CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 050757/S02

APPROVAL LETTER

NDA 50-757/S-002

TAP Holdings, Inc.
Attention: Linda J. Peters
Manager, Regulatory Affairs
2355 Waukegan Rd.
Deerfield, IL 60015

Dear Ms. Peters:

Please refer to your supplemental new drug application dated October 5, 1998, received October 6, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PREVPAC™ (lansoprazole, clarithromycin and amoxicillin) .

We acknowledge receipt of your submission dated January 19, 1999.

This supplemental new drug application provides for the use of PREVPAC™ (lansoprazole, clarithromycin and amoxicillin) for the eradication of *Helicobacter pylori* to reduce the risk of duodenal ulcer recurrence.

We have completed the review of this application, as amended, 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 agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted January 19, 1999). Marketing the product with FPL that is not identical to the approved labeling text 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 "FPL for approved supplement NDA 50-757/S-002." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials 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 this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
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, contact Robin Anderson, Project Manager, at (301) 827-2127.

Sincerely,

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

APPEARS THIS WAY
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APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-757/S-003

APPROVAL LETTER

NDA 50-757/S-003

TAP Holdings Inc.
Attention: Linda J. Peters
2355 Waukegan Road
Deerfield, IL 60015

Dear Ms. Peters:

Reference is made to your supplemental New Drug Application dated February 24, 1999, submitted pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act for PREVPAC® (lansoprazole delayed-release capsules 30 mg, clarithromycin tablets 500 mg, and amoxicillin capsules 500 mg).

This supplemental application provides for a packaging change in which the currently approved blister material [redacted] will be replaced with [redacted]

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 requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours,

Norman Schmuff, Ph.D.
Chemistry Team Leader, DNDC III
Division of Special Pathogen and Immunologic
Drug Products (HFD-590)
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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APPLICATION NUMBER:

50-757/S-004

APPROVAL LETTER

NDA 50-757/S-004

TAP Holdings Inc.
Attention: Janet L. Haskins
2355 Waukegan Road
Deerfield, IL 60015

Dear Ms. Haskins:

Reference is made to your supplemental New Drug Application dated June 23, 1999, submitted pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act for PREVPAC® (lansoprazole delayed-release capsules 30 mg, clarithromycin tablets 500 mg, and amoxicillin capsules 500 mg).

This supplemental application provides for formulation and packaging changes related to the reformulation of BIAXIN® (clarithromycin tablets), 500 mg by its manufacturer, Abbott Laboratories.

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 requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours,

Norman Schmuff, Ph.D.
Chemistry Team Leader, DNDC III
Division of Special Pathogen and Immunologic
Drug Products (HFD-590)
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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