DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-946

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

Dear Ms. Drzewiecki:

Please refer to your new drug application (NDA) dated September 28, 2005, received September 28, 2005 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for XOLEGEL (ketoconazole, USP) Gel, 2%.

We acknowledge receipt of your submissions dated October 6, December 16, and December 21, 2005 and January 9, January 27, March 1, May 5, May 12, May 17, June 12, June 15, July 14, July 18, July 24, July 27 (via electronic mail), and July 28 (via electronic mail), 2006.

This new drug application provides for the use of XOLEGEL (ketoconazole, USP) Gel, 2% for treatment of seborrheic dermatitis in immunocompetent adults and children 12 years of age and older.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-946**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We have waived the pediatric study requirement for this application for ages zero to twelve years.

We remind you of your postmarketing study commitment in your submission dated May 12, 2006. This commitment is listed below.

1. Dermal carcinogenicity study in mice with XOLOGEL Gel, 2%

Protocol Submission:	Submitted October 27, 2005
Study Start:	by October 28, 2006
Final Report Submission:	by 4th Quarter, 2009

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

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:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Margo Owens, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Susan Walker, M.D.
Division 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
7/28/2006 01:36:48 PM
sign off for Susan Walker, Division Director