

We acknowledge the receipt of your letter of October 30, 1996. Please notify our office in writing, within fifteen (15) working days after receipt of this letter, of the current status of the manufacturing, distribution, and inventory of these drug products..

Your reply should be sent to the Food and Drug Administration, 850 Third Avenue, Brooklyn, N.Y. 11232, Attention: Fabio L. Mattiasich, Compliance Officer.

Sincerely,



Alonza Cruse
Acting District Director

orig: addressee

cc: HFI-35 (redacted)

HFA-224

HFC-210 (CF# 2432482)

HFC-230

HFD-300

HFR-NE1

HFR-NE100

HFR-NE140

HFR-NE150 (Platz, Althea Williams, COMSTAT)

EF (Olan Laboratories Inc.)

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