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Approval Package for:

APPLICATION NUMBER:

21-507

Trade Name: Prevacid Naprapac

Generic Name: lansoprozole delayed-release capsules and naproxen tablets kit

Sponsor: TAP Pharmaceuticals Products Inc.

Approval Date: November 14, 2003

Indications: Provides for risk reduction of NSAID-associated gastric ulcers in patients with a history of a documented gastric ulcer who require the use of an NSAID

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APPLICATION NUMBER:

21-507

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APPLICATION NUMBER:

21-507

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-507

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

Dear Dr. Knipfer:

Please refer to your new drug application (NDA) dated September 6, 2002, received September 9, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid Naprapac™ (lansoprozole delayed-release capsules and naproxen tablets kit), 15 mg /250 mg, 15mg/375 mg, and 15 mg/500 mg.

We acknowledge receipt of your submissions dated October 31, November 27, December 19, 2002; January 14, March 7, March 28, June 26, July 24, September 4, November 12, and November 13, 2003.

The July 24, 2003 submission constituted a complete response to our July 9, 2003 action letter.

This new drug application provides for the use of Prevacid Naprapac™ (lansoprozole delayed-release capsules and naproxen tablets kit), 15 mg /250 mg, 15mg/375 mg, and 15 mg/500 mg, for risk reduction of NSAID-associated gastric ulcers in patients with a history of a documented gastric ulcer who require the use of an NSAID.

We completed our review of this application, as amended. It is approved with a two year expiry date, 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 the submitted labeling (package insert, immediate container and carton labels submitted **June 26, 2003 [first printing only] and November 13, 2003 [all subsequent printings]**). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and 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 21-507**." Approval of this submission by FDA is not required before the labeling is used.

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 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 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

APPEARS THIS WAY
ON ORIGINAL

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/s/

Joyce Korvick
11/14/03 01:40:04 PM
for Dr. Robert Justice

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APPLICATION NUMBER:

21-507

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-507

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 (NDA) dated September 6, 2002, received September 9, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid Naprapac (lansoprozole/naproxen), 15 mg/250 mg, 15mg/375 mg, and 15 mg/500 mg.

We acknowledge receipt of your submissions dated October 31, November 27, December 19, 2002; January 14, March 7, March 28, and June 26, 2003.

We completed our review of this application as submitted and it is approvable. Before the application may be approved, however, it will be necessary for you to address the following:

During a recent inspection of the manufacturing facility for this application, our field investigator conveyed significant deficiencies to the facility's representatives. Satisfactory resolution to these deficiencies is required before this application may be approved.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Melissa Hancock Furness, Regulatory 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

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
7/9/03 03:46:03 PM
for Dr. Robert Justice