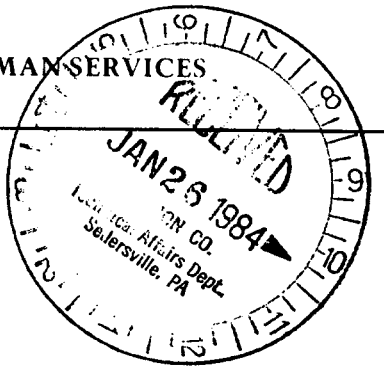
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857



Our reference: 62-506

Lemmon Company
Attention: S. Scheindlin, D.Sc.
Sellersville, Pennsylvania 18960

Gentlemen:

Please refer to your Antibiotic Form 6 application dated December 9, 1983, for Nystatin Oral Tablets, 500,000 Units.

We have completed our review of this application and it is approved. In approving this application, it is understood that the product will be marketed in bottles of 100 tablets, and that the "How Supplied" section of the package insert will be revised at the next printing to reflect this.

An expiration date of 36 months should be used on each batch of the drug to be marketed and packaged as described in the application.

For Initial Campaigns: We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your immediate advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form not final printed. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Advertising and Labeling (HFN-240). Also, please do not use Form FD-2253 for this submission.

For Subsequent Campaigns: We call your attention to regulation 21 CFR 431.60(b)(3) which requires that all material for any subsequent advertising or promotional campaigns at the time of their initial use be submitted to our Division of Drug Advertising and Labeling (HFN-240) with a completed Form FD-2253. A copy of Form FD-2253 is enclosed for your convenience.

The Form 6 should be kept up to date by submitting amendments whenever changes are contemplated in the manufacturing and/or laboratory procedures, controls, equipment and instrumentation, key scientific and production personnel, packaging, labeling, source of antibiotics, etc.

Sincerely yours,

Marvin Seife

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
National Center for Drugs and Biologics