CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S035

Trade Name: Prevacid Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Pharmaceutical Products, Inc.

Approval Date: June 2, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-406/S035

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Reviews / Information Included in this NDA Review.

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S035

APPROVAL LETTER

NDA 20-406/S-035

TAP Pharmaceutical Products, Inc.
Attention: Ms. Betsy B. 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 September 20, 1999, received September 21, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole) Delayed-Release 30 mg Capsules.

We acknowledge receipt of your submission dated December 16, 1999. We also acknowledge receipt of your submission dated February 7, 2000, which constituted a complete response to our January 31, 2000 action letter. Further, we acknowledge receipt of your May 25, 2000 submission in response to the May 24, 2000 teleconference between representatives of your firm and this division.

This supplemental new drug application provides for the addition of a new facility b(4) Prevacid b(4) 30 mg capsules. This facility, will b(4) lansoprazole b(4) approved manufacturing site for drug product b(4) located in b(4).

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, 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-035
HFD-180/Div. Files
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/June 2, 2000
Initialed by: KO/June 2, 2000
Final: CP/June 2, 2000
Filename: N20-406.S035.AP.2Jun00.doc

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S035

APPROVABLE LETTER

NDA 20-406/S-035

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

Dear Dr. Magistrelli:

Please refer to your supplemental new drug application dated September 20, 1999, received September 21, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole, 15/30 mg) Delayed-Release Capsules.

We acknowledge receipt of your faxed submission dated December 16, 1999 containing additional chemistry, manufacturing and control information requested December 1, 1999 in a telephone conversation between Ms. Betsy Brown and Ms. Cheryl Perry.

b(4) This supplement proposes to add a new facility b(4)
the 30mg capsules.

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

b(4) 1. Explain why b(4)
(Page 23 of the original submission).

2. b(4)
b(4) b(4)
please commit to the following:

a. The expiration date will be calculated b(4)
b(4)

b. The appropriate specifications b(4)

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.

This product may be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with this change prior to approval of this supplemental application.

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
HFD-180/Div. Files
HFD-180/C.Perry
HFD-180/L.Zhou
HFD-180/A.Shaw
DISTRICT OFFICE

Drafted by: CP/January 24, 2000
Initialed by:KJ & LZ/January 28, 2000
final: CP/January 31, 2000
filename: N20406.S035.31-Jan-00AE.doc

APPROVABLE (AE)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-406/S035

CHEMISTRY REVIEW(S)

DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls Supplement

NDA #:20-406 SUPPLEMENT #:SCM-035 CHEM REVIEW #: 3 REVIEW DATE: 01-June-2000

SUBMISSION TYPE	DOCUMENT	CDER	ASSIGNED
Amendment BC	25-May-2000	26-May-2000	01-Jun-2000

PREVIOUS DOCUMENTS:

SUBMISSION TYPE	DATE
Original	20-Sep-1999
Amendment BC	16-Dec-1999
Review #1	20-Jan-2000
Letter AE	21-Jan-2000
Review #2	15-May-2000
Telecon	22-May-2000

SUPPLEMENT PROVIDES FOR: additional facility [redacted] in b(4)
[redacted] Prevacid 30 mg capsules b(4)

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

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

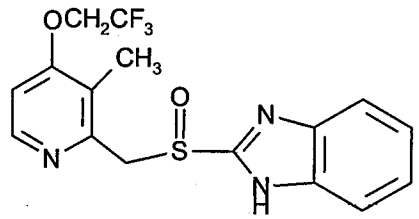
PHARMACOLOGICAL CATEGORY: proton pump inhibitor

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



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

REMARKS/COMMENTS: Telecon on May 24, 2000 was held to discuss the questions from Chem. Review #2, for which no letter was issued.

CONCLUSIONS & RECOMMENDATIONS: The supplement may be approved.

