CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S019

Trade Name: Prevacid Delayed Release Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Holdings Inc

Approval Date: September 17, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-406/S019

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S019

APPROVAL LETTER

NDA 20-406/S-019

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

SEP 17 1997

Dear Ms. Wargel:

Please refer to your supplemental new drug application dated February 14, 1997, received February 18, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid(R) (lansoprazole) Delayed-Release Capsules.

We acknowledge receipt of your submissions dated July 16 and August 27, 1997.

b(4)

The supplemental application provides for an additional [redacted] manufacturing facility [redacted] for the drug substance [redacted]

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 7/17/97

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

cc:
Original NDA 20-406/S-019
HFD-180/Div. Files
HFD-180/CSO/M.Walsh
HFD-180/A.Shaw
E.Duffy
HFD-820/ONDC Division Director
HFD-92/DDM-DIAB
DISTRICT OFFICE

Drafted by: M.Walsh 9/17/97
Initialed by: E.Duffy 9/17/97
final: M.Walsh 9/17/97
filename: 20406S19.AP

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S019

APPROVABLE LETTER

60-1

NDA 20-406/S-019

JUN 17 1997

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

Dear Ms. Wargel:

Please refer to your supplemental new drug application dated February 14, 1997, received February 18, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid(R) (lansoprazole) Delayed-Release Capsules.

The supplemental application provides for an additional [redacted] b(4) manufacturing facility in [redacted] b(4) for the starting material of the drug substance.

We have completed the review of this supplemental application and it is approvable. Before this supplement may be approved, however, it will be necessary for you to do the following.

1. [redacted] b(4)

   A. [redacted] b(4)

   B. [redacted] b(4)

   C. [redacted] b(4)

2. [redacted] b(4) b(4)

   Please provide information regarding the absence of these possible impurities [redacted] b(4) the new procedure.

3. Please provide the address of the proposed [redacted] b(4) facility and also indicate whether the facility is dedicated to pharaceutical manufacturing.

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw the application.

This change may not be implemented until you have been notified in writing that this supplemental application is approved.

If you have any questions, please contact Maria R. Walsh, M.S., Project Manager, at (301) 443-0487.

Sincerely yours,

Eric P. Duffy 6/12/97

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

cc:
Original NDA 20-406/S-019
HFD-180/Div. Files
HFD-92/DDM-DIAB
HFD-180/CSO/M.Walsh
HFD-180/A.Shaw ABS 6/13/97
E.Duffy
DISTRICT OFFICE

Drafted by: M.Walsh 6/9/97
Initialed by: E. Duffy 6/9/97
Final: M.Walsh 6/9/97
C:\wpfiles\cso\n\20406S19.ap

APPROVABLE (AE)

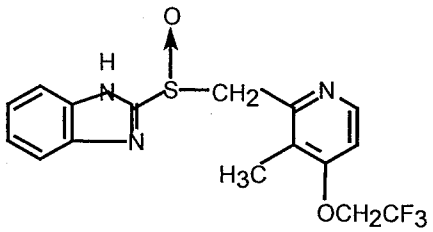
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S019

CHEMISTRY REVIEW(S)

68.1

CHEMIST'S REVIEW 3	1. Organization: HFD-180	2. NDA Number: 20-406
3. Name and Address of Applicant (City & State): TAP Holdings, Inc. Lannockburn Lake Plaza 2355 Waukegan Road Deerfield, IL 60015		4. AF Number: SEP 16 1997 5. Supplement
6. Name of Drug: Prevacid®	7. Nonproprietary Name: lansoprazole	Numbers: SCM-019 / Dates: February 14, 1997
8. Supplement Provides for: qualification of [redacted] manufacturing facility [redacted] b(4) lansoprazole [redacted]		9. Amendments and Other (Reports, etc.) Dates: BC July 16, 1997 BC August 27, 1997
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: In response to our letter dated August 8, 1997 the applicant has provided data to demonstrate the absence of the possible impurities [redacted] b(4) [redacted] lots manufactured using the new procedure. **ACCEPTABLE**

cc: NDA 20-406/SCM-019
HFD-180/Div File
HFD-181/CSO
HFD-180/LTalarico
HFD-180/AShaw
HFD-180/EDuffy
R/D init by:EDuffy 9/12/97 EDUFFY 9/16/97
ABS/**F/T abs** /WP: N:\WPFILES\CHEM\FINAL\SUP\20406019.3AS

