CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S026

Trade Name: Prevacid Delayed Release Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Holdings Inc

Approval Date: March 19, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-406/S026

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S026

APPROVAL LETTER

73.

NDA 20-406/S-026

MAR 19 1998

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

Dear Dr. Magistrelli:

We acknowledge your supplemental new drug application dated February 2, 1998, received February 3, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid (lansoprazole) Delayed-Release Capsules.

The supplemental application, submitted under 21 CFR 314.70(c), "Special Supplement - Changes Being Effected," provides for the expanded use of the shipping container, used for [redacted] b(4) [redacted] b(4).

Changes of the kind you have proposed, in our opinion, are not the kind of changes permitted by regulation to be put into effect prior to approval of a supplement. An approved supplement is required for the proposed changes, therefore this supplement has been reviewed under 21 CFR 314.70(b).

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

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 3/19/98

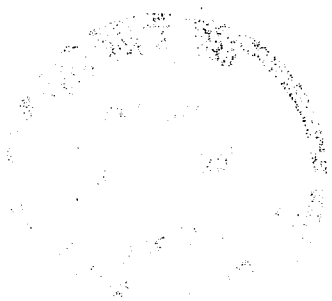
Eric P. Duffy, Ph.D.
Chemistry Team Leader
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:

Original NDA 20-406/S-026
HFD-180/Div. Files
HFD-180/M.Walsh
HFD-180/A.Shaw
HFD-820/ONDC Division Director
HFD-92/DDM-DIAB
DISTRICT OFFICE

Drafted by: M.Walsh 3/18/98
Initialed by: E.Duffy 3/19/98
final: M.Walsh 3/19/98
filename: 20406S26.ap

APPROVAL (AP)



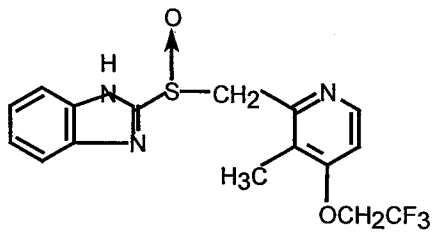
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S026

CHEMISTRY REVIEW(S)

73.1

CHEMIST'S REVIEW 1	1. Organization: HFD-180	2. NDA Number: 20-406
3. Name and Address of Applicant (City & State): TAP Holdings, Inc. Bannockburn Lake Plaza, 2355 Waukegan Road Deerfield, IL 60015		4. AF Number: MAR 18 1998 5. Supplement(s)
6. Name of Drug: Prevacid®	7. Nonproprietary Name: lansoprazole	Numbers: SCP-026 / Dates: February 2, 1998
8. Supplement Provides for: use of a b(4) b(4) product.		9. Amendments and Other (Reports, etc.) Dates: C February 3, 1998
10. Pharmacological Category: anti-ulcer	11. How Dispensed: RX X OTC __	12. Related IND/NDA/DMF(s):
13. Dosage Form: Delayed-Release Capsules	14. Potency: 15 and 30 mg	
15. Chemical Name and Structure: 2-[[[3-methyl-4-(2,2,-trifluoroethoxy)-2-pyridyl-]methyl]-sulfinyl]benzimidazole 		16. Records and Reports: Current Yes X No __ Reviewed Yes X No __

17. Comments: See "Notes."

cc: NDA 20-406/SCP-026
HFD-180/Div File
HFD-181/CSO
HFD-180/EDuffy
HFD-180/LTalarico
HFD-180/AShaw
R/D init by:EDuffy/3-17-98 EDUFFY 3/18/98
ABS/dob **F/T 3-18-98**/WP: c:\wpfiles\chem\S\20406026.1AS

18. Conclusions and Recommendations: The supplement may be approved.

19. Reviewer

Name:	Signature	Date Completed:
Arthur B. Shaw, Ph. D.	Arthur B. Shaw 3/18/98	March 16, 1998

Form FDH 2266 (7/75) ALT R

1 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-406
5026

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S026

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

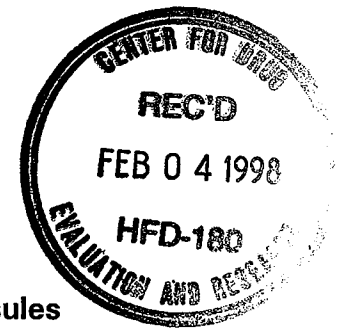
TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

ORIGINAL

February 3, 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
5600 Fishers Lane
Rockville, MD 20857



Attn: Lilia Talarico, M.D.
Director

RE: PREVACID® (lansoprazole) Delayed-Release Capsules
NDA 20-406
Special Supplement-Changes Being Effected
Supplement No. 026, Amendment No. 001

Dear Dr. Talarico:

This submission is a correction to a cover letter from the February 2, 1998, submission of S-026 for NDA 20-406. On page two of the February 2 cover letter reference is made to the [redacted] b(4) b(4) b(4) respectively.