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

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

cc:
NDA 20-406/SCM-035
HFD-180/Div File/NDA 20-406/SCM-035
HFD-180/LTalarico
HFD-180/LZhou
HFD-180/AShaw
HFD-181/CPerry
R/D Init by: LZhou 01-Jun-2000

ABS/F/T/ ABS 01-Jun-00 C:\WORD\Prevacid\20-406 PREVACID SCM-035 Review #3.doc

8 Page(s) Withheld

✓ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Chemistry- 20-406
5035
chom #3

DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls Supplement

NDA #:20-406 SUPPLEMENT #:SCM-035 CHEM REVIEW #: 2 REVIEW DATE: 11-May-2000

SUBMISSION TYPE	DOCUMENT	CDER	ASSIGNED
Amendment	07-Feb-2000	08-Feb-2000	10-Feb-2000

PREVIOUS DOCUMENTS:

SUBMISSION TYPE	DATE
Original	20-Sep-1999
Amendment BC	16-Dec-1999
Review #1	20-Jan-2000
Letter AE	21-Jan-2000

SUPPLEMENT PROVIDES FOR: additional facility [redacted] b(4)

[redacted] Prevacid 30 mg capsules b(4)

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

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

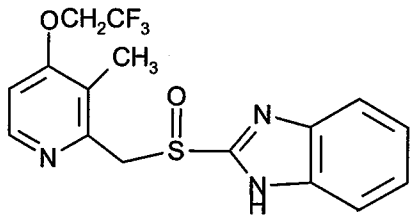
PHARMACOLOGICAL CATEGORY: proton pump inhibitor

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



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

REMARKS/COMMENTS: [redacted] b(4) proposal for lansoprazole [redacted] b(4)

CONCLUSIONS & RECOMMENDATIONS: The application is approvable (AE) provided the applicant agrees [redacted] b(4) b(4)

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

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

cc:
NDA 20-406/SCM-035
HFD-180/Div File/NDA 20-406/SCM-035
HFD-180/LTalarico
HFD-180/LZhou
HFD-180/AShaw
HFD-181/CPerry
R/D Init by: Lzhou 05/12/00

AbsF/T/ ABS 15-May-00 C:\WORD\Prevacid\20-406 PREVACID SCM-035 Review #2.doc

11 Page(s) Withheld

✓ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Chemistry- 20-406
5055
Chem #2

DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls Supplement

NDA #:20-406 SUPPLEMENT #:SCM-035 CHEM REVIEW #: 1 REVIEW DATE: 21-Jan-2000

SUBMISSION TYPE	DOCUMENT	CDER	ASSIGNED
Original	20-Sep-1999	21-Sep-1999	21-Sep-1999
Amendment BC	16-Dec-1999	22-Dec-1999	23-Dec-1999

SUPPLEMENT PROVIDES FOR: additional facility [redacted] in [redacted] Prevacid 30 mg capsules b(4) b(4)

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

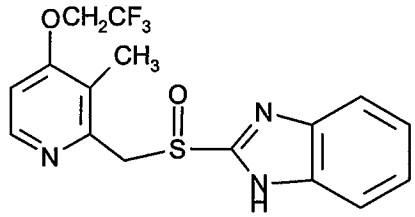
DRUG PRODUCT NAME: Proprietary: Prevacid Nonproprietary/USAN: lansoprazole

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



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

REMARKS/COMMENTS: The supplement is, in general, acceptable. However, there are a number of questions for the applicant concerning the stability protocol [redacted] b(4)

CONCLUSIONS & RECOMMENDATIONS: The supplement is approvable (AE). The applicant should be asked to reply to the questions in the draft letter.

