DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-967/S-010

Bristol Myers Squibb
Attention: David L. Silberstein
New Opportunities & 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 August 30, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultravate® (halobetasol propionate cream) Cream, 0.05%.

We acknowledge receipt of your submission dated March 17, 2004.

Your submission of March 17, 2004 constituted a complete response to our April 2, 2003 action letter.

This supplemental new drug application provides Final Printed Labeling (FPL) incorporating Agency recommended language for the Geriatric Use subsection. In addition, changes requested in the April 2, 2003, approval letter for supplement 004 are also included.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 17, 2004.

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 & Dental Drug Products
Office of Drug Evaluation V
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/

Jonathan Wilkin
9/17/04 09:56:52 AM