



NDA 21-566/S-004

TAP Pharmaceutical Products, Inc.
Attention: Leslie Abelson, RAC
Assistant Director of Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Ms Abelson:

Please refer to your supplemental new drug application dated November 15, 2006, received November 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid I.V. (lansoprazole) for Injection.

We also acknowledge receipt of your submissions dated April 24, 2007.

This "Changes Being Effected" supplemental new drug application provides for consistency with the Prevacid NapraPAC label approved on August 31, 2006; the addition of "myositis" and "interstitial nephritis" to the Adverse Reactions section, Postmarketing, Body as a Whole sub-section of the package insert; and symbols and dose designations were updated in accordance with the Institute of Safe Medical Practices.

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 you submitted on April 24, 2007.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Chantal Phillips, Regulatory Project Manager, at (301) 796-2259.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastroenterology 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
this page is the manifestation of the electronic signature.**

/s/

Joyce Korvick
5/16/2007 11:45:27 AM