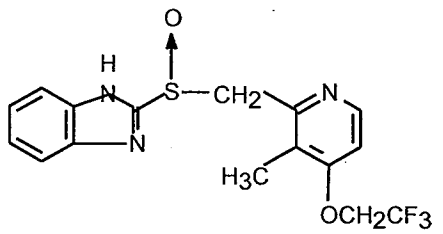
18. Conclusions and Recommendations: The applicant should be sent an Approval Letter(AP).

19. Reviewer

Name:	Signature	Date Completed:
Arthur B. Shaw, Ph. D.	Arthur B. Shaw 9/12/97	September 9, 1997

Form FDH 2266 (7/75) ALT R

60.1

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: JUN - 5 1997 5. Supplement
6. Name of Drug: Prevacid®	7. Nonproprietary Name: lansoprazole	Numbers: SCM-019 Dates: February 14, 1997
8. Supplement Provides for: qualification of a [redacted] b(4) [redacted] b(4)		9. Amendments and Other (Reports, etc.) Dates:
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: Review notes show tables comparing new and old procedures.
cc: NDA 20-406/SCM-019
HFD-180/Div File
HFD-181/CSO
HFD-180/SFredd
HFD-180/AShaw
R/D init by:EDuffy/6-2-97 EDuffy 6/5/97
ABS/dob **F/T 6-3-97**/WP: c:\wpfiles\chem\S\20406019.1AS

18. Conclusions and Recommendations: The applicant should be sent an Approvable letter.

19. Reviewer

Name:	Signature	Date Completed:
Arthur B. Shaw, Ph. D.	Arthur B. Shaw 6/3/97	April 9, 1997

Form FDH 2266 (7/75) ALT R

5 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
S019

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S019

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

60-1

NDA 20-406/S-019

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

FEB 25 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-019

Therapeutic Classification: Standard

Date of Supplement: February 14, 1997

Date of Receipt: February 18, 1997

This supplement provides for an additional manufacturing facility for the starting material of the drug substance.

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 April 18, 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

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-019
HFD-180/Div. Files
HFD-180/PM/M.Walsh MRW 2/24/97
HFD-180/E.Duffy
A.Shaw
DISTRICT OFFICE

Final: M.Walsh 2/24/97

SUPPLEMENT ACKNOWLEDGEMENT (AC)

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

2/24/97
SR

February 14, 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. 20-406 SUPP. NO. 019
NDA SUPPL FOR SCM

Attn: Stephen B. Fredd, M.D.

RE: PREVACID® (Lansoprazole) Delayed-Release Capsules
NDA: 20-406
Supplemental Application for Manufacturing Change/ New Facility **SNDA 019**

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).

The purpose of this supplement is to qualify a second manufacturing facility for ——— to ——— b(4) ——— the starting material for manufacturing lansoprazole. This second facility, ——— b(4) located ——— b(4)

Several changes have also been made to the manufacturing process in this new facility. These changes are thoroughly described in the overview as well as in the appended reports.

——— has produced ——— lots of lansoprazole drug substance ——— b(4) ——— placed them on stability. Interim results are presented in ——— b(4) ——— manufacturing procedure. Both 15 mg and 30 mg capsules ——— b(4) ——— b(4) ——— stability. This plan b(4) was presented to the Agency on June 10, 1996 (IND Amendment No. 294) and their concurrence received by letter dated July 22, 1996. Results showed (4) no difference in the stability profile ——— b(4) ——— b(4) ——— A comparison of results in tabular form is included as well as the stability reports.

b(4)

b(4) [redacted] (teleconference with Ms. Walsh on January 7, 1997).

