



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service  
11357611  
Food and Drug Administration  
New Orleans District  
Nashville Branch  
297 Plus Park Blvd.  
Nashville, TN 37217

March 23, 2000

*Quip*  
3/24/00  
*JCN*

CERTIFIED - RETURN RECEIPT REQUESTED

Mr. Andy Howell  
President  
Aslan, Inc.  
12004 Southmount Drive  
Demopolis, AL 36732

Dear Mr. Howell:

Ref: Warning Letter No. 00NSV212

This letter is in reference to the product "Nail Cure" marketed by your firm. According to the label, "Nail Cure" is offered for the treatment of nail fungus. The label lists the ingredients as dimethyl sulfoxide, miconazole, polyglycol and ibuprofen.

Based on the intended use described above, "Nail Cure" is a drug pursuant to Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act), and is subject to a final rule covering Topical Antifungal Drugs for Over-the-Counter Human Use [Title 21 Code of Federal Regulations (21 CFR) Part 310.54(a)(22)(ii)]. Under the rule, 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 201(p) of the Act). Thus, "Nail Cure" is a "new drug" that may not be marketed in the United States without an approved new drug application (NDA) (Section 505(a) of the Act). The product is also misbranded (Section 502(f)(1) of the Act), because it does not bear adequate directions for use.

During the inspection of your facility on December 8-15, 1999 our investigator documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) which cause your "Nail Cure" product to be adulterated within the meaning of (Section 501(a)(2)(B) of the Act).

The deviations included no batch production records, no stability testing program, inadequate standard operating procedures and no records of component and finished product testing. We acknowledge receipt of the December 20, 1999 letter from Chris Foxhall, Director of Operations; however, Mr. Foxhall did not indicate what corrections

Astan, Inc. - Page 2

would be made in regard to the deviations noted on the FDA-483 issued to him on December 15, 1999 other than that corrections would be completed by April or May 2000.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that may exist for products marketed by your firm. It is your responsibility to assure that all your drug products are in compliance with federal laws and 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. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of your receipt of this letter of the specific steps you will take to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,



Lawrence A. D'Hoostelaere, Ph.D.  
Acting Director, New Orleans District

LAD/kl

Enclosures:

21 CFR Part 211  
21 CFR Part 310.545