



NDA 50-757/S-009, S-010

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 applications dated January 30, 2004, received February 2, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PREVPAC[®] (lansoprazole/amoxicillin/clarithromycin).

We acknowledge receipt of your submission dated March 2, 2004.

Supplement S-009 provides for revised labeling to comply with the Final Rule entitled “**Labeling Requirements for Systemic Antimicrobial Drug Products Intended for Human Use**” (68FR 6062, February 6, 2003) and respond to our CBE request letter dated September 11, 2003. Supplement S-010 provides for the addition of postmarketing adverse events information for Prevacid capsules, and for the name change of hydroxypropyl ethylcellulose to hypromellose, per the change in USP.

These “Changes Being Effected” supplemental new drug applications provide for the following additions to the package insert:

Location	Change in text
At the beginning of the label, under “ PRODUCT NAME ”	Addition of: To reduce the development of drug-resistant bacteria and maintain the effectiveness of PREVPAC [®] and other antibacterial drugs, PREVPAC [®] should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
DESCRIPTION Under BIAXIN [®] Filmtab [®]	Replace hydroxypropyl methylcellulose with hypromellose, per the change in USP.
CLINICAL PHARMACOLOGY section under PREVACID:	Removal of: Peak plasma concentrations of lansoprazole (C _{max}) and 1.7 hours.
INDICATIONS AND USAGE	Addition of: To reduce the development of drug-resistant bacteria and maintain the effectiveness of PREVPAC [®] and other antibacterial drugs,

	PREVPAC [®] should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
PRECAUTIONS section, under “General” subsection	Addition of: Prescribing PREVPAC [®] in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication it is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.
PRECAUTIONS section, under “Information for patients”	Addition of: Patients should be counseled that antibacterial drugs including PREVPAC [®] should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When PREVPAC [®] is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full courses of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by PREVPAC [®] or other antibacterial drugs in the future.
ADVERSE REACTIONS Section, under PREVACID: “Postmarketing”	Addition of: pancreatitis to the subsection <i>Digestive System</i> ; and the complete subsection <i>Skin and Appendages</i> – severe dermatologic reactions including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, (some-fatal).

We have completed the review of these supplemental applications, 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 final printed label submitted on January 30, 2004 (enclosed). Accordingly, this supplemental application is approved effective on the date of this letter.

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, HFD-410
 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, please call Kristen Miller, Pharm.D., Regulatory Project Manager at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Immunologic
Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

Renata Albrecht
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