CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S005

Trade Name: Prevacid Delayed Release Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Holdings Inc

Approval Date: May 6, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-406/S005

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S005

APPROVAL LETTER

34.1

NDA 20-406/S-005

MAY - 6 1996

TAP Holdings Incorporated
Attention: Judy Decker Wargel
2355 Waukegan Road
Deerfield, Illinois 60015

Dear Ms. Wargel:

Please refer to your November 6, 1995 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PREVACID® (lansoprazole) Delayed Release Capsules.

We acknowledge receipt of your amendments dated December 12, 1995 and January 25, 1996.

The supplemental application provides for a for an additional packager, [redacted] b(4)
[redacted] for physician sample packages. b(4)

We have completed the review of 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
Regulatory Health Project Manager
(301) 443-0487

Sincerely yours,

John J. Gibbs, 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-005
HFD-180/Div File

HFD-181/MWalsh
HFD-820/YChiu
HFD-80
DISTRICT OFFICE
HFD-180/SFredd
HFD-180/GChen GC 4/30/96
R/D init: JGibbs/4-28-96
GC/dob **F/T 5-1-96**\WP:c:\wpfiles\chem\S\20406005.agc

4/3/96

APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S005

CHEMISTRY REVIEW(S)

39.1

CHEMIST'S REVIEW 1	1. Organization: HFD-180	2. NDA Number: 20-406
3. Name and Address of Applicant (City & State): TAP Holdings Inc. 2355 Waukegan Road Deerfield, Il 60015		4. AF Number: MAY - 3 1996 5. Supplement(s)
6. Name of Drug: Prevacid®	7. Nonproprietary Name: Lansoprazole	Numbers: SCP-005 Dates: 06Nov95
8. Supplement Provides for: site change for proposed secondary labeler and distributor, b(4)		9. Amendments and Other (Reports, etc.) Dates: SCP-005/BC 12Dec95 SCP-005/BC 25Jan96
10. Pharmacological Category: H_2 Histamine Antagonist	11. How Dispensed: RX X OTC___	12. Related IND/NDA/DMF(s):
13. Dosage Form: capsules	14. Potency: 15mg and 30mg	
15. Chemical Name and Structure: 2[[[3-methyl-4-(2, 2, 2-trifluoroethoxy)-2-pyridyl]methyl]sulfinyl]benzimidazole		16. Records and Reports: Current _____ Yes ___ No Reviewed _____ Yes ___ No

17. Comments:
See Review Notes

cc: NDA 20-406
HFD-180/Div File
HFD-181/MWalsh
HFD-180/SFredd
HFD-180/GChen
R/D init by:JGibbs 4-28-96
GC/dob **F/T 5-1-96**\Wp: c:\wpfiles\S\20406604.1gc

18. Conclusions and Recommendations: This supplement may be **approved** (AP).

19. Reviewer 5/3/96

Name:	Signature	Date Completed:
George T. Chen, Ph.D.	4/30/96	26Apr96

Form FDH 2266 (7/75) ALT R

1 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
0005

A/NDA NOTIFICATION

DATE: 4/25/96

FROM: [redacted] b(4)

SUBJECT: NDA #20-406 S-005

TO: Compliance Evaluation Staff (HFD-324)

INFO: [redacted] b(4)

PRODUCT: Iansoprazole Caps 15 & 30 mg.

PROFILE: CTR

APPLICANT: CFN:
Tap Holdings Inc.
2355 Waukegan Rd.
Deerfield, IL 60015

ESTAB: [redacted] b(4)

ESTAB TYPE: Packaging Operation

DATE RECD: 3/7/96

DISTRICT RECOMMEND: APPROVE

DATE CDER RQD CONCUR: 5/7/96

DATE AUDIT: 4/23/96

COMMENTS: b(4) [redacted] APPROVAL based on Inspectional findings. Approval limited to packaging of drug product into starter samples for physician distribution. No FDA 483 issued.

SAMPLES: None

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S005

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ORIGINAL

347

MEMORANDUM OF TELECON

DATE: December 8, 1995

APPLICATION NUMBER: NDA 20-406/S-005

BETWEEN:
Name: Ms. Judy Decker Wargel
Phone: (708) 317-5781
Representing: TAP Holdings Inc.

