



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-406/S-064  
NDA 21-281/S-021  
NDA 21-428/S012

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

Dear Ms. Abelson:

Please refer to your supplemental new drug applications dated November 20, 2006, received November 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid (lansoprazole) Delayed-Release Capsules, Delayed-Release Suspension, and Delayed-Release Orally Disintegrating Tablets.

These "Changes Being Effected" supplemental new drug applications provide for consistency with the Prevacid NapraPAC label approved on August 31, 2006. In addition, in response to the Agency's request on July 31, 2006, "myositis" and "interstitial nephritis" were added to the Adverse Reactions section, Postmarketing, Body as a Whole sub-section of the package insert. Symbols and dose designations were also updated in accordance with the Institute of Safe Medical Practices. Wording has been modified to emphasize the location of contraindication and warnings information for other drugs that may be used in conjunction with Prevacid. Text was added to reflect modifications to the Biaxin (clarithromycin) package insert (NDA 50-662) approved on July 5, 2006.

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 enclosed labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. FOR sNDAs: For administrative purposes, please designate this submission "SPL for approved supplement NDAs 20-406/S-064, 21-281/S021, 21-428/S012."

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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 inserts directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
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  
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

Enclosure

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

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Joyce Korvick  
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