CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 20406/S021

Trade Name: PREVACID DELAYED-RELEASE CAPSULES

Generic Name: LANSOPRAZOLE

Sponsor: TAP HOLDINGS INC.

Approval Date: 7/20/98

Indication(s): COMBINED WITH AMOXICILLIN AND CLARITHROMYCIN TO TREAT DUODENAL ULCER DISEASE AND ERADICATION OF H. Pylori.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 20406/S021

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter	X			
Final Printed Labeling		X		
Medical/Statistics Reviews	X			
Chemistry Review(s)				X
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)	(See Above)			
Microbiology Review(s)	X			
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)				X
Administrative Document(s)/ Correspondence	X			

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 20406/S021

APPROVAL LETTER

NDA 20-406/S-021

TAP Holdings Inc.
Attention: Linda J. Peters, M.S.
2355 Waukegan Road
Deerfield, IL 60015

APPEARS THIS WAY
ON ORIGINAL

Dear Ms. Peters:

Please refer to your supplemental new drug application dated June 25, 1997, received June 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid (lansoprazole) Delayed-Release Capsules.

We acknowledge receipt of your submissions dated August 13, August 27, and September 19, 1997, and May 18, May 29, June 24, and July 14, 1998. Your submission of July 14, 1998 consitutes a full response to our May 11, 1998 action letter.

This supplemental new drug application provides for a 10-day dosing regimen for triple therapy, Prevacid in combination with clarithromycin and amoxicillin, for the eradication of *Helicobacter pylori* in patients with duodenal ulcer disease.

We have completed the review of this supplemental 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 submitted final printed labeling (package insert dated July 14, 1998). Accordingly, the supplemental application is approved effective on the date of this letter.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

If a letter communicating important information about this drug product (i.e., a "Dear Healthcare Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

APPEARS THIS WAY
ON ORIGINAL

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, contact Maria R. Walsh, M.S., Project Manager, at (301) 443-0487.

Sincerely,

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

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:20406/S021

APPROVABLE LETTER

Walsh

NDA 20-406/S-021

TAP Holdings Inc.
Attention: Linda J. Peters, M.S.
2355 Waukegan Road
Deerfield, IL 60015

MAY 11 1998

Dear Ms. Peters:

Please refer to your supplemental new drug application dated June 25, 1997, received June 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid (lansoprazole) Delayed-Release Capsules.

We acknowledge receipt of your submissions dated August 13, August 27, and September 19, 1997. The User Fee goal date for this application is June 26, 1998.

The supplemental application provides for a 10-day dosing regimen for triple therapy, Prevacid in combination with clarithromycin and amoxicillin, for the eradication of *Helicobacter pylori* in patients with duodenal ulcer disease.

We have completed the review of this supplemental application as submitted with draft labeling, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit final printed labeling (FPL) revised as follows:

1. Under **PHARMACODYNAMICS, *Antisecretory Activity*:**

Revise the following sentence

from: "Higher levels of acid suppression have been predicted to potentiate the activity of antibiotics in eradicating Helicobacter (*H. pylori)*."

to: "Acid suppression may enhance the effect of antibiotics in eradicating Helicobacter pylori (*H. pylori)*."

2. Under **PHARMACODYNAMICS, *Microbiology*:**

Delete the entire text under this section and replace it with the attached text (see attachment 1).

3. Under **CLINICAL STUDIES, *H.pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence.**

Replace the table entitled, " *H. pylori* Eradication Rates - 14-Day Triple Therapy" with

the attached table which includes the results from the evaluable and MITT analyses of Study M95-399 (see attachment 2).

4. Under **INDICATIONS AND USAGE, *H.pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence,** Dual Therapy (PREVACID/amoxicillin):

Delete the following sentence:

"Resistance to amoxicillin has not been demonstrated in clinical studies with PREVACID and amoxicillin."

Note: There is insufficient information at this time to support this statement.

In addition, all previous revisions as reflected in the most recently approved package inserts must be included.

Please submit 20 copies of the printed labeling, ten of which are individually mounted on heavy-weight paper or similar material.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

In addition, please submit three copies of the introductory promotional material 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 material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw the application.

This change may not be implemented until you have been notified in writing that this supplemental application is approved.

If you have any questions, please contact Maria R. Walsh, M.S., Project Manager, at (301) 443-0487.

Sincerely yours,

/S/ 5-11-98

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

APPEARS THIS WAY
ON ORIGINAL

cc:
Original NDA 20-406/S-021
HFD-180/Div. Files
HFD-002/ORM
HFD-103/Office Director
HFD-101/L.Carter
HFD-92/DDM-DIAB
HFD-40/DDMAC (with draft labeling)
DISTRICT OFFICE
HFD-180/PM/M.Walsh
HFD-180/J.Senior
H.Gallo-Torres
L.Talarico
HFD-590/M.Goldberger
M.Albuerne
R.Hopkins
N.Silliman
L. Utrup
R.Anderson

APPEARS THIS WAY
ON ORIGINAL

Drafted by: M.Walsh 5/7/98
Initialed by: H.Gallo-Torres 5/8/98
L.Talarico 5/8/98
Final: M.Walsh 5/11/98
filename: 20406s21.ae

APPROVABLE (AE)