DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-619/S-004

Bristol-Myers Squibb Company
Attention: David L. Silberstein
Associate Director, Global Regulatory Strategy
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Silberstein:

Please refer to your supplemental new drug application dated August 23, 2000, received August 25, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MYCOSTATIN® (nystatin lozenges, USP) PASTILLES, 200,000 units.

We acknowledge receipt of your submission dated January 24, 2003.

In accordance with 21 CFR 201.57 (f)(10), this supplemental new drug application provides for the addition of a new **Geriatric Use** subsection to the **PRECAUTIONS** section. The text of this subsection is presented below.

Geriatric Use

Clinical studies of MYCOSTATIN (nystatin lozenges, USP) PASTILLES did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Since MYCOSTATIN PASTILLES must be allowed to dissolve slowly in the mouth for maximum effect, elderly patients for whom they are prescribed must be competent to use the dosage form as intended.

In addition, the supplemental new drug application includes a logo change from(b)(4)----------
Oncology to BMS Oncology and a few editorial and format changes to the label.

We have completed the review of this supplemental application, as amended, 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 agreed upon labeling text submitted on January 24, 2003. Accordingly, this supplemental application is approved effective on the date of this letter. The final printed labeling (FPL) must be identical to the draft labeling submitted on January 24, 2003. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 50-619/S-004**." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" 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, HFD-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call Yon Yu, Pharm D., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
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/

Renata Albrecht

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