

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**20-406/S025**

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

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

***Sponsor:*** TAP Holdings Inc

***Approval Date:*** July 23, 1998

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**20-406/S025**

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**CENTER FOR DRUG EVALUATION AND  
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*APPLICATION NUMBER:*

**NDA 20-406/S025**

**APPROVAL LETTER**

NDA 20-406/S-025

TAP Holdings  
Attention: Gary C. Magistrelli, Ph.D.  
2355 Waukegan Road  
Deerfield, IL 60015

Dear Dr. Magistrelli:

Please refer to your supplemental new drug application dated January 28, 1998, received January 29, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid (lansoprazole) Delayed-Release Capsules.

The user fee goal date for this application is July 29, 1998.

We note that this supplement was submitted as a "Special Supplement - Changes Being Effected" under 21 CFR 314.70(c).

**(4)** This supplemental new drug application provides for an alternate blister material, ~~\_\_\_\_\_~~ **b(4)**  
~~\_\_\_\_\_~~ for the unit dose packages of 15 mg and 30 mg capsules and the physician's sample unit packages.

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, contact Maria R. Walsh, M.S., Project Manager, at (301) 443-0487.

Sincerely,

Eric P. Duffy, 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

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cc:

Archival NDA 20-406/S-025

HFD-180/Div. Files

HFD-180/PM/M.Walsh

HFD-180/A.Shaw

E.Duffy

HFD-820/DNDC Division Director

DISTRICT OFFICE

Drafted by: M.Walsh 7/23/98

Initialed by: E.Duffy 7/24/98

final: M.Walsh 7/27/98

filename: 20406S25807.ap.doc

APPROVAL (AP)

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**NDA 20-406/S025**

**CHEMISTRY REVIEW(S)**

**DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS**

Review of Chemistry, Manufacturing, and Controls Supplement  
NDA:20-406 SUPPLEMENT:SCP-025 CHEM REVIEW #1 REVIEW DATE: July 16, 1998

SUBMISSION TYPE	DOCUMENT	CDER	ASSIGNED
ORIGINAL	28-Jan-98	29-Jan-98	05-Feb-98

SUPPLEMENT PROVIDES FOR: replacement of approved blister material, with \_\_\_\_\_ which is \_\_\_\_\_ b(4)

NAME & ADDRESS OF APPLICANT: TAP Holdings, Inc.  
2855 Waukegan Road  
Deerfield, IL 60015

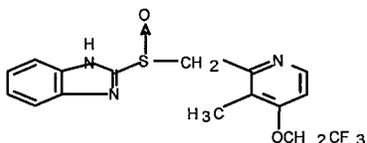
DRUG PRODUCT NAME: Proprietary: Prevacid Nonproprietary/USAN: lansoprazole

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 b(4) RELATED DOCUMENTS: N/A CONSULTS: N/A b(4)

**REMARKS/COMMENTS:**

This is a CBE supplement. The only change is the use of a \_\_\_\_\_ in the \_\_\_\_\_ of the \_\_\_\_\_ is \_\_\_\_\_ the currently-approved \_\_\_\_\_ b(4)

CONCLUSIONS & RECOMMENDATIONS: The supplement may be approved.

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

\_\_\_\_\_  
Eric P. Duffy, Ph.D.  
Chemistry Team Leader, HFD-180

CC:

NDA 20-406/SCP-025  
HFD-180/Div File/NDA 20-406/SCP-025  
HFD-180/LTalarico  
HFD-180/AShaw  
HFD-181/MWalsh

R/D Init by: E.Duffy/7-20-98

ABS/dob F/T 7-22-98

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1     Page(s) Withheld

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

           § 552(b)(4) Draft Labeling

           § 552(b)(5) Deliberative Process

~~\_\_\_\_\_~~  
~~\_\_\_\_\_~~

b(4)

**B. Suitability:**

~~\_\_\_\_\_~~  
~~\_\_\_\_\_~~

b(4)

**C. Quality Control:** Appendices B.2. and B.3 contain the  
acceptance specifications \_\_\_\_\_

b(4)

b(4)

ACCEPTABLE

**II. Stability:** In their cover letter the applicant \_\_\_\_\_

b(4)

b(4)  
b(4)

ACCEPTABLE

**cc:**

- NDA 20-406/SCP-025
- HFD-180/NDA 20-406/SCP-025
- HFD-181/MWalsh
- HFD-180/LTalarico
- HFD-180/EDuffy
- HFD-180/AShaw
- R/D Init by EDuffy 10-Aug-99
- ABS/ABS/11-Aug-99
- C:\WORD\Sg\20-406 PREVACID SCP-025 Addendum to Review.doc