CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406/S023

Trade Name:  Prevacid Delayed Release Capsules

Generic Name:  (lansoprazole)

Sponsor:  TAP Holdings Inc

Approval Date:  June 11, 1998
<table>
<thead>
<tr>
<th>Reviews / Information Included in this NDA Review.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Letter</td>
</tr>
<tr>
<td>Approvable Letter</td>
</tr>
<tr>
<td>Labeling</td>
</tr>
<tr>
<td>Summary Review</td>
</tr>
<tr>
<td>Officer/Employee List</td>
</tr>
<tr>
<td>Office Director Memo</td>
</tr>
<tr>
<td>Cross Discipline Team Leader Review</td>
</tr>
<tr>
<td>Medical Review(s)</td>
</tr>
<tr>
<td>Chemistry Review(s)</td>
</tr>
<tr>
<td>Environmental Assessment</td>
</tr>
<tr>
<td>Pharmacology Review(s)</td>
</tr>
<tr>
<td>Statistical Review(s)</td>
</tr>
<tr>
<td>Microbiology Review(s)</td>
</tr>
<tr>
<td>Clinical Pharmacology/Biopharmaceutics Review(s)</td>
</tr>
<tr>
<td>Risk Assessment and Risk Mitigation Review(s)</td>
</tr>
<tr>
<td>Proprietary Name Review(s)</td>
</tr>
<tr>
<td>Administrative/Correspondence Document(s)</td>
</tr>
</tbody>
</table>
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-406/S023

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

Dear Dr. Magistrelli:


The goal date for this application is June 11, 1998.

The supplemental application provides for the use of an child resistant cap, and HDPE bottle design for the 30 and 100 count bottles of the 15 and 30 mg capsules.

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, 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  
HFD-180/Div. Files  
HFD-180/CSO/M.Walsh  
HFD-180/ASHaw  
HFD-180/EDuffy  
HFD-92/DDM-DIAB  
DISTRICT.OFFICE

Drafted by: kj/June 10, 1998/revised by EPD June 11, 1998/c:\wordfiles\chemS\20406023.Aed
ED/dob/F/T 6-11-98
APPLICATION NUMBER:
NDA 20-406/S023

CHEMISTRY REVIEW(S)
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:
5. Supplement(s):
   Numbers       Dates
   SCP-023       Dec 10, 1997
6. Name of Drug: Prevacid
7. Nonproprietary Name: lansoprazole
8. Supplement Provides for: use of a child-resistant closure, a and a
   the plastic bottles
9. Amendments and Other (Reports, etc.) Dates:
10. Pharmacological Category: anti-ulcer
11. How Dispensed: RX X OTC
12. Related IND/NDA/DMF(s): DMFs
13. Dosage Form: Delayed-Release Capsules
14. Potency: 15 and 30 mg
15. Chemical Name and Structure:

\[
\text{2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl-} \\
\text{3-methyl]-sulfinyl]benzimidazole}
\]

16. Records and Reports:
   Current Yes X No
   Reviewed Yes X No

17. Comments: This is a "Changes Being Effectuated" supplement pursuant to a
    letter from Dr. Sheinin to the applicant dated October 29, 1997.
    cc: NDA 20-406/SCP-023
    HFD-180/Div File
    HFD-181/CSO
    HFD-180/Ltalarico
    HFD-180/Ashaw
    R/D init by: E Duffy/6-5-98
    ABS/dob F/T 6-9-98/WORD c:\wordfiles\chem\S\20406023.1AS

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

   Name: Arthur B. Shaw, Ph. D.
   Signature
   Date Completed: June 3, 1998

Form FDH 2266 (7/75) ALT R
APPLICATION NUMBER:
NDA 20-406/S023

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS
June 18, 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
560 Fishers Lane
Rockville, MD 20857

Attn: Lilia Talarico, M.D.
Director

RE: PREVACID® (lansoprazole) Delayed-Release Capsules
NDA 20-406/S-023
General Correspondence
Response to FDA Request

Dear Dr. Talarico:

This submission is in response to a request received from Ms. Maria Walsh of your Division via voice mail on June 1, 1998. Enclosed is an example of an (b4) bottle, container-closure for PREVACID. A CBE submission for (b4) was submitted to your Division on December 10, 1997, and it was approved June 11, 1998. For comparison, we have also enclosed an example of the child-resistant, (b4) container-closure system that was in use prior to the

(b4) 
(b4) 
(b4)

On June 5, 1998, examples of these containers were inadvertently submitted to NDA 20-406 S(4) Amendment 002 in error. I apologize if this has caused any confusion.

If you have any questions please contact me at the number listed below.

Sincerely,

Gary C. Magistrelli, Ph.D.
Associate Director, Regulatory Affairs
Phone: (847) 267-4961
Fax: (847) 317-5795