DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-406/S-058
NDA 21-281/S-017
NDA 21-428/S-006

Tap Pharmaceutical Products Inc.
Attention: John R. Lieberman, Ph.D.
Regulatory Advisor
675 North Field Drive
Lake Forest, IL 60045

Dear Dr. Lieberman:

Please refer to your supplemental new drug application dated March 10, 2005, received March 11, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole) Delayed-Release Capsules, Prevacid® (lansoprazole) for Delayed-Release Oral Suspension, and Prevacid® Solutab™ (lansoprazole) Delayed-Release Orally Disintegrating Tablets.

In addition, we acknowledge receipt of your submission dated August 31, 2005.

Your submission of October 11, 2005 constituted a complete response to our September 9, 2005 action letter.

These supplemental new drug applications provide for changes to the Drug Interactions sub-section of the PRECAUTIONS section of the package insert.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (package insert submitted October 11, 2005).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions"**FPL for approved supplements** NDA 20-406/S-058, NDA 21-281/S-017, and NDA 21-428/S-006." Approval of these submissions 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 these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division, and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
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/

Joyce Korvick

4/12/2006 10:07:25 AM