CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S043

Trade Name: Prevacid Delayed Release Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Holdings Inc

Approval Date: April 11, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-406/S043

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S043

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-406/S-043

TAP Pharmaceutical Products
Attention: Ms. Leslie D. Abelson
Associate Director, Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Abelson:

Please refer to your supplemental new drug application dated December 18, 2000, received December 19, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole) Delayed-Release Capsules.

This supplement proposed to add of [redacted] in the unit dose blister package for the following: b(4)

- Prevacid® Unit Dose Package of 100: 15 mg capsules
- Prevacid® Unit Dose Package of 100: 30 mg capsules
- Prevacid® Physician's Sample Unit Dose Package of 7: 15 mg capsules
- Prevacid® Physician's Sample Unit Dose Package of 7: 30 mg capsules.

We have completed the review of this supplemental application, and it is approved.

In addition, we wish to inform you that on March 31, 2001, additional information was requested from the Drug Master File (DMF) holder [authorized reference for DMF [redacted] in support of your drug product application]. The identified DMF deficiencies do not effect the approval of this supplemental application. b(4)

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 Project Manager, at (301) 827-7457.

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/

Liang Zhou
4/11/01 01:03:33 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S043

CHEMISTRY REVIEW(S)

DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls Supplement

NDA #:20-406 **SUPPLEMENT #:**SCP-043 **CHEM REVIEW #:** 1 **REVIEW DATE:** 06-Apr-2001

SUBMISSION TYPE	DOCUMENT	CDER	ASSIGNED
Original	22-Dec-2000	25-Dec-2000	28-Dec-2000

SUPPLEMENT PROVIDES FOR: [redacted] b(4)

[redacted] b(4)

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

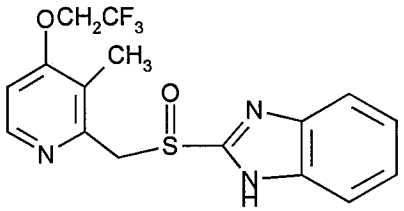
DRUG PRODUCT NAME: Proprietary: Prevacid Nonproprietary/USAN: lansoprazole

PHARMACOLOGICAL CATEGORY: proton pump inhibitor **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: DMF [redacted] **RELATED DOCUMENTS:** N/A **CONSULTS:** N/A b(4)

REMARKS/COMMENTS: DMF [redacted] has minor deficiencies. Stability data b(4) **ACCEPTABLE**

CONCLUSIONS & RECOMMENDATIONS: The Supplement may be APPROVED (AP). The applicant should be informed that information has been requested from the DMF holder but that this will not have an effect on the approval.

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-043.doc

2 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
S043

/s/

Art Shaw
4/10/01 12:16:39 PM
CHEMIST

Liang Zhou
4/10/01 12:42:58 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S043

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-406/S-043

PRIOR APPROVAL SUPPLEMENT

TAP Pharmaceutical Products Inc.
Attention: Ms. Leslie D. Abelson
Associate Director, Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Abelson:

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:	043
Date of Supplement:	December 22, 2000
Date of Receipt:	December 26, 2000

This supplement proposes to add [redacted] b(4)
in the unit dose blister package for the following:

- Prevacid® Unit Dose Package of 100: 15 mg capsules
- Prevacid® Unit Dose Package of 100: 15 mg capsules
- Prevacid® Physician's Sample Unit Dose Package of 7: 15 mg capsules
- Prevacid® Physician's Sample Unit Dose Package of 7: 30 mg capsules

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 February 24, 2001 in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be April 26, 2001 and the secondary user fee goal date will be June 26, 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, please 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

/s/

Cheryl Perry
1/2/01 04:56:30 PM

TAP PHARMACEUTICAL PRODUCTS INC.

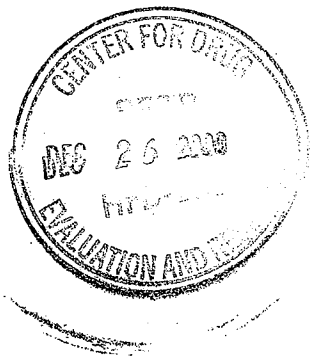
675 North Field Drive
Lake Forest, IL 60045

ORIGINAL

December 22, 2000

Lilia Talarico, M.D.
Director
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 REF. NO. SCP-043
NDA SUPPL FOR Packaging Change



Attn: Cheryl Perry, Project Manager

RE: Lansoprazole (Prevacid® Delayed-Release Capsules)
NDA 20-406

Prior Approval Supplement-Packaging Change
Supplement No. 043

Dear Dr. Talarico:

The sponsor, TAP Pharmaceutical Products Inc., (TAP) submits in accordance with section 505(i) of the Federal Food, Drug and Cosmetic Act and Title 21 CFR 314.70(b)(2)(vii), a Prior Approval Supplement for a packaging change to approved NDA 20-406 for Prevacid® (lansoprazole) Delayed-Release Capsules.

The aforementioned packaging change affects the following:

- Prevacid® Unit Dose Package of 100: 15 mg capsules
- Prevacid® Unit Dose Package of 100: 30 mg capsules
- Prevacid® Physician's Sample Unit Dose Package of 7: 15 mg capsules
- Prevacid® Physician's Sample Unit Dose Package of 7: 30 mg capsules

Prevacid® Capsules are packaged using [redacted] b(4)

[redacted] b(4)

[redacted]. TAP proposes to add an alternate [redacted]

The proposed [redacted] b(4)

[redacted] b(4)

All [redacted] for the proposed and the current Physician's Sample Unit Dose Package and Unit Dose Package are identical.

[redacted] of Prevacid® Capsules were packaged in the Unit Dose Package [redacted] stability at [redacted]

TAP commits to place one lot of each product strength on long term stability using the approved protocol. Standard tests [redacted] Release specifications and labeling for the drug product packaged in the proposed packaging remain unchanged.

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

Attached is Form FDA 356h to complete this submission. Please contact Dr. Nancianne Knipfer (847-236-2193) regarding any questions or comments on this submission.

Sincerely,

Leslie D. Abelson

Leslie D. Abelson (Ms.)
Assistant Director, Regulatory Affairs
(847) 236-2631
(847) 236-2880 (fax)

TAP PHARMACEUTICAL PRODUCTS INC.

675 North 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 Prior-Approval Supplement submission to NDA 20-406 as Supplement 043.

Leslie D. Abelson (Ms.)
Assistant Director, Regulatory Affairs
TAP Pharmaceutical Products Inc.