DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-026/S-004

Barrier Therapeutics, Inc.
Attention: Isabel B. Drzewiecki
Vice President, Regulatory Affairs
600 College Road East, Suite 3200
Princeton, NJ 08540

Dear Ms. Drzewiecki:

Please refer to your supplemental new drug application dated April 5, 2007, received April 6, 2007, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for VUSION™ (0.25% miconazole nitrate, 15% zinc oxide, 81.35% white petrolatum) Ointment.

We acknowledge receipt of your submission dated May 22, 2007.

This supplemental new drug application provides for changes to remove the 30-gram and 30-gram sample tube sizes and to add a 50-gram tube size.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

If you have any questions, call Catherine Carr, Regulatory Project Manager, at (301) 796-2311.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Deputy Director, Division of Dermatology
and Dental Products
Office of Drug Evaluation III
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

10/3/2007 12:07:02 PM