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

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

cc:
NDA 20-406/SCM-035
HFD-180/Div File/NDA 20-406/SCM-035
HFD-180/LTalarico
HFD-180/LZhou
HFD-180/AShaw
HFD-181/CPerry
R/D Init by: Lzhou 21-Jan-2000
abs C:\WORD\Sg\20-406 Prevacid SCS-029 Review 1.doc

6 Page(s) Withheld

✓ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Chemistry- 20-406
5035
Chem #_7

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S035

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW			
IND:	20-406	**Serial Number:**	SCM-035
Drug: **[Sponsor's Code / Generic / Brand]**	Lansoprazole Prevacid ® Delayed Release Capsules	**Sponsor:**	Whitehall-Robins Madison, NJ
Correspondence Date / **Date Received:**	20 September 1999 21 September 1999	**Type of Submission:**	Supplemental NDA for an [redacted] b(4)
Background	• Currently, delayed release lansoprazole [redacted] b(4) • This application requests approval of [redacted] Prevacid® (Lansoprazole) Delayed Release Capsules 30 mg [redacted] b(4) • The manufacture [redacted] remains unchanged. b(4)		
Reviewer Comments:	The sponsor filed this supplement to comply with 21CFR sec.314.70; *Supplements and other changes to an approved application.* The sponsor conducted comparative dissolution studies. Since, this is a delayed release product a [redacted] quickly in [redacted]. Dissolution studies in buffer were then conducted [redacted] Dissolution is rapid and nearly complete [redacted] b(4) Consequently, Q is readily achieved. True dissolution profiles are not available since sampling was insufficient to describe the early part of the profile. As would be expected, there were no differences in dissolution data between batches from the two sites. There should be no clinical changes with the change [redacted] site since this should not be a critical change. b(4) The site change is acceptable from a biopharmaceutic perspective and bioequivalence studies will not be required.		
To be Sent to Firm:	None.		
Date:	21 January 2000	**Code:**	NL
Signatures:	**Ronald E. Kavanagh, BS Pharm, Pharm.D., Ph.D.,OCPB/DPE-2** **David Lee, Ph.D., Team Leader, OCPB/DPE-2**		
CC:	**IND 20-406 (orig., 1 copy)** **HFD-180 (Shaw, Walsh)** **HFD-870 (HuangS, HuntJ, LeeD, Kavanagh)** **CDR (B.Murphy)**		

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-406/S035

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

MEMORANDUM OF TELECON

DATE: May 24, 2000

APPLICATION NUMBER: NDA 20-406/S-035

BETWEEN: TAP Pharmaceutical Products, Inc.
Betsy Brown, Assistant Director, Regulatory Affairs
Dean Sundberg, Director, Regulatory Affairs
Linda Fleming, Chemist
847-317-5781

AND

Arthur Shaw, Ph.D., Chemistry Reviewer, HFD-180
Liang Zhou, Ph.D., Chemistry Team Leader, HFD-180
Cheryl Perry, Project Manager, HFD-180

SUBJECT: Pending Action Letter. 4 Month Goal date is June 8, 2000.

BACKGROUND: This supplement provides for the addition of a new facility b(4) b(4)
Prevacid 30 mg capsules. This facility, lansoprazole b(4)
at the currently approved manufacturing site for drug product b(4) b(4)
The CMC Review #2 was completed 15-May-00 with the following conclusion: The review of this supplemental application is approvable. Before this supplement may be approved, it will be necessary for the sponsor to commit to either: b(4)
lansoprazole The CMC b(4)
Reviewer supported his conclusion with the following points:

1. The data provided in Attachment C regarding b(4) b(4)
The data for these b(4)
b(4) b(4)
following stability studies:
   a. Capsules b(4) b(4)
   b. Capsules b(4) b(4)
   c. Immediate Capsules Annual Report Y-004, Pages 191, 199, and 207). b(4)
   d.
2. TAP's proposal to accept b(4)
not acceptable. b(4)
b(4)

TELECON between TAP Pharmaceutical Products and FDA
NDA 20-406/SCM-035
May 24, 2000

FACSIMILE COMMUNICATION Sent: 5/22/00 10:00 p.m. CST

To: Dr. Shaw
From: Betsy A. Brown

Based on a 5/17/00 telephone conversation with Ms. Cheryl Perry, it is TAP's understanding that the Agency has the following comments:

FDA comment:

1. The data in the 2/7/00 response to NDA 20-406/S-35 for [redacted] b(4)

TAP's response:

