



NDA 20-406/S-045
NDA 21-281/S-002

TAP Pharmaceutical Products, Inc.
Attention: Nancianne Knipfer, Ph.D.
Project Manager, Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045-4832

Dear Dr. Knipfer:

Please refer to your supplemental new drug applications dated November 5, 2001, received November 6, 2001, 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 submission via e-mail attachment dated April 24, 2002.

These "Changes Being Effected" supplemental new drug applications provide for updates to the ADVERSE REACTIONS section, reformatting of the DOSAGE AND ADMINISTRATION section and minor editorial changes to the package insert.

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

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted November 5, 2001) and include the revision to the DOSAGE AND ADMINISTRATION section submitted April 24, 2002.

Please submit the copies of final printed labeling (FPL) electronically to each application 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, these submissions should be designated "FPL for approved supplement NDA 20-406/S-045, and NDA 21-281/S-002." Approval of these submissions by FDA is not required before the labeling is used.

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, call Cheryl Perry, Regulatory Project Manager, at (301) 827-7475.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, MD, MPH
Deputy Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Joyce Korvick
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