CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S041

Trade Name: Prevacid Delayed Release Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Holdings Inc

Approval Date: June 29, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-406/S041

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S041

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-406/S-041

TAP Pharmaceutical Products, Inc.
Attention: Ms. Betsy 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 July 17, 2000, received July 18, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole) Delayed-Release Capsules, 15 mg and 30 mg.

We acknowledge receipt of your submissions dated January 30, March 15, and April 6, 2001.

Your submission of March 15, 2001 constituted a complete response to our January 17, 2001 action letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a new packaging configuration for 15 mg Prevacid® Delayed-Release Capsules – [redacted] HDPE bottle for distribution to Veterans Administration facilities. b(4)

We have completed the review of this supplemental new drug application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed and shipping labeling submitted on April 6, 2001. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

As stated in your letter dated January 30, 2001, we remind you of your commitment to place samples on routine stability and to provide accelerated stability data submitted to the annual report. We also 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 Project Manager, at (301) 827-7475.

Sincerely,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Marie Kowblansky
6/29/01 01:02:30 PM
Acting Team Leader for Liang Zhou

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S041

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-406/S-041

TAP Pharmaceutical Products, Inc.
Attention: Ms. Betsy 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 July 17, 2000, received July 18, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole) Delayed-Release Capsules, 15 mg and 30 mg.

This "Changes Being Effected in 30 days" supplemental new drug application proposes a new packaging configuration for 15 mg Prevacid® Delayed-Release Capsules - [redacted] HDPE bottle. b(4)

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

1. A commitment to provide accelerated stability data for the new bottle configuration and to submit the data in the annual report.
2. A commitment to place the new bottle configuration on routine stability testing and to submit the data to the annual report.
3. Final printed labeling (FPL) of the carton and immediate container labels for the new packaging configuration.
4. Final printed labeling for the package insert to incorporate appropriate changes related to the new package configuration. All previous revisions as reflected in the most recently approved labeling must be included.

Please submit 20 paper copies of the final printed labeling, ten of which are individually mounted on heavy weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999).

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

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 any such action FDA may proceed to withdraw the application. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

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

Sincerely,

{See appended electronic signature page}

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

/s/

Liang Zhou
1/17/01 01:45:19 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S041

CHEMISTRY REVIEW(S)

DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls Supplement

NDA #:20-406 **SUPPLEMENT #:**SCS-041 **CHEM REVIEW #:** 3 **REVIEW DATE:** 09-Apr-2001

SUBMISSION TYPE	**DOCUMENT**	**CDER**	**ASSIGNED**
Amendment BC	06-Apr-2001	09-Apr-2001	09-Apr-2001
Telecon	30-Mar-2001		
Amendment	15-Mar-2001	20-Mar-2001	20-Mar-2001
Amendment	30-Jan-2001	31-Jan-2001	01-Feb-2001

PREVIOUS DOCUMENTS

DOCUMENT	**DATE**
Original	17-Jul-2000
Review #1	10-Jan-2001
AE Letter	23-Jan-2001
Acknowledge INCOMPLETE	06-Mar-2001

Response To An Action Letter

b(4) b(4)

SUPPLEMENT PROVIDES FOR: new packaging configuration for 15 mg capsules ← [redacted] HDPE bottle

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

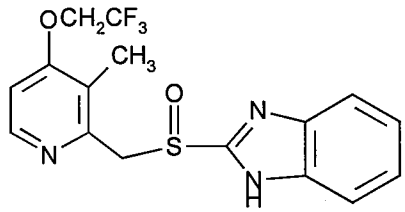
DRUG PRODUCT NAME: Proprietary: Prevacid Nonproprietary/USAN: lansoprazole

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



SUPPORTING DOCUMENTS: N/A **RELATED DOCUMENTS: IND** 30,159 **CONSULTS:** N/A

REMARKS/COMMENTS: Applicant has committed to providing accelerated stability data and placing samples on routine stability testing. No change in package insert (PI) necessary. PI will be attached to each bottle. Carton shipping label provided for VA hospitals.

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

R/D Init by: LZhou 10-Apr-2001
abs **F/T/ ABS 10-Apr-2001** C:\F\N20406 SCP-041 Rev 2.doc

2 Page(s) Withheld

✓ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Chemistry- 20-406
5041

/s/

Art Shaw
4/11/01 12:28:29 PM
CHEMIST

I sent this yesterday but I attached the wrong review.

