CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION:NDA 20877

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Chemistry Review(s)			X	
EA/FONSI			X	
Pharmacology Review(s)			X	
Statistical Review(s)	X			
Microbiology Review(s)			X	
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)			X	
Administrative Document(s)	X			
Correspondence	X			

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number:NDA 20877

Trade Name: Prevacid Delayed-Release Capsules

Generic Name:(lansoprazole)

Sponsor:Tap Holdings, Inc.

Approval Date:June 17, 1997

Indication: Provides for the addition of a new indication to the PREVACID (lansoprazole) Delayed-Release Capsules labeling for the use of lansoprazole in combination with clarithromycin and amoxicillin for the eradication of Helicobacter pylori in patients with active duodenal ulcer disease or a one-year history of a duodenal ulcer.

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Application Number: NDA 20877

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-876

JUN 17 1997

TAP HOLDINGS, INC
Attention: Ms. Linda J. Peters, M.S.
Regulatory Products Manager
2355 Waukegan Road
Deerfield, IL 60015

Dear Ms. Peters:

Please refer to your new drug application dated September 30, 1996, received on October 1, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PREVACID®(lansoprazole) Delayed-Release Capsules.

The User Fee goal date for this application is October 1, 1997.

This new drug application provides for the addition of a new indication to the PREVACID® (lansoprazole) Delayed-Release Capsules labeling for the use of lansoprazole in combination with clarithromycin and amoxicillin for the eradication of *Helicobacter pylori* in patients with active duodenal ulcer disease or a one-year history of a duodenal ulcer.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated June 9, 1997. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on June 9, 1997. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-876. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Anti-Infective Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and
Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

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 call Mr. Jose R. Cintron, R.Ph., M.A., Project Manager, at (301) 827-2120.

Sincerely yours,

David W. Feigal, Jr., M.D., M.P.H.
Director
Office of Drug Evaluation IV
Center for Drug Evaluation and
Research

cc:

Original NDA 20-876
HFD-520/Div. files
HFD-520/Div. files
HF-2/Medwatch (with labeling)
HFD-40/DDMAC (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFI-20/Press Office (with labeling)
HFD-101/LCarter
HFD-104/TNearing
HFD-520/MO/LGirardi 6/11/97
HFD-520/TLPharm/ROsterberg
HFD-520/TLChem/DKatague
HFD-520/Chem/JTimper
HFD-520/TLMicro/ASheldon
HFD-590/Micro/LUtrup
HFD-725/TLStat/DLin
HFD-725/ATLStat/NSilliman
HFD-830/ONDC Division Director
HFD-880/TLBiopharm/FPelsor
HFD-880/Biopharm/HSun
DISTRICT OFFICE
HFD-520/PMS/JCintron
HFD-520/

Concurrence Only:
HFD-520/CMPS/JBona 6/10/97
HFD-520/TLMO/MAlbuerne 6/11/97
HFD-520/Act.Div/GChikami 6/12/97
HFD-590/Act.Div/MGoldberger 6/12/97

Drafted by: jrc/June 5, 1997/
Initialed by:
final:

APPROVAL (AP)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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HFD-590/Micro/LUtrup
HFD-725/TLStat/DLin
HFD-725/ATLStat/NSilliman
HFD-830/ONDC Division Director
HFD-880/TLBiopharm/FPelsor
HFD-880/Biopharm/HSun
DISTRICT OFFICE
HFD-520/PMS/JCintron
HFD-520/

Drafted by: jrc/June 5, 1997/
Initialed by:
final:

APPROVAL (AP)

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