

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-026

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-026 Vusion

Barrier Therapeutics, Inc.
ATTN: Isabel Drzewiecki,
Global Head, Regulatory Operations
600 College Road East
Suite 3200
Princeton, New Jersey 08540

Dear Ms. Drzewiecki:

Please refer to your new drug application (NDA) dated August 24, 1998, received August 24, 1998 submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for VUSION (0.25% miconazole nitrate, 15% zinc oxide, and 81.35% white petrolatum) Ointment.

We acknowledge receipt of your submissions dated August 15 and 25, October 18 and 24, November 14, 2005; January 26 and 30, and February 2, 6, 7, 9, 14 (via electronic mail) and 15 (2) (via electronic mail) 2006.

The August 15, 2005 submission constituted a complete response to our May 24, 2005 action letter.

This new drug application provides for the use of VUSION Ointment for the adjunctive treatment of diaper dermatitis only when complicated by documented candidiasis, (microscopic evidence of pseudohyphae and/or budding yeasts), in immunocompetent pediatric patients 4 weeks 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 Agency acknowledges your submission dated January 26, 2005, in which you reported that launch quantities of the tube and carton labels had already been printed. We acknowledge the February 8, 2006, agreement between the Agency and Barrier that the printed launch tube and carton labeling can be used, but the tube and carton labeling must be in compliance with the attached, agreed upon labeling by June 16, 2006.

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 21-026.**” 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 are waiving the pediatric study requirement for ages 3 to 18 years for this application.

We remind you of your postmarketing study commitments in your submission dated February 7, 2006. These commitments are listed below.

1. An open label study to assess the systemic absorption and safety of the marketed formulation of topically applied 0.25% miconazole nitrate, 15% zinc oxide, and 81.35% white petrolatum ointment in infants with moderate to severe diaper dermatitis when complicated by candidiasis

Protocol Submission: by April 30, 2006
Study Start: by August 30, 2006
Final Report Submission: by August 30, 2007

2. A prospective 2-year longitudinal study to assess for miconazole resistance in *Candida* spp. with repeated treatment courses of marketed formulation of topically applied 0.25% miconazole nitrate, 15% zinc oxide, and 81.35% white petrolatum ointment in infants with recurrent moderate to severe diaper dermatitis with candidiasis. Clinical isolates of *Candida* spp. should be obtained from patients who fail to improve with marketed formulation of 0.25% miconazole nitrate, 15% zinc oxide, and 81.35% white petrolatum ointment treatment followed by properly conducted in vitro susceptibility testing. Isolates should be saved in the event that further investigation is necessary.

Draft Protocol Submission: by June 30, 2006
Protocol Submission: by December 30, 2006
Study Start: by February 28, 2007
Final Report submitted: by November 30, 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 the Division of Dermatology and Dental Products 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
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

If you have any questions, call Millie Wright, Project Manager, at (301) 796-2110.

Sincerely,
{See appended electronic signature page}
Stanka Kukich, M.D.
Acting Division Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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/s/

Stanka Kukich
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