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# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### *APPLICATION NUMBER:*

**21-428**

***Trade Name:*** Prevacid SoluTab Delayed-Release Orally Disintegrating Tablets, 15 mg and 30 mg.

***Generic Name:*** lansoprazole

***Sponsor:*** TAP Pharmaceutical Products, Inc.

***Approval Date:*** August 30, 2002

***Indications:*** Provides for a new dosage form of Prevacid to treat:

- 1) Short-Term Treatment of Active Duodenal Ulcer
- 2) *H. pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence
- 3) Maintenance of Healed Duodenal Ulcers
- 4) Short-Term Treatment of Active Benign Gastric Ulcer
- 5) Healing of NSAID-Associated Gastric Ulcer
- 6) Risk Reduction of NSAID-Associated Gastric Ulcer
- 7) Gastroesophageal Reflex Disease (GERD)
- 8) Maintenance of Healing of Erosive Esophagitis
- 9) Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome

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*APPLICATION NUMBER:*

**21-428**

**APPROVAL LETTER**



NDA 21-428  
NDA 20-406/S-052  
NDA 21-281/S-007

TAP Pharmaceutical Products, Inc.  
Attention: Nancianne Knipher, Ph.D.  
Project Manager, Regulatory Affairs  
675 North Field Drive  
Lake Forest, IL 60045

Dear Dr. Knipher:

Please refer to your new drug application dated October 30, 2001, received October 31, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® SoluTab (lansoprazole) Delayed-Release Orally Disintegrating Tablets, 15 mg and 30 mg. We also refer to your supplemental new drug applications submitted August 30, 2002 and received August 30, 2002 for Prevacid® (lansoprazole) Delayed-Release Capsules and Prevacid® (lansoprazole) for Delayed-Release Oral Suspension.

We acknowledge receipt of your submissions dated December 13, 2001, February 20, February 22, February 27, March 5, March 21, April 11, April 12, April 26, June 20, June 28, July 11, August 14, August 21, August 26 and August 29, 2002.

The new drug application (NDA 21-428) provides for a new dosage form of Prevacid®, Prevacid® SoluTab (lansoprazole) Delayed-Release Orally Disintegrating Tablets. This new dosage form is formulated to disintegrate in the mouth without chewing. The drug product described in this NDA has the same active pharmaceutical ingredient (API) and indications as NDA 20-406, Prevacid® (lansoprazole) Delayed-Release Capsules.

The supplemental new drug applications (NDA 20-406/S-052 and NDA 21-281/S-007) provide for the incorporation of the labeling changes approved in this letter into NDA's 20-406 and 21-281.

We completed our review of these applications, as amended. They 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, except for including the revisions listed, the enclosed agreed upon labeling (text for the package insert) and submitted labeling (immediate container and carton labels submitted June 20, 2002).

1. Change the product name to Prevacid® SoluTab (lansoprazole) Delayed-Release Orally Disintegrating Tablets on all blister and carton labels.
2. Delete the storage statement from the blister label.

These revisions are terms of the NDA approval. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the FPL electronically 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

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it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-428, and supplements NDA 20-406/S-052 and NDA 21-281/S-007. Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment to NDA 21-428 in your submission dated August 21, 2002. This commitment is listed below.

#### Imprinting

- Conduct experimental studies to evaluate the feasibility of tablet imprinting within one year after approval of NDA 21-428. A prior approval supplement with 3 month stability data should be submitted 6 months after the feasibility study is completed.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

Your application does not address the pediatric study requirements. Submit your pediatric drug development plans or a request for a waiver, if you believe one is appropriate, within three months from the date of this letter. If you believe a waiver is justified, submit your request with supporting information and documentation.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. 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:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

We have not completed validation of the regulatory methods. Please submit three copies of the methods validation information contained in your application. We expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Melissa Furness, Regulatory Project Manager, at (301) 827-7450.

Sincerely,

{See appended electronic signature page}

Victor Raczkowski, M.D., M.Sc.  
Acting Director  
Division of Gastrointestinal & Coagulation Drug Products, HFD-180  
Center for Drug Evaluation and Research

Enclosure

**APPEARS THIS WAY  
ON ORIGINAL**

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Joyce Korvick  
8/30/02 04:21:15 PM  
for Dr. Victor Raczkowski

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ON ORIGINAL