DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-406/S-048 and NDA 21-281/S-004

TAP Pharmaceutical Products, Inc.
Attention: Nancianne Knipher, Ph.D.
Project Manager, Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Dr. Knipher:

Please refer to your supplemental new drug application dated May 31, 2002, received June 3, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole) Delayed-Release Capsules and Prevacid® (lansoprazole) for Delayed-Release Oral Suspension.

We acknowledge receipt of your submissions dated August 22, October 17, and November 21, 2002.

These supplemental new drug applications provide for revisions to incorporate changes approved in NDA 20-406/S-047 and NDA 21-428 as well as changes to the Alternate Administrative Options subsection of the PRECAUTIONS section of the package.

We completed our 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 labeling text with revisions listed below. Accordingly, this application is approved, effective on the date of this letter.

CONTRAINDICATIONS

(Please refer to full prescribing information for amoxicillin and clarithromycin before prescribing.)

The final printed labeling (FPL) must be identical, and include the revisions indicated, to the submitted labeling (package insert submitted November 21, 2002). These revisions are terms of the approval of this application.

Please submit the 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, in no case 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 20-406/SLR-048 and NDA 21-281/SLR-004." Approval of this submission by FDA is not required before the labeling is used.

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 Gastrointestinal and Coagulation Drug Products 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, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Melissa Furness, Consumer Safety Officer, at (301)-827-7450.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastrointestinal &
Coagulation Drug Products
Office of Drug Evaluation ODE III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick

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