DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-155/S-019 & S-020

Bristol-Myers Squibb Company
Attention: David L. Silberstein
Associate Director, RDP&M
PO Box 4000
Princeton, NJ 08543-4000

Dear Mr. Silberstein:

Please refer to your supplemental new drug applications dated August 24, 2000 and January 24, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lac-Hydrin (ammonium lactate) Lotion, 12%.

These supplemental new drug applications provide for labeling changes to parallel the changes recently approved for Lac-Hydrin Cream, and incorporation of other minor editorial revisions.

Your submission of December 19, 2003, constituted a complete response to our May 28, 2003 action letter.

We completed our review of these supplemental new drug applications as amended, and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted. At the next printing, please make the following change in the labeling for LacHydrin: the percentage of strength should follow the dosage form preceded by a comma (LacHydrin (ammonium lactate) Lotion, 12%).

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
4/28/04 06:06:12 PM
Sign off for Dr. Wilkin