



NDA 18-713/S-019

Bayer Pharmaceutical Division
Attention: Margaret Foley
Senior Regulatory Compliance Associate
400 Morgan Lane
West Haven, CT 06516-4175

Dear Ms. Foley:

Please refer to your supplemental new drug application, NDA 18-713/S-019, dated August 7, 2002, received August 8, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for **Mycelex (clotrimazole) Troche**.

This supplemental new drug application provides for a labeling revision to add a Geriatric Use subsection to the PRECAUTIONS section of the package insert to comply with 21 CFR 201.57(f)(10).

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted draft labeling dated August 7, 2002. Accordingly, this supplemental drug application is approved effective on the date of this letter

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, the submission should be designated "FPL for approved supplement NDA 18-713/S-019." Approval of this submission by FDA is not required before the labeling is used.

Please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Jonathan Wilkin
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