

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**20-406/S020**

***Trade Name:*** Prevacid Delayed Release Capsules

***Generic Name:*** (lansoprazole)

***Sponsor:*** TAP Holdings Inc

***Approval Date:*** September 4, 1997

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**20-406/S020**

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**CENTER FOR DRUG EVALUATION AND  
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*APPLICATION NUMBER:*  
**NDA 20-406/S020**

**APPROVAL LETTER**

62.1

NDA 20-406/S-020

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

SEP - 4 1997

Dear Ms. Wargel:

Please refer to your supplemental new drug application dated May 22, 1997, received May 23, 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 submission dated July 17, 1997.

The supplemental application provides for a new capsule filling machine ~~\_\_\_\_\_~~ for the drug product manufacture ~~\_\_\_\_\_~~ manufacturing facility ~~\_\_\_\_\_~~ 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* 9/3/97

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

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cc:

Original NDA 20-406/S-020  
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 9/2/97

Initialed by: E. Duffy 9/2/97

final: M. Walsh 9/3/97

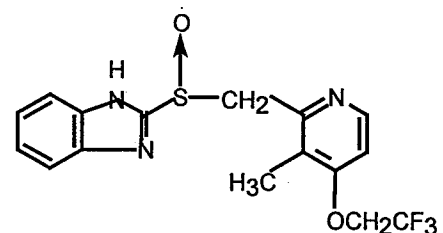
filename: 20406S20.AP

APPROVAL (AP)

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**NDA 20-406/S020**

**CHEMISTRY REVIEW(S)**

CHEMIST'S REVIEW 1		1. <u>Organization:</u> HFD-180		2. <u>NDA Number:</u> 20-406	
3. <u>Name and Address of Applicant (City &amp; State):</u> TAP Holdings, Inc. Bannockburn Lake Plaza 2355 Waukegan Road Deerfield, IL 60015				4. <u>AF Number:</u> AUG 28 1997	
6. <u>Name of Drug:</u> Prevacid®				7. <u>Nonproprietary Name:</u> lansoprazole	
8. <u>Supplement Provides for:</u> addition of a new capsule-filling machine for the drug product				9. <u>Amendments and Other (Reports, etc.) Dates:</u> BC July 17, 1997	
10. <u>Pharmacological Category:</u> anti-ulcer		11. <u>How Dispensed:</u> RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		12. <u>Related IND/NDA/DMF (s):</u>	
13. <u>Dosage Form:</u> Delayed-Release Capsules		14. <u>Potency:</u> 15 and 30 mg		16. <u>Records and Reports:</u>	
15. <u>Chemical Name and Structure:</u> 2-[[[3-methyl-4-(2,2,-trifluoroethoxy)-2-pyridyl]-methyl]-sulfinyl]benzimidazole				Current Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
				Reviewed Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
17. <u>Comments:</u> This supplement provides for the _____ <p style="text-align: right;">The _____ b(4)</p> <p>validation data (Page 90) and the early stability data demonstrate the acceptability of the new machine.</p> <p>cc: NDA 20-406/SCM-020  HFD-180/Div File  HFD-181/CSO  HFD-180/LTalarico  HFD-180/AShaw  HFD-180/EDuffy <i>EDuffy 8/28/97</i>  R/D init by:EDuffy/8-27-97  ABS/dob <b>F/T 8-27-97</b>/WP: c:\wpfiles\chem\S\20406020.1AS</p>					
18. <u>Conclusions and Recommendations:</u> The application may be approved. (AP)					
19. <u>Reviewer</u>					
Name: Arthur B. Shaw, Ph. D.		Signature <i>Arthur B. Shaw</i>		Date Completed: August 18, 1997	

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RESEARCH**

*APPLICATION NUMBER:*  
**NDA 20-406/S020**

**ADMINISTRATIVE and CORRESPONDENCE**  
**DOCUMENTS**



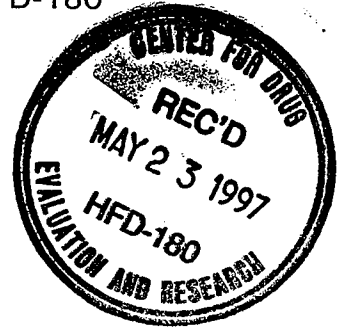


TAP HOLDINGS INC.  
parent of TAP Pharmaceuticals Inc.

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

May 22, 1997

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 SUPPL. NO. 020  
NDA SUPPL FOR SCM

Attn: Lilia Talarico, M.D.

RE: PREVACID® (lansoprazole) Delayed-Release Capsules  
NDA: 20-406, Supplement 020  
Supplemental Application for a Manufacturing Change:  
New Capsule Filling Machine

Dear Dr. Talarico:

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).

The purpose of this supplement is to qualify a new \_\_\_\_\_ PREVACID 15 mg and 30 mg capsules. b(4)

b(4)

This new \_\_\_\_\_ The manufacture of the drug substance and drug product remain unchanged. Only the filling of the capsules is affected. b(4)

Included in this submission are the following \_\_\_\_\_ reports which describe and detail the use of the \_\_\_\_\_ b(4)

b(4)

• \_\_\_\_\_

b(4)

• \_\_\_\_\_

b(4)

• \_\_\_\_\_

W 6-3-97



b(4)

• \_\_\_\_\_  
\_\_\_\_\_

b(4)

• \_\_\_\_\_  
\_\_\_\_\_

b(4)

\_\_\_\_\_ lots \_\_\_\_\_ 15 mg and 30 mg capsules \_\_\_\_\_

100 count HDPE bottles and placed on stability. Results obtained after three months of storage \_\_\_\_\_  
\_\_\_\_\_

b(4)

b(4)

A comparison of the results in tabular form is included as well as the stability protocol and the stability reports. \_\_\_\_\_

b(4)

b(4)

Should you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

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

JDW/mea

602.1  
NDA 20-406/S-020

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

JUN - 3 1997

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-020

Therapeutic Classification: Standard

Date of Supplement: May 22, 1997

Date of Receipt: May 23, 1997

This supplement provides for a new capsule filling machine \_\_\_\_\_

b(4)

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 July 22, 1997 in accordance with 21 CFR 314.101(a).

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

Food and Drug Administration  
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

NDA 20-406/S-020

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

Sincerely yours,

Maria R. Walsh, M.S.  
Project Manager  
Division of Gastrointestinal and  
Coagulation Drug Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

cc:

Original NDA 20-406/S-020

HFD-180/Div. Files

HFD-180/CSO/M. Walsh

HFD-180/E. Duffy

A. Shaw

DISTRICT OFFICE

MRW 6/2/97

Final: M. Walsh 6/2/97

SUPPLEMENT ACKNOWLEDGEMENT (AC)