CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S026

Trade Name: Prevacid Delayed Release Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Holdings Inc

Approval Date: March 19, 1998
## Reviews / Information Included in this NDA Review.

<table>
<thead>
<tr>
<th>Reviews / Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Letter</td>
<td>X</td>
</tr>
<tr>
<td>Approvable Letter</td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td></td>
</tr>
<tr>
<td>Summary Review</td>
<td></td>
</tr>
<tr>
<td>Officer/Employee List</td>
<td></td>
</tr>
<tr>
<td>Office Director Memo</td>
<td></td>
</tr>
<tr>
<td>Cross Discipline Team Leader Review</td>
<td></td>
</tr>
<tr>
<td>Medical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Chemistry Review(s)</td>
<td>X</td>
</tr>
<tr>
<td>Environmental Assessment</td>
<td></td>
</tr>
<tr>
<td>Pharmacology Review(s)</td>
<td></td>
</tr>
<tr>
<td>Statistical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Microbiology Review(s)</td>
<td></td>
</tr>
<tr>
<td>Clinical Pharmacology/Biopharmaceutics Review(s)</td>
<td></td>
</tr>
<tr>
<td>Risk Assessment and Risk Mitigation Review(s)</td>
<td></td>
</tr>
<tr>
<td>Proprietary Name Review(s)</td>
<td></td>
</tr>
<tr>
<td>Administrative/Correspondence Document(s)</td>
<td>X</td>
</tr>
</tbody>
</table>
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-406/S026

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

MAR 19 1998

Dear Dr. Magistrelli:


The supplemental application, submitted under 21 CFR 314.70(c), "Special Supplement - Changes Being Effected," provides for the expanded use of the shipping container, used for

Changes of the kind you have proposed, in our opinion, are not the kind of changes permitted by regulation to be put into effect prior to approval of a supplement. An approved supplement is required for the proposed changes, therefore this supplement has been reviewed under 21 CFR 314.70(b).

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

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, M.S., Project Manager, at (301) 443-0487.

Sincerely yours,

Eric P. Duffy, Ph.D.
Chemistry Team Leader
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

3/9/98
cc:
  Original NDA 20-406/S-026
  HFD-180/Div. Files
  HFD-180/M.Walsh
  HFD-180/A.Shaw
  HFD-820/ONDC Division Director
  HFD-92/DDM-DIAB
  DISTRICT OFFICE

Drafted by: M.Walsh 3/18/98
Initialed by: E.Duffy 3/19/98
final: M.Walsh 3/19/98
filename: 20406S26.ap

APPROVAL (AP)
APPLICATION NUMBER:
NDA 20-406/S026

CHEMISTRY REVIEW(S)
CHEMIST'S REVIEW

1. Organization: HFD-180
2. NDA Number: 20-406

3. Name and Address of Applicant (City & State): TAP Holdings, Inc.
   Bannockburn Lake Plaza, 2355 Waukegan Road
   Deerfield, IL 60015

4. AF Number: MAR 18 1998
5. Supplement(s)

6. Name of Drug: Prevacid®
7. Nonproprietary Name: Lansoprazole

8. Supplement Provides for: use of a [ ] product.

9. Amendments and Other (Reports, etc.) Dates:
   SCP-026 February 2, 1998
   C February 3, 1998

10. Pharmacological Category: anti-ulcer
11. How Dispensed: RX [X] OTC

12. Related TND/NDA/DMF(s):

13. Dosage Form: Delayed-Release Capsules
14. Potency: 15 and 30 mg

15. Chemical Name and Structure:

2-[[3-methylene-(2,2,2-trifluoroethoxy)-2-pyridyl-[methyl]-sulfinyl]benzimidazole

![Chemical Structure]

16. Records and Reports:
   Current Yes [X] No

   Reviewed Yes [X] No

17. Comments: See "Notes."

cc: NDA 20-406/SCP-026
   HFD-180/Div File
   HFD-181/CSO
   HFD-180/EDuffy
   HFD-180/LTalarico
   HFD-180/AShaw
R/D init by: EDuffy/3-17-98
ABS/dob F/T 3-18-98/WP: c:\wpfiles\chem\S\20406026.1AS

EDUFFY 3/18/98

18. Conclusions and Recommendations: The supplement may be approved.

19. Reviewer
Name: Arthur B. Shaw, Ph. D.
Signature 3/17/98
Date Completed: March 16, 1998

Form FDH 2266 (7/75) ALT R
APPLICATION NUMBER:
NDA 20-406/S026

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS
February 3, 1998

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: Lilia Talarico, M.D.
Director

RE: PREVACID® (Lansoprazole) Delayed-Release Capsules
NDA 20-406
Special Supplement—Changes Being Effected
Supplement No. 026, Amendment No. 001

Dear Dr. Talarico:

This submission is a correction to a cover letter from the February 2, 1998, submission of S-026 for NDA 20-406. On page two of the February 2 cover letter reference is made to the respectively.