Liang Zhou
4/11/01 02:15:12 PM
CHEMIST

DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls Supplement

NDA #:20-406 **SUPPLEMENT #:**SCP-041 **CHEM REVIEW #:** 1 **REVIEW DATE:** 05-Dec-2000

SUBMISSION TYPE	**DOCUMENT**	**CDER**	**ASSIGNED**
Original	17-Jul-2000	18-Jul-2000	18-Jul-2000

SUPPLEMENT PROVIDES FOR: new packaging configuration for 15 mg capsules b(4) [redacted] b(4) HDPE bottle

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

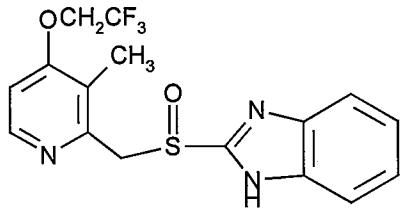
DRUG PRODUCT NAME: Proprietary: Prevacid Nonproprietary/USAN: lansoprazole

PHARMACOLOGICAL CATEGORY: proton pump inhibitor **INDICATION:** treatment of ulcers

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



SUPPORTING DOCUMENTS: N/A **RELATED DOCUMENTS: IND** 30,159 **CONSULTS:** N/A

REMARKS/COMMENTS: CBE Supplement Applicant should commit to providing accelerated stability data and placing samples on routine stability testing.

CONCLUSIONS & RECOMMENDATIONS: Approvable. Applicant should be sent an Information request Letter.

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

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

cc:
NDA 20-406/SCP-041
HFD-180/Div File/NDA 20-406/SCP-041
HFD-180/LTalarico
HFD-180/LZhou
HFD-180/AShaw
HFD-181/CPerry
R/D Init by: AAlHakim 28-Dec-2000
Abs**F/T ABS 28-Dec-2000** C:\F\N20406 SCP-041.doc

1 Page(s) Withheld

✓ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Chemistry- 20-406 S041

/s/

Art Shaw
12/28/00 02:35:37 PM
CHEMIST

Liang Zhou
1/10/01 12:29:28 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S041

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-406/S-041

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

Dear Ms. Brown:

We acknowledge receipt on January 31, 2001 of your January 30, 2001 submission to your new drug application (NDA) for Prevacid® (lansoprazole) Delayed-Release Capsules, 15 mg and 30 mg.

This submission contains additional CMC and labeling information submitted in response to our January 17, 2001 action letter.

We do not consider this a complete response to our action letter. Therefore, the review clock will not be started until we have received a complete response. The following deficiencies from our action letter still need to be addressed:

1. b(4) Provide final printed labeling (FPL) of the carton for the new packaging configuration for alternatively, justify a cartonless bottle (since all other Prevacid configurations have cartons) and provide a detailed description of the shipping process for the bottle, including shipping label(s).

2. Submit confirmation that the new packaging configuration will be distributed only to Veterans Administration facilities.

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

Sincerely,

{See appended electronic signature page}

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

/s/

Cheryl Perry
3/6/01 05:41:21 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-406/S-041

DISCIPLINE REVIEW LETTER

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

Dear Ms. Brown:

Please refer to your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole) Delayed-Release Capsules, 15 mg and 30 mg.

Our review of the Chemistry, Manufacturing, and Controls section of your submission is complete, and we have identified the following deficiencies:

1. A commitment to provide accelerated stability data for the new bottle configuration and to submit the data in the annual report.
2. A commitment to place the new bottle configuration on routine stability testing and to submit the data in the annual report.

We are providing these comments to you before we complete our review of the entire application to give you preliminary notice of issues that we have identified. In conformance with the prescription drug user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and subject to change as we finalize our review of your application. In addition, we may identify other information that must be provided before we can approve this application. If you respond to these issues during this review cycle, depending on the timing of your response, and in conformance with the user fee reauthorization agreements, we may not be able to consider your response before we take an action on your application during this review cycle.

