CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S020

Trade Name: Prevacid Delayed Release Capsules

Generic Name: (lansoprazole)

Sponsor: TAP Holdings Inc

Approval Date: September 4, 1997
# Reviews / Information Included in this NDA Review.

<table>
<thead>
<tr>
<th>Approval Letter</th>
<th>X</th>
</tr>
</thead>
<tbody>
<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/S020

APPROVAL LETTER
NDA 20-406/S-020

TAP Holdings Inc.
Attention: Judy Decker Wargel
2355 Waukegan Road
Deerfield, IL 60015

SEP - 4 1997

Dear Ms. Wargel:


We acknowledge receipt of your submission dated July 17, 1997.

The supplemental application provides for a new capsule filling machine for the drug product manufacture manufacturing facility.

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

Sincerely yours,

Eric P. Duffy 7/3/97

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
cc:
  Original NDA 20-406/S-020
  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 9/2/97
Initialed by: E.Duffy 9/2/97
final: M.Walsh 9/3/97
filename: 20406S20.AP

APPROVAL (AP)
APPLICATION NUMBER:
NDA 20-406/S020

CHEMISTRY REVIEW(S)
### CHEMIST'S REVIEW

<table>
<thead>
<tr>
<th>No.</th>
<th>Information</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>Name and Address of Applicant (City &amp; State):</td>
<td>TAP Holdings, Inc. Bannockburn Lake Plaza</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2355 Waukegan Road Deerfield, IL 60015</td>
</tr>
<tr>
<td>4.</td>
<td>NDA Number:</td>
<td>20-406</td>
</tr>
<tr>
<td>5.</td>
<td>AF Number:</td>
<td>AUG 28 1997</td>
</tr>
<tr>
<td>6.</td>
<td>Name of Drug:</td>
<td>Prevacid®</td>
</tr>
<tr>
<td>7.</td>
<td>Nonproprietary Name:</td>
<td>Lansoprazole</td>
</tr>
<tr>
<td>8.</td>
<td>Supplement Provides for:</td>
<td>Addition of a new capsule-filling machine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>for the drug product</td>
</tr>
<tr>
<td>10.</td>
<td>Pharmacological Category:</td>
<td>Anti-ulcer</td>
</tr>
<tr>
<td>11.</td>
<td>How Dispensed:</td>
<td>RX X OTC</td>
</tr>
<tr>
<td>13.</td>
<td>Dosage Form:</td>
<td>Delayed-Release Capsules</td>
</tr>
<tr>
<td>14.</td>
<td>Potency:</td>
<td>15 and 30 mg</td>
</tr>
<tr>
<td>15.</td>
<td>Chemical Name and Structure:</td>
<td>2-[[3-methyl-4-(2,2, trifluoroethoxy)-2-pyridyl]-methyl]-sulfinyl]benzimidazole</td>
</tr>
</tbody>
</table>

### Chemical Structure

![Chemical Structure](image)

### Comments:
This supplement provides for the validation data (Page 90) and the early stability data demonstrate the acceptability of the new machine.

cc: NDA 20-406/SCM-020
HFD-180/Div File
HFD-181/CSO
HFD-180/LTalarico
HFD-180/AShaw
HFD-180/EDuffy
R/D init by: E. Duffy/8-27-97
ABS/dob **F/T 8-27-97/WP:** c:\wpfiles\chem\S\20406020.1AS

**EDuffy 8/28/97**

### Conclusions and Recommendations:
The application may be approved. (AP)

### Reviewer

<table>
<thead>
<tr>
<th>Name:</th>
<th>Signature</th>
<th>Date Completed:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthur B. Shaw, Ph. D.</td>
<td></td>
<td>August 18, 1997</td>
</tr>
</tbody>
</table>
May 22, 1997

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.

RE: PREVACID® (lansoprazole) Delayed-Release Capsules
NDA: 20-406, Supplement 020
Supplemental Application for a Manufacturing Change:
New Capsule Filling Machine

Dear Dr. Talarico:

The sponsor, TAP Holdings Inc., submits this Supplemental Application under the provisions of Section 505 (i) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.70 (b) (3).

The purpose of this supplement is to qualify a new PREVACID 15 mg and 30 mg capsules. The manufacture of the drug substance and drug product remain unchanged. Only the filling of the capsules is affected.

Included in this submission are the following reports which describe and detail the use of the

- 
- 
- 

b(4)
b(4)

•

b(4)

•

b(4)

lots 15 mg and 30 mg capsules

100 count HDPE bottles and placed on stability. Results obtained after three months of storage

b(4)

A comparison of the results in tabular form is included as well as the stability protocol and the stability reports.

b(4)

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

Sincerely,

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

JDW/mea
NDA 20-406/S-020

TAP Holdings Inc.
Attention: Judy Decker Wargel
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-020

Therapeutic Classification: Standard

Date of Supplement: May 22, 1997

Date of Receipt: May 23, 1997

This supplement provides for a new capsule filling machine (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 July 22, 1997 in accordance with 21 CFR 314.101(a).

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

Food and Drug Administration
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
If you have any questions, please contact me at (301) 443-0487.

Sincerely yours,

Maria R. Walsh, M.S.
Project Manager
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Original NDA 20-406/S-020
HFD-180/Div. Files
HFD-180/CSO/M. Walsh
HFD-180/E. Duffy
A. Shaw
DISTRICT OFFICE  

Final: M. Walsh 6/2/97

SUPPLEMENT ACKNOWLEDGEMENT (AC)