CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S039

Trade Name: Prevacid Delayed Release Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Holdings Inc

Approval Date: November 3, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-406/S039

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S039

APPROVAL LETTER

NDA 20-406/S-039

TAP Pharmaceutical Products Inc.
Attention: Ms. Betsy A. Brown
Assistant Director, Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Brown:

Please refer to your supplemental new drug application dated May 5, 2000, received May 8, 2000 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole) Delayed-Release Capsules, 40 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a packaging change in the Physicians' Sample Unit Dose Package of 7 (15 mg and 30 mg). b(4)
b(4) The proposed revised packaging will be comprised of the in the current packaging. However, the proposed blister will will be b(4)
eliminated. All drug contact surfaces and labeling for the proposed packaging will be identical to the current packaging.

We have completed the review of this supplemental new drug 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, call Cheryl Perry, Regulatory Health Project Manager, at (301) 827-7475

Sincerely,

Liang Zhou, Ph.D.
Chemistry Team Leader
Division of Gastrointestinal and Coagulation Drug Products, (HFD-180)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:
Archival NDA 20-406/S-039
HFD-180/Division file
HFD-180/C.Perry
HFD-180/A.Shaw
HFD-180/L.Zhou
HFD-095/DDMS-IMT
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: CP/October 24, 2000
Initialed by: KJ/October 29,2000
Final: CP/October 30, 2000
Filename: N20406.S039.AP.30-Oct-00.doc

(AP) APPROVAL

/s/

Liang Zhou
11/3/00 03:03:03 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S039

CHEMISTRY REVIEW(S)

DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls Supplement

NDA #:20-406 SUPPLEMENT #:SCP 039 CHEM REVIEW #: 1 REVIEW DATE:19-Oct-2000

SUBMISSION TYPE	DOCUMENT	CDER	ASSIGNED
Original	05-May-2000	08-May-2000	11-May-2000

SUPPLEMENT PROVIDES FOR: change in blister packaging for Physicians' Sample Unit Packages to / b(4)

NAME & ADDRESS OF APPLICANT: TAP Holdings, Inc.
2355 Waukegan Road
Deerfield, IL 60015

DRUG PRODUCT NAME: Proprietary: Prevacid Nonproprietary/USAN: lansoprazole

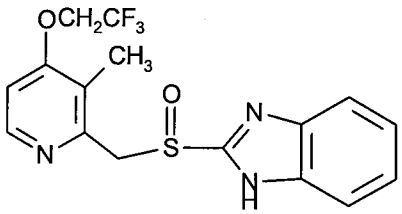
PHARMACOLOGICAL CATEGORY: proton pump inhibitor

DOSAGE FORM: CAPSULE, DELAYED RELEASE PELLETS STRENGTH: 15 and 30 mg

ROUTE OF ADMINISTRATION: oral HOW DISPENSED: X Rx ___ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

2[[[3-methyl-4-(2,2,trifluoroethoxy)-2-pyridyl-]methyl]-sulfinyl]benzimidazole



b(4)

SUPPORTING DOCUMENTS: DMFs RELATED DOCUMENTS: IND 30,159

CONSULTS: N/A

REMARKS/COMMENTS: CBE-30 supplement. There is no change in the product b(4) contact surfaces, which were found to be acceptable in the original application. testing shows the is b(4) equivalent. DMFs acceptable from earlier reviews. ACCEPTABLE

CONCLUSIONS & RECOMMENDATIONS: The supplement may be approved (AP)

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

Liang Zhou, Ph.D.
Chemistry Team Leader, HFD-180

cc:
NDA 20-406/SCP-039
HFD-180/Div File/NDA 20-406/SCP-039
HFD-180/LTalarico
HFD-180/LZhou
HFD-180/AShaw
HFD-181/CPerry
R/D Init by: LZhou 23-Oct-2000
ABS/F/T/ ABS 23-Oct-2000C:\WORD\Prevacid\20-406 Prevacid SCP-039.doc

23-OCT-2000 FDA CDER EES Page 1 of 1

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Application: **NDA 20406/039**
Stamp: **08-MAY-2000** Regulatory Due: **08-NOV-2000**
Applicant: **TAP PHARM**
675 NORTH FIELD DR
LAKE FOREST, IL 60045