AND
Name: Maria R. Walsh, Project Manager
Div. Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: Review of supplement 005

Background: The sponsor submitted supplemental application 005 as "Special Supplement - Changes Being Effected" dated November 6, 1995. This supplement provides for a new packager for a new physician sample package. The sample package will contain the blistered capsules as approved in the NDA. b(4) b(4)

I called Ms. Wargel on December 4, 1995 and asked her to fax a copy of the proposed physician sample package. She agreed and commented that the sponsor plans to submit the proposed package to the Division of Drug Marketing, Advertising, and Communications (DDMAC) for review.

I also called Ms. Wargle on December 6, 1995 and spoke with Ms. Janet Haskins in her absence. I informed Ms. Haskins that this supplement will require pre-approval before the proposed change can be put into effect (an appropriate supplement acknowledgement letter is in draft). I requested, per Dr. Arthur Shaw, reviewing chemist, that a letter of authorization (LOA) be submitted for the Type DMF cited in the supplement. I also requested that the supplement be amended with a statement of the sponsor's intent to submit the proposed package to DDMAC for review. Ms. Haskins agreed and the call was concluded. b(4)

Today's Call: I called Ms. Wargel and informed her that after some internal discussion, it was decided that a DMF will not be necessary for the changes proposed in this supplement and therefore the request for a LOA is hereby rescinded.

Ms. Wargel informed me that according to an FDA initiated inspection was undertaken between August 31 and September 5, 1995. I told Ms. Wargel that we will inform the Office of Compliance of this fact in our request for an establishment inspection. b(4) b(4)

The call was then concluded.

Maria R. Walsh 12/8/95
Maria R. Walsh, Project Manager

cc:
Orig NDA 20-406/S-005
HFD-180/Division file
HFD-180/S.Fredd
J.Gibbs
A.Shaw
HFD-181/M.Walsh
HFD-40/S.Danese
MRW/12/8/95/C:\wpfiles\cso\n\20406S05.TMW

34.1

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: March 18, 1996

FROM: Maria R. Walsh, Project Manager

SUBJECT: Correspondence with the [redacted] b(4)

TO: NDA 20-406/SCP-005; Prevacid (lansoprazole) Delayed-Release Capsules

The attached is a series of communications (via E-mail) with [redacted] b(4)
[redacted] regarding the pre-approval inspection of [redacted] b(4)
[redacted] for NDA 20-406/SCP-005.

cc:
HFD-180/Division File
HFD-180/J.Gibbs
G.Chen
HFD-181/M.Walsh

E L E C T R O N I C M A I L M E S S A G E

Date: 08-Mar-1996 11:25am EST
From: [redacted] @FDAOC
Dept:
Tel No: b(4)

TO: GIBBS@A1@FDACD
TO: LYNCHM@A1@FDACD
TO: FERGUSONS@A1@FDACD

CC: ETHOMAS@FDAEM@SSWMBX@FDAOC

Subject: NDA20-406 S-005 Pre Approval Inspection Request

Product:*Iansoprazole Caps. 15 & 30 mg CTR

Establishment: [redacted] b(4)

User Fee
Due Date:*5/7/96 b(4)

*On 3/7/96 [redacted] received an assignment to conduct a Pre Approval Inspection ([redacted] Samples for Physician distributtion). b(4)

b(4) [redacted] does not have a copy of this NDA (20-406) or Supplement (S-005). We need a copy of the Supplement and appropriate sections of the NDA w identify [redacted] commitments for this drug product as outlined in the current application/submission. b(4)

*This assignment is currently on hold pending receipt of the backgrouund information as outlined above.

