CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S007

Trade Name: Prevacid Delayed Release Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Holdings Inc

Approval Date: July 25, 1996

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APPLICATION NUMBER:

20-406/S007

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APPLICATION NUMBER:

NDA 20-406/S007

APPROVAL LETTER

NDA 20-406/S-007

TAP Holdings Incorporated
Attention: Judy Decker Wargel
2355 Waukegan Road
Deerfield, Illinois 60015

JUL 25 1996

Dear Ms. Wargel:

Please refer to your January 26, 1996 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for PREVACID® (lansoprazole) Delayed Release Capsule.

We also acknowledge receipt of your amendment dated July 19, 1996.

b(4) The supplemental application provides for the removal of the [redacted] from the approved 30 and 100 count bottles for both the 15 and 30 mg capsules. b(4)

We have completed the review of this supplemental application and it is are approved.

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, please contact:

Ms. Maria Walsh
Consumer Safety Officer
(301) 443-0487

Sincerely yours,

Eric P. Duffy 7/24/96

Eric P. Duffy, Ph.D.
Acting Chemistry Team Leader
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
NDA 20-406
HFD-180/Div.File
DISTRICT OFFICE
HFD-181/MWalsh
HFD-820/YChiu
HFD-180/GChen GC 7/24/96
GC/dob F/T 7-23-96
R/D init: EDuffy/7-23-96
GC/dob F/T 7-23-96\WP: c:\wpfiles\chem\S\20406007.agc

APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S007

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

39.1

NDA 20-406/S-007

FEB - 6 1996

TAP Holdings Inc.
Attention: Judy Decker Wargel
2355 Waukegan Road
Deerfield, IL 60015

Dear Ms. Wargel:

We acknowledge receipt of your supplemental application for the following:

Name of Drug Product: Prevacid (lansoprazole) Delayed-Release Capsules

NDA Number: NDA 20-406

Supplement Number: S-007

Therapeutic Classification: Standard

Date of Supplement: January 26, 1996

Date of Receipt: January 29. 1996

This supplement, submitted as "Special Supplement - Changes Being Effected" under 21 CFR 314.70(c), provides for the removal of the

b(4) [redacted] from the 30 and 100 count bottles.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on March 30, 1996 in accordance with 21 CFR 314.101(a).

All communications concerning this supplemental application should be addressed as follows:

Center for Drug Evaluation and Research
Division of Gastrointestinal and
Coagulation Drug Products, HFD-180
Attention: DOCUMENT CONTROL ROOM
5600 Fishers Lane
Rockville, Maryland 20857

Should you have any questions, please contact me at (301) 443-0487.

Sincerely yours,

Maria Walsh
Consumer Safety Officer
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

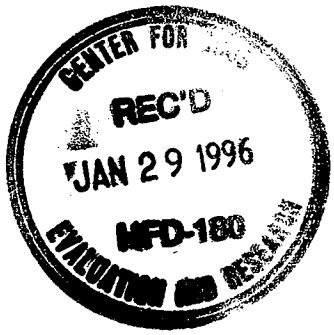
cc:
Original NDA 20-406/S-007
HFD-180/Div. Files
HFD-181/M.Walsh
DISTRICT OFFICE
Final: M.Walsh 2/2/96

SUPPLEMENT ACKNOWLEDGEMENT

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

Bannockburn Lake Office Plaza
2355 Waukegan Rd.
Deerfield, IL 60015

ORIGINAL



January 26, 1996

Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Document Control Room 6B-24
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

NDA NO. 20406 SUPP. NO. 007
NDA SUPPL FOR SCP

Attn: Stephen B. Fredd, M.D.

RE: PREVACID® (lansoprazole) Delayed-Release Capsules
NDA 20-406
Supplement S-007
Changes Being Effected

Dear Dr. Fredd:

The sponsor, TAP Holdings Inc., submits this Supplemental Application under the provisions of Section 505 (i) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.70 (b) (3).

This is to notify the Agency that effective November 17, 1995, b(4) [redacted] b(4) is no longer being used in PREVACID 30 and 100 count bottles.

In your letter dated October 23, 1995, you agreed that it was acceptable to make this change and notify the Agency in a "Changes Being Effected" supplement.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

Judy Decker Wargel

Judy Decker Wargel
Associate Director, Regulatory Affairs
Phone: (847) 317-5781
Fax: (847) 317-5795

JDW/pjp

1/29/96

2/6/96