The sponsor, TAP Holdings Inc., submits this change to an approved NDA for PREVACID Delayed-Release Capsules as a Changes Being Effected (CBE) supplement according to 21 CFR 314.70(c).

b(4) The [redacted] container described in this submission is currently being utilized as the approved shipping container [redacted] PREVACID Delayed-Release Capsules, 15 mg and 30 mg, manufactured [redacted] b(4) By this CBE submission, TAP Holdings Inc., intends to [redacted] b(4) b(4) b(4)

b(4)

Information describing the [redacted] container have been previously submitted in the original pre-filing of the CMC section for NDA 20-406. Real time stability data for PREVACID supporting [redacted] b(4) expiry in this container have previously been submitted in the 1996 annual report for this NDA. All of the previously submitted information has been included in this supplement. b(4)

b(4)

TAP proposes a [redacted] month expiry for the [redacted] container described in this submission.

b(4)

b(4) The approved [redacted] container has the [redacted] b(4) [redacted] PREVACID [redacted] b(4)

NDA 20-406 was approved on May 10, 1995.

b(4)

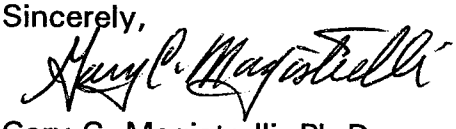
TAP commits to place [redacted] each product strength on long-term stability using the approved drug product protocol. Long-term stability will be conducted [redacted] b(4) b(4) b(4) are more practical and cost efficient [redacted] [redacted] container. The containers used for stability testing are composed of b(4) [redacted] found in the [redacted] b(4) [redacted] containers. In all other respects the containers are b(4) similar. We do not expect this difference in [redacted] b(4) adversely effect the stability of the drug product since the container remains impervious to moisture; nor do we expect the [redacted] the containers used for stability testing to adversely effect results. b(4)

We plan to implement this change 30 days after it has been filed in your Division.

A field copy of this submission has been submitted to the Chicago District Office.

If you have any questions or if you require additional information please contact me at the number listed below or contact Ms. Judy Wargel at (847) 317-5781.

Sincerely,



Gary C. Magistrelli, Ph.D.
Associate Director, Regulatory Affairs

(847) 267-4961
(847) 317-5795 (FAX)

CC: R. Mlecko (Chicago District Office, FDA)

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

ORIGINAL

February 2, 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
5600 Fishers Lane
Rockville, MD 20857

NDA NO: 20406 REF. NO. 026
NDA SUPPL FOR SCP

Attn: Lilia Talarico, M.D.
Director

RE: PREVACID® (lansoprazole) Delayed-Release Capsules
NDA 20-406
Special Supplement-Changes Being Effected
Supplement No. 026

Dear Dr. Talarico:

The sponsor, TAP Holdings Inc., submits this change to an approved NDA for PREVACID Delayed-Release Capsules as a Changes Being Effected (CBE) supplement according to 21 CFR 314.70(c).

The container described in this submission is currently being utilized as b(4)
the approved shipping container
15 mg and 30 mg, manufactured b(4)
b(4)
By this CBE submission, TAP Holdings
Inc., intends to expand its use of this approved shipping container b(4)
b(4)
b(4)

Information describing the components of this container have been previously submitted in the original pre-filing of the CMC section for NDA 20-406. Real time stability data for PREVACID supporting a 1 -month expiry in this container have previously been submitted in the 1996 annual report for this NDA. All of the previously submitted information has been included in this supplement.

TAP proposes a [redacted] month expiry for the [redacted] container described in this submission.

The approved [redacted] container has the [redacted] REVACID [redacted]

NDA 20-406 was approved on May 10, 1995

TAP commits to place [redacted] of each product strength on long-term stability using the approved drug product protocol. Long-term stability will be conducted [redacted] are more practical and cost efficient [redacted] container. The containers used for stability testing [redacted] containers. In all other respects the containers are similar. We do not expect this difference [redacted] adversely effect the stability of the drug product since the container remains impervious to moisture; nor do we expect the [redacted] the containers used for stability testing to adversely effect results.

We plan to implement this change 30 days after it has been filed in your Division.

A field copy of this submission has been submitted to the Chicago District Office.

If you have any questions or if you require additional information please contact me at the number listed below or contact Ms. Judy Wargel at (847) 317-5781.

Sincerely,

Gary C. Magistrelli, Ph.D.
Associate Director, Regulatory Affairs

(847) 267-4961
(847) 317-5795 (FAX)

CC: R. Mlecko (Chicago District Office, FDA)