If you have any questions, please direct them to my attention.

Sincerely,

Judy Decker Wargel

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

JDW/pjp

60-1

USER FEE DATA ENTRY/VALIDATION FORM

Ver.2(9/1/93)

NDA # 20-406 DOCUMENT ID/LETTER DATE SCM019 2/14/97 - 2/18/97

APPLICANT NAME Taro Holding TAIC

PRODUCT NAME Precedex DRC

FORM MUST BE COMPLETED BY (10 DAYS FROM DOCUMENT RECEIPT): _____

1. YES (NO) **CLINICAL DATA?**
[Check YES if contains study reports or literature reports of what are explicitly or implicitly represented by the applicant to be adequate and well-controlled trials. "Clinical data" do not include data used to modify the labelling to add a restriction that would improve the safe use of the drug (e.g., to add an adverse reaction, contraindication or warning to the labeling).]

REF **IF NO CLINICAL DATA IN SUBMISSION, INDICATE IF CLINICAL DATA ARE CROSS REFERENCED IN ANOTHER SUBMISSION?**

IF SUPPLEMENT and NO CLINICAL DATA INCLUDED, SKIP TO ITEM 11!

2. YES NO **505(b)(2) NDA?** An application in which one or more of the pivotal studies (rather than all) was not conducted or sponsored by the applicant and the applicant does not have a right of reference to that study. In addition, the firm must have made a patent certification under section 505(b) (2) (A) and (B) of the Act and must have cited a reference listed drug on which it is basing its application.

YES NO **If 505(b)(2) NDA - FEE APPLIES?**
[Check YES if application is for a new chemical entity or Indication. Check NO if application is for a previously approved drug substance or indication.]

3. YES NO **LARGE VOLUME PARENTERAL APPROVED BEFORE 9/1/92?** [Check YES only if a supplement with clinical data submitted to an LVP application first approved before 9/1/92.]

4. YES NO **505(j) NDA?** Abbreviated Application **IF YES, SKIP TO ITEM 11!**

5. YES NO **506 NDA?** Insulin Product **IF YES, SKIP TO ITEM 11!**

6. YES NO **NDA BEING SPLIT FOR ADMINISTRATIVE CONVENIENCE (OTHER THAN BUNDLING)?** IF YES, list ALL NDA numbers, review divisions & indicate those for which application fees apply.

NDA #	DIVISION		
N_____	_____	FEE	NO FEE
N_____	_____	FEE	NO FEE

7. YES NO **BUNDLING POLICY APPLIED CORRECTLY?** NO DATA ENTRY REQUIRED FOR ELEMENT
[Check YES if application is properly designated as one application or is properly submitted as a supplement instead of an original application. Check NO if application should be split into more than one application or submitted as an original instead of a supplement. IF NO, list resulting NDA numbers, and review divisions.]

NDA #	DIVISION	NDA #	DIVISION
N_____	_____	N_____	_____

8. YES NO **SMALL BUSINESS EXCEPTION GRANTED?** [Check YES only if the NDA contains a copy of a written notice from the FDA Waiver Officer that a exception has been granted.]

9. YES NO **WAIVER GRANTED?** [Check YES only if the NDA contains a copy of a written notice from the FDA Waiver Officer that a waiver has been granted.]

10. YES NO **PRIORITY SUBMISSION?** [Check YES if Priority. Check NO if Standard.]

11. Maria Walsh 2/20/97
CSO SIGNATURE/DATE

K Johnson 2/24/97
SCSO CONCURRENCE SIGNATURE/DATE

COPY DISTRIBUTION: ORIGINAL TO ARCHIVAL AFTER DATA ENTRY, ONE COPY EACH TO DIVISION FILE AND CDER, ASSOCIATE DIRECTOR FOR POLICY HFD-1-1