



NDA 21-281/S-022  
NDA 20-406/S-065  
NDA 21-428/S-013

TAP Pharmaceutical Products Inc.  
Attention: Tonya Haynes  
Regulatory Product Manager  
675 North Field Drive  
Lake Forest, IL 60045

Dear Ms. Haynes:

Please refer to your supplemental new drug applications dated September 11, 2007, received September 12, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid (lansoprazole) Delayed-Release Oral Suspension, Delayed-Release Capsules, and Delayed-Release Orally Disintegrating Tablets.

We acknowledge receipt of your submissions dated September 11, 2007.

These “Changes Being Effected” supplemental new drug applications provide for:

- Revised warning section for inclusion of Clostridium difficile associated diarrhea based on FDA requested changes for Biaxin (clarithromycin) package insert.
- Additional text in the drug interactions section based on published clinical study results showing an interaction between Prevacid and Atazanavir in healthy subjects.
- Modification of text for consistency with Prevpac.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 11, 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

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

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

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/s/

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Joyce Korvick  
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