*NOTE: The original assignment had the establishment identified as [redacted] b(4)

******Thank You,

** [redacted] b(4)

E L E C T R O N I C M A I L M E S S A G E

Date: 13-Mar-1996 02:20pm EST
From: Maria Walsh
WALSH
Dept: HFD-181 PKLN 6B45
Tel No: 301-443-0487 FAX 301-443-9285

TO: [redacted] b(4) (FDAORA) [redacted] b(4) @FDAOC)

CC: John Gibbs (GIBBS)
CC: Mark Lynch (LYNCHM)
CC: Shirnette Ferguson (FERGUSONS)

Subject: NDA 20-406/S-005 Pre-Approval Inspection

Dear [redacted] b(4)

NDA 20-406/SCP-005 (dated 11/6/95), submitted as "Special Supplement - Changes Being Effected", consists of a two page cover letter and Form FDA 356h. The cover letter identifies [redacted] as a secondary packager for the blistered capsules. The blistered capsules [redacted] b(4) physicians. I would be happy to fax this supplement to you if you would kindly let me know your fax number. b(4)

Regarding the original NDA: [redacted] not involved in the original NDA. This supplement adds them as a secondary packager. Dr. Arthur Shaw, then the reviewing chemist for this supplement and chair of the DMF Committee, stated in a [redacted]/19/95 memo that "DMF's are not needed for these secondary packaging o[redacted]tions since they do not involve product contact surfaces or sealing of the drug product." In light of this, would you tell me what additional information you need?

By the way, the original EER (dated 1/4/96) was not acceptable because the [redacted] b(4) headquarters. The sponsor amended the supplement with the correct address of [redacted] b(4) a follow-up EER (dated 2/21/96) was sent to HFD-324.

Maria Walsh

E L E C T R O N I C M A I L M E S S A G E

Date: 14-Mar-1996 10:00am EST
From: [redacted] @FDAOC
Dept: b(4)
Tel No:

TO: WALSH@A1@FDACD

Subject: NDA20-406 S-005 Pre Approval Inspection

Please FAX Supplement to [redacted] b(4)

****THANKS,

[redacted] b(4)

FOOD AND DRUG ADMINISTRATION
DIVISION OF GASTROINTESTINAL
AND COAGULATION DRUG PRODUCTS
DOCUMENT CONTROL ROOM 6B-24
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857

DATE March 18, 1996

TO:

Name [redacted] b(4)

Fax No [redacted]

Phone No. _____

Location _____

FROM:

Name Maria Walsh

Fax No. (301) 443-9285

Phone No. (301) 443-0487

Total No. of Pages
Including Cover 7

Comments:

Per your request, attached is a copy of NDA 20-406/S-005 (dated 11/6/95) and the amendment (dated 1/25/96) specifying the new address of [redacted] b(4)

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

ORIGINAL

NDA SUPPL AMEND
SCP/BC
005

April 30, 1996

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

Attn: Stephen B. Fredd, M.D.

RE: PREVACID® (lansoprazole) Delayed-Release Capsules
NDA 20-406
Supplement S-005
Amendment No. 003

Dear Dr. Fredd:

In accordance with section 505(b) of the Food, Drug and Cosmetic Act and 21 CFR 314.60, TAP Holdings Inc. submits this amendment to the pending SNDA 005 for PREVACID® (lansoprazole) Delayed-Release Capsules.

Appended is a letter from the b(4) of the FDA concerning the inspection of b(4) facility. As you will recall, b(4) will do secondary packaging and labeling of PREVACID samples.

Should you need further information or have any questions, please do not hesitate to contact me.

Sincerely,

Judy Decker Wargel

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

JDW/pjp

CENTER FOR DRUG
REC'D
MAY X 1 1996
HFD-180
EVALUATION AND RESEARCH

5/6/96
SP

NDA NO. 20406 REF. NO. 005
NDA SUPPL FOR SAP

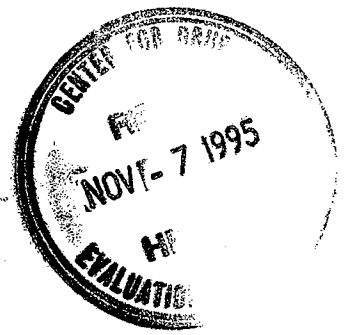
TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

November 6, 1995

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

ORIGINAL



Attn: Stephen B. Fredd, M.D.

