DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-566

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

Dear Dr. Knipfer:

Please refer to your new drug application (NDA) dated December 20, 2002, received December 23, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid I.V. (lansoprazole) for Injection, 30 mg.

We acknowledge receipt of your submissions dated April 18, April 21, August 12, August 20, August 28, September 4, September 8, September 24, September 26, October 1, October 13, October 17, October 21, 2003, January 10, April 29, and May 17, 2004.

The January 10, 2004 submission constituted a complete response to our October 23, 2003 action letter.

This new drug application provides for the use of Prevacid I.V. (lansoprazole) for Injection when patients are unable to take the oral formulations PREVACID I.V. for Injection is indicated as an alternative for the short-term treatment (up to 7 days) of all grades of erosive esophagitis.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling must be identical to the enclosed labeling (text for the package insert) and/or submitted labeling (immediate container and carton labels submitted January 10, 2004) with the inclusion of the following changes agreed to via facsimile dated May 27, 2004. In your May 27, 2004 facsimile you agreed to make changes A, B, and C at your second printing of your carton, filter and peel-off sticker labeling and change D prior to the first printing of your package insert.

A. CARTON LABELING

1. Include the instructions on the “FRONT PANEL” to read, “After reconstitution with 5 mL of Sterile Water for Injection, USP, the resulting solution will contain lansoprazole 6 mg/mL (30 mg/5 mL).”

B. FILTER PACK LABELING

1. Revise the statement "In-line filter for use with" to read "In-line filter" and increase its prominence. Additionally, the brand name and size of the filter (PALL Supor 1.2 µm) should appear in parenthesis immediately following the statement "In-line filter."

2. Decrease the prominence of the statement "Prevacid IV (lansoprazole) for Injection" and precede this

statement with "For use with."

3. Revise the statement "Caution: Federal (USA) law restricts…." To read "Rx Only."

C. PEEL-OFF STICKER

1. Revise the statement "USE OF IN-LINE FILTER PROVIDED IS REQUIRED" to read 'IN-LINE FILTER MUST BE USED."

D. PACKAGE INSERT

1. Provide the instructions for use to priming the filter in the DOSAGE AND ADMINISTRATION section of the Package Insert in case the labeling is lost or misplaced.

These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as stated, in the product's labeling may render the product misbranded and an unapproved new drug Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL 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 it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-566**." Approval of this submission by FDA is not required before the labeling is used.

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. We note that you have submitted pediatric studies for ages 12-17 with NDA 20-406/S-057, completed studies for ages 1-11 (NDA 20-406/S-047), and plan to initiate studies in children less than 1 year of age after the completion of your required rat toxicity study. For Prevacid I.V. (lansoprazole) for Injection, a bridging PK (pharmacokinetic) study will be needed in children due to our concerns regarding the basic nature of this formulation of Prevacid.

We remind you of your postmarketing study commitment in your submission dated May 17, 2004. These commitments are listed below.

1. Conduct studies to identify the cause of instability of the drug product in some admixture solutions. This should include a full chemical characterization of the particulates.

2. Reformulate the product so that it is compatible with admixture solutions, independent of the composition of the diluent container or administration kit.

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**."

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

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, 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).

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

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Joyce Korvick
5/27/04 04:37:57 PM
for Dr. Robert Justice