Priority: **1S** Org Code: **180**
Action Goal: District Goal: **04-OCT-2000**
Brand Name: **PREVACID (LANSOPRAZOLE) 15/30 MG CAPSULE**
Established Name:
Generic Name: **LANSOPRAZOLE**
Dosage Form: **DRC (DELAYED RELEASE CAPSULE)**
Strength: **15 & 30MG**

FDA Contacts:			
C. PERRY	**(HFD-180)**	**301-827-7310**	**, Project Manager**
A. SHAW	**(HFD-180)**	**301-827-7310**	**, Review Chemist**
L. ZHOU	**(HFD-150)**	**301-594-5765**	**, Team Leader**

Overall Recommendation:

ACCEPTABLE on 17-AUG-2000 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: b(4) [redacted] b(4)
DMF No:
AADA No:

Profile: **CTR** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **17-AUG-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE PACKAGER**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S039

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

NDA 20-406/S-039

CBE-30 SUPPLEMENT

TAP Pharmaceutical Products Inc.
Attention: Ms. Betsy A. Brown
Assistant Director, Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Brown:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Prevacid® (lansoprazole) Delayed-Release Capsules
NDA Number:	20-406
Supplement Number:	S-039
Date of Supplement:	May 5, 2000
Date of Receipt:	May 8, 2000

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes the following changes: a packaging change in the Physicians' Sample Unit Dose Package of 7 (15mg and 30 mg). The proposed revised packaging will be comprised of the b(4) current packaging. However, the proposed blister b(4) b(4) All drug contact surfaces for the proposed packaging will be identical to the current packaging.

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 3, 2000 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be November 8, 2000.

Your submission stated that you would be implementing these changes 30 days after it has been filed in our Division.

Please cite the application number listed above at the top of the first page of any communications

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

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Attention: Division Document Room, Room 6B-24
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call Cheryl Perry, Regulatory Health Project Manager, at (301) 827-7475.

Sincerely,

Liang Zhou, Ph.D.
Chemistry Team Leader
Division of Gastrointestinal and Coagulation Drug Products, HFD-180
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:
Archival NDA 20-406/S-039
HFD-180/Div. Files
HFD-180/C.Perry
HFD-180/A.Shaw
HFD-180/L.Zhou

DISTRICT OFFICE

Drafted by:	CP/June 8, 2000
Initialed by:	LZ/June 8, 2000
	AS/June 14, 2000
Final:	CP/June 15, 2000
Filename:	N20-406.S039.Ack.8-Jun-00.doc

CBE-30 SUPPLEMENT ACKNOWLEDGEMENT (AC)

ORIGINAL

TAP PHARMACEUTICAL PRODUCTS INC.

3 N. Field Drive
Lake Forest, IL 60045

SCP-039 S-039
NDA 20406
NDA SUPPL FOR SCP

May 5, 2000

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, Maryland 20857

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
MAY 08 2000
HFD-180

Attention: Lilia Talarico, M.D.

Re: PREVACID® (lansoprazole) Delayed-Release Capsules
NDA 20-406

SPECIAL SUPPLEMENT-CHANGES BEING EFFECTED IN 30 DAYS
Supplement No. 039

Dear Dr. Talarico:

The sponsor, TAP Pharmaceutical Products Inc., (formerly TAP Holdings Inc.), submits in accordance with 21 CFR 314.70(c), a **Change Being Effected (CBE) in 30 Days Supplement** for a packaging change to approved NDA 20-406 for PREVACID® Delayed-Release Capsules.

The aforementioned packaging change only affects the following:

- PREVACID Physicians' Sample Unit Dose Package of 7: 15 mg capsules
- PREVACID Physicians' Sample Unit Dose Package of 7: 30 mg capsules

Currently, PREVACID Physicians' Sample Unit Dose Packages are supplied in [redacted] b(4)

The proposed revised packaging [redacted] current packaging. However, the proposed blister [redacted] drug contact surfaces for the proposed packaging will be identical to the current packaging.

b(4) [redacted] testing has been conducted and the results of this testing has demonstrated [redacted] b(4) equivalency between the current and proposed packaging.

