CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S025

Trade Name: Prevacid Delayed Release Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Holdings Inc

Approval Date: July 23, 1998
## CONTENTS

Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:
NDA 20-406/S025

APPROVAL LETTER
NDA 20-406/S-025

TAP Holdings
Attention: Gary C. Magistrelli, Ph.D.
2355 Waukegan Road
Deerfield, IL 60015

Dear Dr. Magistrelli:


The user fee goal date for this application is July 29, 1998.

We note that this supplement was submitted as a “Special Supplement - Changes Being Effectuated” under 21 CFR 314.70(e).

This supplemental new drug application provides for an alternate blister material, \( b(4) \), for the unit dose packages of 15 mg and 30 mg capsules and the physician’s sample unit packages.

We have completed the review of this supplemental application and it is 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, contact Maria R. Walsh, M.S., Project Manager, at (301) 443-0487.

Sincerely,

Eric P. Duffy, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal and Coagulation Drug Products, (HFD-180)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research
APPLICATION NUMBER:
NDA 20-406/S025

CHEMISTRY REVIEW(S)
DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls Supplement

SUBMISSION TYPE DOCUMENT CDER ASSIGNED
ORIGINAL 28-Jan-98 29-Jan-98 05-Feb-98

SUPPLEMENT PROVIDES FOR: replacement of approved blister material, which is

NAME & ADDRESS OF APPLICANT: TAP Holdings, Inc.
2855 Waukegan Road
Deerfield, IL 60015

DRUG PRODUCT NAME: Proprietary: Prevacid Nonproprietary/USAN: lansoprazole
PHARMACOLOGICAL CATEGORY: proton pump inhibitor INDICATION: treatment of ulcers

DOSAGE FORM: CAPSULE, DELAYED RELEASE PELLETS STRENGTH: 15 and 30 mg
ROUTE OF ADMINISTRATION: Oral HOW DISPENSED: RX OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:
2-[[3-methyl-4-(2,2',-trifluoroethoxy)-2-pyridyl]-methyl]-sulfinyl]benzimidazole

SUPPORTING DOCUMENTS: DMF RELATED DOCUMENTS: N/A CONSULTS: N/A

REMARKS/COMMENTS:
This is a CBE supplement. The only change is the use of a in the The of the is the currently-approved

CONCLUSIONS & RECOMMENDATIONS: The supplement may be approved.

Arthur B. Shaw, Ph.D.,
Review Chemist, HFD-180

Eric P. Duffy, Ph.D.
Chemistry Team Leader, HFD-180

CC:
NDA 20-406/SCP-025
HFD-180/Div File/NDA 20-406/SCP-025
HFD-180/LTalarico
HFD-180/ASHaw
HFD-181/MWalsh
R/D Init by: E.Duffy/7-20-98
ABS/dob F/T 7-22-98
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Page(s) Withheld

☑ § 552(b)(4) Trade Secret / Confidential

☐ § 552(b)(4) Draft Labeling

☐ § 552(b)(5) Deliberative Process
B. Suitability:

C. Quality Control: Appendices B.2. and B.3 contain the acceptance specifications

II. Stability: In their cover letter the applicant

cc:
NDA 20-406/SCP-025
HFD-180/NDA 20-406/SCP-025
HFD-181/MWalsh
HFD-180/LTalarico
HFD-180/EDuffy
HFD-180/ASHaw
R/D Init by EDuffy 10-Aug-99
ABS/ABS/11-Aug-99
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