NDA 20-406/S-021

TAP Holdings Inc.
Attention: Linda J. Peters, M.S.
2355 Waukegan Road
Deerfield, IL 60015

Dear Ms. Peters:

Please refer to your supplemental new drug application dated June 25, 1997, received June 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid (lansoprazole) Delayed-Release Capsules.

We acknowledge receipt of your submissions dated August 13, August 27, and September 19, 1997, and May 18, May 29, June 24, and July 14, 1998. Your submission of July 14, 1998 consitutes a full response to our May 11, 1998 action letter.

This supplemental new drug application provides for a 10-day dosing regimen for triple therapy, Prevacid in combination with clarithromycin and amoxicillin, for the eradication of *Helicobacter pylori* in patients with duodenal ulcer disease.

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 submitted final printed labeling (package insert dated July 14, 1998). Accordingly, the supplemental application is approved effective on the date of this letter.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

If a letter communicating important information about this drug product (i.e., a "Dear Healthcare Practitioner" 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, contact Maria R. Walsh, M.S., Project Manager, at (301) 443-0487.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research