Information pertaining to the current PREVACID Physicians' Sample Unit Dose Packages was submitted in NDA 20-406 Special Supplement-Changes Being Effected Supplement No. 025 dated January 28, 1998.

TAP Pharmaceuticals Product Inc., commits to place samples from [redacted] b(4) of each product strength and marketed packaging configuration, as appropriate, on long-term stability using the approved product protocol. No stability impact is expected since the proposed and current blister packages display an equivalent permeable barrier to moisture. Standard tests for leaks in flexible packages have been performed. Release specifications and labeling for the drug product packaged in the proposed packaging remain unchanged.

b(4)

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 require additional information, please contact me at the number listed below.

Sincerely,

Betsy A. Brown

Betsy A. Brown
Assistant Director, Regulatory Affairs

(847) 317-5781
(847) 317-5795

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0297
Expiration Date: 04-30-01

USER FEE COVER SHEET

See Instructions on Reverse Side Before Completing This Form

APPLICANT'S NAME AND ADDRESS

TAP Pharmaceutical Products Inc.
675 N. Field Dr.
Lake Forest, IL 60045

2. TELEPHONE NUMBER *(Include Area Code)*

(847) 317-5781

3. PRODUCT NAME

PREVACID® (lansoprazole) Delayed-Release Capsules

4. DOES THIS APPLICATION REQUIRE CLINICAL DATA FOR APPROVAL? No
IF YOUR RESPONSE IS "NO" AND THIS IS FOR A SUPPLEMENT, STOP HERE AND SIGN THIS FORM.

IF RESPONSE IS 'YES', CHECK THE APPROPRIATE RESPONSE BELOW:

☐ THE REQUIRED CLINICAL DATA ARE CONTAINED IN THE APPLICATION.

☐ THE REQUIRED CLINICAL DATA ARE SUBMITTED BY REFERENCE TO _____ (APPLICATION NO. CONTAINING THE DATA).

5. USER FEE I.D. NUMBER

6. LICENSE NUMBER / NDA NUMBER

7. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCLUSIONS**? IF SO, CHECK THE APPLICABLE EXCLUSION.

☐ A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT BEFORE 9/1/92 *(Self Explanatory)*

☐ A 505(b)(2) APPLICATION THAT DOES NOT REQUIRE A FEE *(See item 7, reverse side before checking box.)*

☐ THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)(1)(E) of the Federal Food, Drug, and Cosmetic Act *(See item 7, reverse side before checking box.)*

☐ THE APPLICATION IS A PEDIATRIC SUPPLEMENT THAT QUALIFIES FOR THE EXCEPTION UNDER SECTION 736(a)(1)(F) of the Federal Food, Drug, and Cosmetic Act *(See item 7, reverse side before checking box.)*

☐ THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALLY *(Self Explanatory)*

FOR BIOLOGICAL PRODUCTS ONLY

☐ WHOLE BLOOD OR BLOOD COMPONENT FOR TRANSFUSION

☐ A CRUDE ALLERGENIC EXTRACT PRODUCT

☐ AN APPLICATION FOR A BIOLOGICAL PRODUCT FOR FURTHER MANUFACTURING USE ONLY

☐ AN "IN VITRO" DIAGNOSTIC BIOLOGICAL PRODUCT LICENSED UNDER SECTION 351 OF THE PHS ACT

☐ BOVINE BLOOD PRODUCT FOR TOPICAL APPLICATION LICENSED BEFORE 9/1/92

8. HAS A WAIVER OF AN APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION? ☐ YES ☐ NO
(See reverse side if answered YES)

A completed form must be signed and accompany each new drug or biologic product application and each new supplement. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0297)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Please **DO NOT RETURN** this form to this address.

SIGNATURE OF AUTHORIZED COMPANY REPRESENTATIVE	TITLE	DATE
Betsy A. Brown	Assistant Director, Regulatory Affairs	May 5, 2000

FORM FDA 3397 (5/98)

Created by Electronic Document Services/USDHHS: (301) 443-2454 EF