DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-524/S-005

Bertek Pharmaceuticals, Inc.
Attention: Bhaskar Chaudhuri, Ph.D.
Executive Vice President, Scientific Affairs
320 Lakeside Drive, Suite A
Foster City, CA 94404

Dear Dr. Chaudhuri:

Please refer to your supplemental new drug application dated August 4, 2000, received August 7, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mentax® (butenafine HCl cream) Cream, 1%.

We acknowledge receipt of your submissions dated September 8, November 1, 6, and 30, 2000, and April 6 and 24, May 8, 25 and 29, and June 1 and 6, 2001 (facsimile).

This supplemental new drug application provides for the use of Mentax® (butenafine HCl cream) Cream, 1%, for the topical treatment of tinea (pityriasis) versicolor due to Malassezia furfur (formerly Pityrosporum orbiculare).

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

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).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-524/S-005." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632).

We are waiving pediatric studies in the pediatric population in the age group 12 years to 16 years old, because there are sufficient data to determine efficacy and safety down to and including age 12 years. In the below age 12 year group, the necessary studies are impossible or highly impractical to conduct because the number of patients is too small.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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, please call Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, 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

Enclosure