CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-105

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-105

ABLE Laboratories Inc.
Attention: Shashikant Shah, R.Ph.
Vice President of Quality/Regulatory Affairs
6 Hollywood Court CN1013
South Plainfield, NJ 07080

JUN 26 2001

Dear Mr. Shah:

Please refer to your new drug application (NDA) dated February 18, 1999, received February 19, 1999 (accepted for filing June 7, 1999), submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Sulfamethoxazole and Trimethoprim Tablets, USP and Phenazopyridine Hydrochloride Tablets, USP.

We acknowledge receipt of your submissions dated May 7 and May 23, 2001. Your submission of May 7, 2001, constituted a complete response to our September 5, 2000, action letter.

This new drug application provides for a blister package containing Sulfamethoxazole and Trimethoprim Tablets, USP and Phenazopyridine Hydrochloride Tablets, USP for the treatment of urinary tract infections and for the symptomatic relief of pain, burning, urgency, frequency, and other discomforts arising from irritation of the lower urinary tract mucosa caused by infection.

We have completed the review of this 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 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). 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 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 NDA 21-105." 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 the pediatric study requirement for this action on this application.

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

Please note, if you choose to use a proprietary name for this product, the name and its use in the label must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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

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 Beth Duvall-Miller, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely yours,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure