

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S023

Trade Name: Prevacid Delayed Release Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Holdings Inc

Approval Date: June 11, 1998

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APPLICATION NUMBER:

20-406/S023

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	X

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APPLICATION NUMBER:
NDA 20-406/S023

APPROVAL LETTER

NDA 20-406/S-023

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

Dear Dr. Magistrelli:

Please refer to your supplemental new drug application dated December 10, 1997, received December 11, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid (lansoprazole) Delayed-Release Capsules.

The goal date for this application is June 11, 1998.

The supplemental application provides for the use of an ~~HDPE~~ child resistant cap, and ~~HDPE~~ HDPE bottle design for the 30 and 100 count bottles of the 15 and 30 mg capsules.

b(4)

b(4)

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

Sincerely yours,

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

cc:
Original NDA 20-406
HFD-180/Div. Files
HFD-180/CSO/M. Walsh
HFD-180/AShaw
HFD-180/EDuffy
HFD-92/DDM-DIAB
DISTRICT OFFICE

Drafted by: kj/June 10, 1998/revised by EPD June 11, 1998/c:\wordfiles\chem\S\20406023.Aed
ED/dob/F/T 6-11-98

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APPLICATION NUMBER:
NDA 20-406/S023

CHEMISTRY REVIEW(S)

3 Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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NDA 20-406/S023

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS



TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

ORIGINAL

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

June 18, 1998

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

*SCP/C
023*

Attn: Lilia Talarico, M.D.
Director

RE: PREVACID® (lansoprazole) Delayed-Release Capsules
NDA 20-406/S-023
General Correspondence
Response to FDA Request



Dear Dr. Talarico:

This submission is in response to a request received from Ms. Maria Walsh of
b(4) your Division via voice mail on June 1, 1998. Enclosed is an example of an
_____ bottle, container-closure for PREVACID . A CBE
submission for _____ was submitted to b(4)
your Division on December 10, 1997, and it was approved June 11, 1998.
For comparison, we have also enclosed an example of the child-resistant,
b(4) _____ container-closure system that was in use prior to the

On June 5, 1998, examples of these containers were inadvertently
submitted to NDA 20-406 ~~_____~~ b(4) amendment 002 in error. I apologize if
this has caused any confusion.

If you have any questions please contact me at the number listed below.

Sincerely,

Gary C. Magistrelli

Gary C. Magistrelli, Ph.D.
Associate Director, Regulatory Affairs
Phone: (847) 267-4961
Fax: (847) 317-5795