The Agency's position is understood and TAP will comply with the stated requirements. Therefore, the expiration date [redacted] b(4)

TAP also wishes to discuss and establish with the Agency, the data requirements to support a [redacted] b(4)

FDA comment:

2. Acceptance [redacted] b(4)
   is not acceptable

TAP's response:

Upon receipt of [redacted] b(4)

We would like to better understand the Agency's concerns regarding why acceptance of a [redacted] is not acceptable. b(4)

SUMMARY OF May 24, 2000 TELEPHONE CONFERENCE:

Ms. Brown: TAP is seeking an approval letter on N20-406/S-035 and agrees to the Agency's request concerning the expiration dating of the drug product. [redacted] b(4)

TELECON between TAP Pharmaceutical Products and FDA
NDA 20-406/SCM-035
May 24, 2000

Dr. Shaw: [redacted], expiration dating [redacted] b(4)
[redacted] question was mentioned by the field inspector's visit report [redacted] facility. b(4) b(4)

Mr. Sundberg: Our amendment [redacted] b(4) b(4) b(4)

Dr. Shaw: That is true. [redacted] b(4)

Mr. Sundberg: The drug product [redacted] b(4)
plan to test [redacted] b(4)
[redacted] testing. b(4)

Dr. Shaw: That sounds reasonable.

Ms. Brown: Once you receive our amendment, how soon can we expect an approval letter?

Dr. Shaw: If the amendment information is acceptable, the approval letter will be sent in a couple of weeks.

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-035
HFD-180/Division Files
HFD-180/A.Shaw
HFD-180/C.Perry
HFD-180/L.Zhou

Drafted by: CPerry/May 24, 2000
Initialed by: AS/June 1, 2000
Final: CP/June 2, 2000
Filename: N20406.S035.TCon.24May00.doc

TELECON

MEMORANDUM

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

DATE: December 16, 1999

FROM: Arthur B. Shaw, Ph.D., Review Chemist, Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: Further Information Requested Concerning [redacted] Prevadi b(4) b(4)
(NDA 20-406)

TO: Cheryl Perry, Project Manager, Division of Gastrointestinal and Coagulation Drug Products, HFD-180

There have been a number of telephone calls back and forth to TAP, the applicant for NDA 20-401 (Prevacid), concerning the issues raised in the original memo (attached). It is not clear whether the necessary information to support [redacted] b(4)
manufacturing sites has been submitted. Therefore please send the following information request to TAP:

1. Please be advised that the addition [redacted] b(4) b(4) b(4) b(4) pre-approval supplement.
2. If [redacted] currently-approved manufacturing sites for Prevacid, [redacted] The supplement must contain adequate stability data [redacted] b(4) b(4) b(4) b(4) b(4) b(4) b(4) b(4)
3. If [redacted] for Prevacid, the current supplement for that manufacturing site change (S-035, submitted September 20, 1999) [redacted] b(4) b(4) b(4)

cc:
NDA 20-406
HFD-180/NDA 20-406
HFD-180/LZhou
HFD-180/AShaw
HFD-820/SKoepke
HFD-820/JGibbs
HFD-181/CPerry
HFR-SE350/GFlynn
ABS//F/T 16-Dec-1999C:\WORD\Prevacid\20-406 PREVACID MEMO FOR SCM-035.doc

Attachment Original Memo

I received a telephone call from George Flynn, the Field Investigator who went to inspect [redacted] b(4) proposed for [redacted] "Prevacid Capsules. This proposed change is the subject of SCM-035. The [redacted] Mr. Flynn informed me that the people at [redacted] told him that they intend to [redacted] They also told Mr. Flynn that this practice was already in place at the [redacted] I don't recall anything concerning this. [redacted]

Please ask TAP to provide any information they have about [redacted] Specifically they should explain whether this is currently being done [redacted] If this information has already been submitted, please ask them where it is.

