CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-676

APPROVAL LETTER

FEB 11 1997

NDA 20-676

Bristol-Myers Squibb Company
Attention: Carole Schumann
1350 Liberty Avenue
Hillside, New Jersey 07207-6050

Dear Ms. Schumann:

Please refer to your new drug application dated November 10, 1995, received November 13, 1995, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vagistat-1 (tioconazole) Vaginal Ointment, 6.5%.

We acknowledge receipt of your submissions dated November 20, 1995; March 8, June 12, August 7, November 11, and December 18, 1996; January 22 and 31, and February 7, 1997. The original User Fee goal date for this application was November 13, 1996. Your submission of November 11, 1996, extended the User Fee goal date to February 13, 1997.

This new drug application provides for the over-the-counter marketing of Vagistat-1 (tioconazole) Vaginal Ointment, 6.5%, 1-day vaginal antifungal treatment regimen for the treatment of recurrent vaginal yeast infections (*candidiasis*).

We have completed the review of this application, including the submitted draft labeling, 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 draft labeling in the submission dated February 7, 1997. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on February 7, 1997. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case 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, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-676. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. 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 material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising
and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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 contact Mr. Stephen T. Trostle, Consumer Safety Officer, at (301) 827-2125.

Sincerely yours,

2-11-97

David W. Feigal, Jr., M.D., M.P.H.
Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

cc:

Original NDA 20-676
HFD-520/Div. files
HFD-520/CSO/STrostle
HFD-520/JWinfield
HFD-520/BLeissa 2/11/97
HFD-520/DKatague
HFD-520/ROsterberg
HFD-520/ASheldon
HFD-002/ORM (with labeling)
HFD-104/TNearning (with labeling)
HFD-101/LCarter
HFD-830/ONDC Division Director
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-40/KLechter/JSpearmon
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling)
HFD-560/OTC (with labeling)
HFD-560/SWalther
HFD-560/HCothran
HFD-560/LChin/LKatz/DBowen
HFI-20/Press Office (with labeling)

For concurrence only:
HFD-520/JBona for 2/11/97
HFD-520/DFeigal 2.11.97

Drafted by: STrostle\February 10, 1997\n20676ap.000
Revised by: STrostle\February 11, 1997

APPROVAL (AP)