The sponsor, TAP Holdings Inc., submits this change to an approved NDA for PREVACID Delayed-Release Capsules as a Changes Being Effected (CBE) supplement according to 21 CFR 314.70(c).

The container described in this submission is currently being utilized as the approved shipping container PREVACID Delayed-Release Capsules, 15 mg and 30 mg, manufactured by this CBE submission, TAP Holdings Inc., intends to
February 3, 1998
NDA 20-406, S-026, A-001
Page 2

Information describing the ____________ container have been previously submitted in the original pre-filing of the CMC section for NDA 20-406. Real time stability data for PREVACID supporting ____________ expiry in this container have previously been submitted in the 1996 annual report for this NDA. All of the previously submitted information has been included in this supplement. ____________ ____________

TAP proposes a ____________ month expiry for the ____________ container described in this submission. ____________

The approved ____________ container has the ____________ PREVACID ____________

NDA 20-406 was approved on May 10, 1995. ____________

TAP commits to place ____________ each product strength on long-term stability using the approved drug product protocol. Long-term stability will be conducted ____________ are more practical and cost efficient ____________ container. The containers used for stability testing are composed of ____________ found in the ____________ containers. In all other respects the containers are similar. We do not expect this difference in ____________ adversely effect the stability of the drug product since the container remains impervious to moisture; nor do we expect the ____________ the containers used for stability testing to adversely effect results. ____________

We plan to implement this change 30 days after it has been filed in your Division.

A field copy of this submission has been submitted to the Chicago District Office.
February 3, 1998
NDA 20-406, S-026, A-001
Page 3

If you have any questions or if you require additional information please contact me at the number listed below or contact Ms. Judy Wargel at (847) 317-5781.

Sincerely,

Gary C. Magistrelli, Ph.D.
Associate Director, Regulatory Affairs

(847) 267-4961
(847) 317-5795 (FAX)

CC: R. Mlecko (Chicago District Office, FDA)
February 2, 1998

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: Lilia Talarico, M.D.
Director

RE: PREVACID® (lansoprazole) Delayed-Release Capsules
NDA 20-406
Special Supplement-Changes Being Effected
Supplement No. 026

Dear Dr. Talarico:

The sponsor, TAP Holdings Inc., submits this change to an approved NDA for
PREVACID Delayed-Release Capsules as a Changes Being Effected (CBE)
supplement according to 21 CFR 314.70(c).

The container described in this submission is currently being utilized as
the approved shipping container


15 mg and 30 mg, manufactured


By this CBE submission, TAP Holdings
Inc., intends to expand its use of this approved shipping container


Information describing the components of this container have been previously
submitted in the original pre-filing of the CMC section for NDA 20-406. Real
time stability data for PREVACID supporting a 1-month expiry in this
container have previously been submitted in the 1996 annual report for this
NDA. All of the previously submitted information has been included in this
supplement.
February 2, 1998
NDA 20-406, S-026
Page 2

TAP proposes a <crossed-out> month expiry for the <crossed-out> container described in this submission.

The approved <crossed-out> container has the <redacted> REVACID <redacted> <redacted>

NDA 20-406 was approved on May 10, 1995 <redacted>

TAP commits to place <redacted> of each product strength on long-term stability using the approved drug product protocol. Long-term stability will be conducted <redacted> are more practical and cost efficient <redacted> container. The containers used for stability testing <redacted> containers. In all other respects the containers are similar. We do not expect this difference <redacted> adversely affect the stability of the drug product since the container remains impervious to moisture; nor do we expect the <redacted> the containers used for stability testing to adversely effect results. <redacted>

We plan to implement this change 30 days after it has been filed in your Division.

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

If you have any questions or if you require additional information please contact me at the number listed below or contact Ms. Judy Wargel at (847) 317-5781.

Sincerely,

[Signature]
Gary C. Magistrelli, Ph.D.
Associate Director, Regulatory Affairs

(847) 267-4961
(847) 317-5795 (FAX)

CC: R. Mlecko (Chicago District Office, FDA)