DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20406/S-047

TAP Pharmaceutical Products, Inc.
Attention: Doug Donovan,
Assistant Director Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Mr. Donovan:

Please refer to your supplemental new drug application dated January 30, 2002, received January 31, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole) Delayed-Release Capsules, 15 mg and 30 mg .

We acknowledge receipt of your submissions dated April 4, April 17, and July 18, 2002.

This supplemental new drug application provides for the following changes in the Prevacid® (lansoprazole) package insert: pediatric labeling for the 1 to 11 year age group by updating the Clinical Pharmacology, Clinical Studies, Indication and Usage, Precautions, Adverse Events, and Dosage and Administration sections.

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. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed agreed upon labeling (text for the package insert).

Please submit the FPL electronically 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, 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/SE5-047. Approval of this submission by FDA is not required before the labeling is used.

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, Regulatory Project Manager, at (301) 827-7450.

Sincerely,

{See appended electronic signature page}

Victor Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal & Coagulation Drug Products, HFD-180
Center for Drug Evaluation and Research

Enclosure

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

/s/

Victor Raczkowski

7/31/02 04:00:08 PM