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

Sincerely,

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

/s/

Ali Al-Hakim
1/3/01 05:01:38 PM
Ali Al-Hakim, Acting Team Leader for Liang Zhou

NDA 20-406/S-041

CBE-30 SUPPLEMENT

TAP Pharmaceutical Products Inc.
Attention: Gary C. Magistrelli, Ph.D.
Associate Director, Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Dr. Magistrelli:

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:	041
Date of Supplement:	July 17, 2000
Date of Receipt:	July 18, 2000

b(4) This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes the following change: a new packaging configuration for 15 mg Prevacid® Delayed-Release Capsules - [redacted] HDPE bottle.

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 September 16, 2000 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be January 18, 2001.

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, 6B-45
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-7475.

Sincerely,

Cheryl Perry
Regulatory Health Project Manager
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Archival NDA 20-406/S-041
HFD-180/Div. Files
HFD-180/C.Perry
HFD-180/A.Shaw
HFD-180/L.Zhou
DISTRICT OFFICE

Drafted by: CP/July 20, 2000
Initialed by: KO/July 28, 2000
Final: CP/July 28, 2000
Filename: N20406.S041.Ack.28-Jul-00.doc

CBE-30 SUPPLEMENT ACKNOWLEDGEMENT (AC)

SCS. 041

TAP PHARMACEUTICAL PRODUCTS INC.

5 N. Field Drive
Lake Forest, IL 60045

NDA NO. 20406 REF. NO. 41
NDA SUPPL FOR SCS.

July 17, 2000

ORIGINAL

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

07/28/00
HFD-180

Attn: Lilia Talarico, M.D.
Director

RE: PREVACID® (lansoprazole) Delayed-Release Capsules
NDA 20-406/S-041
Special Supplement Changes Being Effected-30 (CBE-30)

Dear Dr. Talarico:

The sponsor, TAP Pharmaceutical Products Inc., submits this CBE-30 pursuant to 21 CFR 314.70[c] for the above-mentioned NDA for PREVACID. This CBE-30 proposes a new packaging configuration for 15-mg PREVACID capsules – [redacted] HDPE bottle. The NDA includes a [redacted] 15-mg capsules in [redacted] HDPE bottle, and a [redacted] for 30-mg capsules in [redacted] bottle. Product contact surfaces are identical for approved and proposed HDPE bottle configurations.

b(4)
b(4)
b(4)

This submission contains the following:

- Report PD-00-048-00 New Packaging Configuration for 15-mg Prevacid Capsules
- Attachment 1 Stability Data for 15-mg Capsules in a [redacted] HDPE Bottle b(4)
- Attachment 2 Stability Data for 15-mg Capsules in a [redacted] HDPE Bottle b(4)
- Attachment 3 Stability Data for 15-mg Capsules [redacted] b(4)

b(4)

- Attachment 4 [redacted] of Closures; Specification for [redacted] Bottle; Specification for [redacted] cap.

b(4)

We plan to implement this supplement 30 days after the date of this submission.

Please direct any questions on this application to my attention.

Sincerely,

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

Enclosure

GCM/gcm

TAP PHARMACEUTICAL PRODUCTS INC.

5 N. Field Drive
Lake Forest, IL 60045

FIELD COPY CERTIFICATION

I hereby certify that the field copy is a true and accurate copy of the archival and review copies of the Special Supplement Changes Being Effected-30 (CBE-30) submission to NDA 20-406 as supplement-041.

Gary C. Magistrelli, Ph.D.
Associate Director
Regulatory Affairs
TAP Pharmaceutical Products Inc

TAP PHARMACEUTICAL PRODUCTS INC.

PHARMACEUTICAL DEVELOPMENT DEPARTMENT OT79

SCIENTIFIC REPORT

Project Name: Lansoprazole

Report Title: New Package Configuration for 15 mg PREVACID® Capsules

Report Number: PD-00-048-00

Prepared by:

Sanjay Sehgal, Ph.D.
Research Investigator
Pharmaceutical Development

7/13/00
Date

Reviewed by:

Falguni Patel

Falguni Patel, B.Sc., MBA
Asst. Coordinator, CMC/GMP Support
Pharmaceutical Development

7/13/00.
Date

Approved by:

for

Shuyen Huang, Ph.D.
Section Manager
Pharmaceutical Development

7/13/00
Date

CONFIDENTIAL INFORMATION

Contains trade secret and/or confidential information which is the property of TAP PHARMACEUTICAL PRODUCTS INC. As provided by 21 CFR § 20.61, DO NOT DISCLOSE to the public.

3 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

*Withheld Track Number: Administrative-*20-406
S041