DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 6-927/S-021
NDA 9-112/S-030

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

Dear Mr. Silberstein:

Please refer to your supplemental new drug applications dated December 19, 2002, received December 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Eurax (crotamiton USP) Cream, 10%, and Eurax (crotamiton USP) Lotion, 10%.

We acknowledge receipt of your facsimile correspondence dated June 24, 2003.

These supplemental new drug applications provide for the addition of "Geriatric Use" labeling to these applications in conformance with the Geriatric Labeling Final Rule. In addition, the labeling review provides for updates in the following sections: Clinical Pharmacology, Information for Patients, Adverse Reactions, Overdosage, Dosage and Administration, Directions for Patients with Scabies, How Supplied, and minor editorial revisions.

We have completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The following additional changes are recommended for inclusion in the carton and container labeling for Eurax Cream and Eurax Lotion. The cautionary statements: "FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE" should be placed on the container label, and on at least one of the label panels of the carton, below or adjacent to the proprietary and established names.

The following change is recommended for inclusion in the carton and container for Eurax Lotion: "SHAKE WELL before using".

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert). These revisions are terms of the approval of these applications.

Please submit the FPL electronically 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, 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, these submissions should be designated "FPL for approved supplement NDA 6-927/S-030 AND NDA 9-112/S-021." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

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

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Margo Owens, Regulatory Project Manager, at (301) 301-827-2020.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

John Kelsey
6/26/03 04:23:55 PM
for Dr. Wilkin