MEMORANDUM

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

DATE: December 1, 1999

FROM: Arthur B. Shaw, Ph.D., Review Chemist, Division of Gastrointestinal and Coagulation Drug Products, HFD-180

THROUGH: Liang Zhou, Ph.D., Acting Chemistry Team Leader, Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: b(4)

TO: Cheryl Perry, Project Manager, Division of Gastrointestinal and Coagulation Drug Products, HFD-180

I received a telephone call from George Flynn, the Field Investigator who went to inspect b(4) b(4) proposed for b(4) "Prevacid Capsules. This proposed change is the subject of SCM-035. The b(4) Mr. Flynn informed me that the people b(4) told him that they intend b(4) They also told Mr. Flynn that this practice was already in place I don't recall anything concerning this. b(4) b(4) b(4) b(4) b(4)

Please ask TAP to provide any information they have about b(4) Specifically they should explain whether this is currently being done b(4) b(4) If this information has already been submitted, please ask them where it is.

cc:
NDA 20-406
HFD-180/NDA 20-406
HFD-180/LZhou
HFD-180/AShaw
HFD-181/CPerry
HFR-SE350/GFlynn
ABS/abs/F/T 01-Dec-1999C:\WORD\Prevacid\20-406 PREVACID MEMO FOR SCM-035.doc

NDA 20-406/S-035

TAP Holdings Inc.
Attention: Ms. Betsy A. Brown
2355 Waukegan Road
Deerfield, IL 60015

Dear Ms. Brown:

We acknowledge receipt on February 8, 2000 of your February 7, 2000 resubmission to your supplemental new drug application for Prevacid® (lansoprazole) Delayed Release Capsules.

This resubmission contains additional related substances reporting, stability, and expiration dating information submitted in response to our January 31, 2000 action letter.

With this amendment, we have received a complete response to our January 31, 2000 action letter.

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-035
HFD-180/Div. Files
HFD-180/C.Perry
HFD-180/A.Shaw

DISTRICT OFFICE

Drafted by: CP/February 9, 2000
Initialed by: KJ/February 11, 2000
final:CP/February 11, 2000
filename: N20406.S035.11-Feb-00.ACK.doc

RESUBMISSION ACKNOWLEDGEMENT (AC)

21-JAN-2000

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Application: **NDA 20406/035**
Stamp: **21-SEP-1999** Regulatory Due: **21-JAN-2000**
Applicant: **TAP HOLDINGS**
2255 WAUKEEGAN RD
DEERFIELD, IL 60015

Priority: **1S** Org Code: **180**
Action Goal: District Goal: **17-DEC-1999**
Brand Name: **PREVACID (LANSOPRAZOLE) 15/30 MG CAPSULE**
Established Name:
Generic Name: **LANSOPRAZOLE**
Dosage Form: **DRC (DELAYED RELEASE CAPSULE)**
Strength: **15 & 30MG**

FDA Contacts:			
M. WALSH	**(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 21-JAN-2000 by M. EGAS (HFD-322) 301-594-0095

Establishment: b(4) b(4) b(4) b(4) b(4)
DMF No:
AADA No:

Profile: **NEC** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **21-JAN-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE MANUFACTURER**

H. COMMENTS AND LIST OF DEFICIENCIES

1. Explain why b(4) (Page 23). b(4)

2. Commit to the following b(4) b(4) b(4) b(4) b(4)

a. The expiration date b(4) b(4)

b. The b(4) b(4)

NDA 20-406/S-035

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

Dear Dr. Magistrelli:

We acknowledge receipt of your manufacturing supplemental 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-035

Date of Supplement: September 20, 1999

Date of Receipt: September 21, 1999

This supplement proposes the following change: addition of a new facility [redacted] the 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 November 19, 1999 in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be January 21, 2000 and the secondary user fee goal date will be March 21, 2000.

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
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, contact me at (301) 443-8017.

Sincerely,

Maria R. Walsh, M.S.
Regulatory 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-035
HFD-180/Div. Files
HFD-180/M.Walsh
DISTRICT OFFICE

final: M.Walsh 9/29/99
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SUPPLEMENT ACKNOWLEDGEMENT (AC)