DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-824/S-024

Bristol-Myers Squibb Company
Attention: David Silberstein
Associate Director, New Opportunities and Product Development,
Global Regulatory Strategy
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Silberstein:

Please refer to your supplemental new drug application dated August 27, 2001, received September 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Halog Ointment (halcinonide ointment, USP), 0.1%.

We acknowledge receipt of your submissions dated March 24, 2004.

Your submission of March 24, 2004, constituted a complete response to our April 4, 2003, action letter.

This supplemental new drug application provides final printed labeling incorporating the Agency proposed addition of the "Geriatric Use" subsection in the PRECAUTIONS section of the labeling.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 24, 2004.

We request the following revisions to the labeling at the next printing:

1. In the STATEMENT OF DOSAGE section, "For Topical Use Only. Not for Ophthalmic Use" should be changed to read "FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE".
2. In the PRECAUTIONS General subsection, "This preparation is not for ophthalmic use" should be changed to read "This preparation is not for ophthalmic, oral or intravaginal use".

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products
Center for Drug Evaluation 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/

Stanka Kukich
9/29/04 03:10:23 PM
Sign off for Dr. Wilkin, Division Director