CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
21-281

Trade Name: Prevacid for Delayed-Release Oral Suspension

Generic Name: lansoprazole

Sponsor: Tap Pharmaceutical Products, Inc.

Approval Date: May 3, 2001

Indications: Provides for the use of Prevacid for Delayed-Release Oral Suspension 15mg and 30mg for the following Indications:

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 ulders.
5. Healing of NSAID-associated gastric ulcer.
6. Risk reduction of NSAID-associated gastric ulcer.
7. Short-term treatment of symptomatic Gastroesophageal reflux disease (GERD).
8. Short-term treatment of erosive esophagitis.
9. Maintenance of healing of erosive esophagitis.
10. Pathological hypersecretory conditions including Zollinger-Ellison syndrome.

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Chemistry Review(s)	X			
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Pharmacology Review(s)				
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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-281

MAY -3 2001

TAP Pharmaceutical Products Inc.
Attention: Ms. Betsy Brown
Assistant Director, Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Brown:

Please refer to your new drug application (NDA) dated June 30, 2000, received July 3, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole) for Delayed-Release Oral Suspension, 15 mg and 30 mg.

We acknowledge receipt of your submissions dated September 22, October 18, and November 30, 2000, and March 6, 7, 15, 28, and 30, and April 6, 2001.

This new drug application provides for the use of Prevacid® (lansoprazole) for Delayed-Release Oral Suspension, 15 mg and 30 mg, for the following indications: short-term treatment of active duodenal ulcer, *H. pylori* eradication to reduce the risk of duodenal ulcer recurrence, maintenance of healed duodenal ulcers, short-term treatment of active benign gastric ulcer, healing of NSAID-associated gastric ulcer, risk reduction of NSAID-associated gastric ulcer, short-term treatment of symptomatic gastroesophageal reflux disease (GERD), short-term treatment of erosive esophagitis, maintenance of healing of erosive esophagitis, and pathological hypersecretory conditions including Zollinger-Ellison syndrome.

We have completed the review of this application, 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 labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and the color mock-ups of the immediate container and carton labels submitted March 15, 2001 with the revisions listed below:

Immediate Container Label

1. Revise the name of the drug to "PREVACID® (lansoprazole) for Delayed-Release Oral Suspension".
2. Increase the prominence of the product strength (15 mg and 30 mg) and assure that the two strengths are differentiated from each other.
3. Revise the first sentence of the text to read: "This packet contains 30 mg of lansoprazole as enteric-coated granules."

4. Revise the second paragraph to read: "Directions for Use: Empty packet contents into a container containing 2 tablespoons of **WATER.** DO NOT USE OTHER LIQUIDS OR FOODS. Stir well, and drink immediately. DO NOT CRUSH OR CHEW THE GRANULES. If any material remains after drinking, add more water, stir, and drink immediately."
5. Delete all reference to "sachet" and replace with the word "packet".

Carton Label

6. Change the name of the drug to "PREVACID® (lansoprazole) for Delayed-Release Oral Suspension".
7. Increase the prominence of the product strength (15 mg and 30 mg) and assure that the two strengths are differentiated from each other.
8. Delete all reference to "sachet" and replace with the word "packet".
9. Revise carton labeling to prevent confusion between quantity per carton and product strength specifically related to the phrase: "Contains 30/30-mg Packets" to "Contains 30 x 30-mg Single Dose Packets"
10. Revise the "Directions for Use" paragraph to read as follows: "Directions for Use: Empty packet contents into a container containing 2 tablespoons of **WATER.** DO NOT USE OTHER LIQUIDS OR FOODS. Stir well, and drink immediately. DO NOT CRUSH OR CHEW THE GRANULES. If any material remains after drinking, add more water, stir, and drink immediately."

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 copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 15 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-281." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27). More data and expert discussion is needed before initiating pediatric studies. Therefore, we are deferring submission of your pediatric studies under the rule. Please re-evaluate available information on this drug and the disease in children and submit your pediatric development plan by June 1, 2003.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" (PPSR) in addition to your plans for pediatric drug development described above. We recommend that you submit a Proposed Pediatric Study Request within 120 days from the date of this letter. If you are unable to meet this time frame but are interested in pediatric exclusivity, please notify the division in writing. FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. If you do not submit a PPSR or indicate that you are interested in pediatric exclusivity, we will review your pediatric drug development plan and notify you of its adequacy. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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, Maryland 20857

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 Cheryl Perry, Regulatory Health Project Manager, at (301) 827-7475.

Sincerely,
{See appended electronic signature page}

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Text for the package insert