RE: Prevacid®(lansoprazole) Delayed-Release Capsules NDA 20-406
Special Supplement - Changes Being Effected

Dear Dr. Fredd:

The purpose of this supplement is to advise the Agency of a secondary labeler and distributor for Prevacid® (lansoprazole) Delayed-Release Capsules samples in both the 15 mg and 30 mg strengths.

b(4) [redacted] will continue to be [redacted] using the same materials as described in NDA 20-406. The [redacted] b(4)

[redacted] b(4)

b(4) [redacted] where they will be incorporated into [redacted] Sample packages b(4)
for [redacted] physicians. We anticipate
b(4) [redacted] plans to submit a
Type [redacted]. Drug Master File for this packaging operation. b(4)

This letter authorizes the Food and Drug Administration to refer to the Chemistry, Manufacturing and Controls section of NDA 20-406 in support of

[redacted] b(4)

11/29/95

This permission and authorization extends only to the above information and shall not be construed to authorize the divulging of such information to anyone outside the FDA except in accordance with Section 301 (j) of the Federal Food, Drug and Cosmetic Act.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

Judy Decker Wargel
Associate Director, Regulatory Affairs
Phone: (708) 317-5781
Fax: (708) 317-5795

JDW/pjp

cc: [redacted] b(4)

lanso/

Ag SCP/15 005 55-1

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

ORIGINAL

December 12, 1995

NDA SUPPL AMEND
SCP/BC 005

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

Attn: Stephen B. Fredd, M.D.

RE: Prevacid® (lansoprazole) Delayed-Release Capsules

NDA 20-406
Supplement S-005
Amendment No. 001

Dear Dr. Fredd:

In accordance with section 505(b) of the Food, Drug and Cosmetic Act and 21 CFR 314.60, TAP Holdings Inc. submits this amendment to the pending SNDA for Prevacid® (lansoprazole) Delayed-Release Capsules.

Reference is made to phone conversations between Ms. Maria Walsh of the Agency and representatives of TAP Holdings on December 6 and 8, 1995. It is our understanding that this supplement naming ——— as a secondary packager ——— for Prevacid requires prior approval. Also, it is not necessary for ——— submit a Type ——— Drug Master File. However, an inspection ——— will be requested. TAP has been advised that ——— was inspected on August 31 and September 5, 1995, and that no FDA 483 was issued. b(4) b(4) b(4) b(4) b(4)

TAP agrees to send two copies of the sample package along with the patient educational material to DDMAC. A copy will also be sent to your attention.

1/2/96 BC

Please do not hesitate to contact me if you have any questions.

Sincerely,

Judy Decker Wargel

Judy Decker Wargel
Associate Director, Regulatory Affairs
Phone: (708) 317-5781
Fax: (708) 317-5795

JDW/pjp

NDA 20-406/S-005

DEC 8 1995

TAP Holdings Inc.
Attention: Ms. Judy Decker Wargel
Bannockburn Lake Office Plaza
2355 Waukegan Road
Deerfield, IL 60015

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-005

Therapeutic Classification: Standard

Date of Supplement: November 6, 1995

Date of Receipt: November 7, 1995

This supplement, submitted as "Special Supplement - Changes Being Effected" under 21 CFR 314.70(c), provides for an alternate packager for physician's samples.

Changes of the kind that you have proposed are not in our opinion the kind of changes permitted by regulation to be put into effect prior to approval of a supplement. This letter is to notify you that an approved supplement is required for the proposed changes and that the supplement is being reviewed under 21 CFR 314.70(b).

We also refer to the December 4, 1995 telephone conversation between you and Ms. Maria Walsh of this Division in which you stated your plans to submit the proposed [redacted] Sample package, including the patient education materials enclosed in the package, to the Division of Drug Marketing, Advertising and Communications for review. b(4)

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 January 6, 1996 in accordance with 21 CFR 314.101(a).

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

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

Should you have any questions, please contact:

Maria Walsh
Consumer Safety Officer
Telephone: (301) 443-0487

Sincerely yours,

John J. Gibbs, Ph.D.
Supervisory Chemist
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Original NDA 20-406/S-005
HFD-180/Div. Files
HFD-40
HFD-80
HFD-181/CSO/M.Walsh
DISTRICT OFFICE

12/8/95

Final: M.Walsh 12/8/95

SUPPLEMENT ACKNOWLEDGEMENT