DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-508/S-006

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

Dear Mr. Silberstein:

Please refer to your supplemental new drug application dated August 24, 2000, received August 29, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LacHydrin® (ammonium lactate) Cream, 12%.

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

Your submission of June 17, 2004 constituted a complete response to our May 28, 2003 action letter.

This supplemental new drug application provides for the addition of a Geriatric Use subsection to the PRECAUTIONS section of the package insert. In addition, as requested in our May 28, 2003, approvable letter and August 6, 2003, acknowledge and retain letter, revisions to the CONTRAINDICATIONS and WARNINGS sections have also been added to the package insert and the term "cream" has been removed from inside of the parentheses as part of the generic name.

We have 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 June 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

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
12/13/04 03:59:57 PM
sign off for Dr. Jonathan wilkin, Division Director