# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**50-757 / S-003**

## CHEMISTRY REVIEW(S)

| SUPPLEMENTAL NDA<br>CHEMIST'S REVIEW # 1 | 1. ORGANIZATION<br>HFD-590 | 2. NDA NUMBER<br>50-757 |
|---|---|---|

**3. NAME AND ADDRESS OF APPLICANT** *(City and State)*
TAP Holdings Inc.
Attention: Linda J. Peters
2355 Waukegan Road
Deerfield, IL 60015

**4. AF NUMBER**

**5. DOCUMENT(S)**

| NUMBERS | DATES |
|---|---|
| SCP-003 | 02/24/99 |

**6. NAME OF DRUG**
PREVPAC®

**7. NONPROPRIETARY NAME**
lansoprazole, amoxicillin, and clarithromycin

**8. SUPPLEMENT(S) PROVIDES FOR:**
A packaging change in which the currently approved blister material [redacted] will be replaced with [redacted]

**9. AMENDMENTS AND OTHER DATES**
N/A

**10. PHARMACOLOGICAL CATEGORY**
anti-ulcer

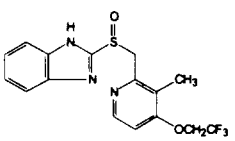
**11. HOW DISPENSED**
|X| Rx | | OTC

**12. RELATED IND/NDA/DMF(s)**
NDA 20-406

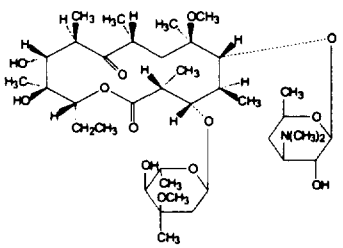
**13. DOSAGE FORM(S)**
Tablets and Capsules

**14. POTENCY (CIES)**
30 mg PREVACID (lansoprazole delayed-release capsules), 500 mg BIAXIN (clarithromycin tablets), and 500 mg TRIMOX (amoxicillin capsules)

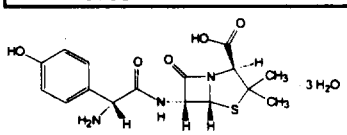
**15. CHEMICAL NAME**



2-[[[3-methyl-4-(2,2,2-tri-fluoroethoxy)-2-pyridyl]-methyl]sulfinyl] benzimidazole
$C_{16}H_{14}F_3N_3O_2S$



6-*O*-methylerythromycin
$C_{38}H_{69}NO_{13}$



(2*S*,5*R*,6*R*)-6-[(*R*)-(–)-2-amino-2-(*p*-hydroxyphenyl) acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate
$C_{16}H_{18}N_3O_5S \cdot 3\ H_2O$

**16. MEMORANDA**
N/A

**17. COMMENTS**

This supplemental application provides for a packaging change in which the currently approved blister material [redacted] will be replaced with [redacted] This supplement was submitted as a changes-being-effected supplement and was accepted as such because another review division had apparently already accepted a similar CBE supplement for a related drug product (in fact, that CBE supplement was already approved).

In support, the applicant provided a description of the change, including an explanation of the difference between the old and new blister materials, data indicating that the protective properties (moisture barrier) were better in the new blister materials, and a copy of the approval letter for NDA 20-406/S-025.

No deficiencies were noted.

**18. CONCLUSIONS AND RECOMMENDATIONS**
Recommend: **APPROVAL.**

**19. REVIEWER**

| NAME | SIGNATURE | DATE COMPLETED |
|---|---|---|
| John Smith | | 08/19/99 |

**20. CONCURRENCE:** HFD-590/NSchmuff

| DISTRIBUTION | X | Original Jacket | X | JSmith | X | MO/RHopkins |
|---|---|---|---|---|---|---|

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**50-757 / S-004**

## CHEMISTRY REVIEW(S)

| SUPPLEMENTAL NDA<br>CHEMIST'S REVIEW # 1 | 1. ORGANIZATION<br>HFD-590 | 2. NDA NUMBER<br>50-757 |
|---|---|---|

**3. NAME AND ADDRESS OF APPLICANT** *(City and State)*
TAP Holdings Inc.
Attention: Janet L. Haskins
2355 Waukegan Road
Deerfield, IL 60015

**4. AF NUMBER**

**5. DOCUMENT(S)**

| NUMBERS | DATES |
|---|---|
| SCP-004 | 06/23/99 |

**6. NAME OF DRUG**
PREVPAC®

**7. NONPROPRIETARY NAME**
lansoprazole, amoxicillin, and clarithromycin

**8. SUPPLEMENT(S) PROVIDES FOR:**
Formulation and packaging changes related to the reformulation of BIAXIN® (clarithromycin tablets) by its manufacturer.

**9. AMENDMENTS AND OTHER DATES**
N/A

**10. PHARMACOLOGICAL CATEGORY**
anti-ulcer

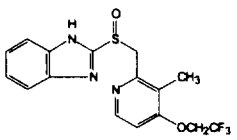
**11. HOW DISPENSED**
|X| Rx | | OTC

**12. RELATED IND/NDA/DMF(s)**
NDA 50-662

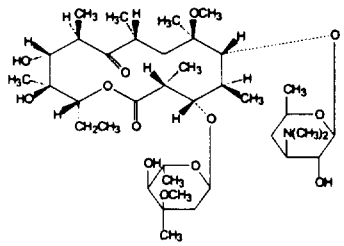
**13. DOSAGE FORM(S)**
Tablets and Capsules

**14. POTENCY (CIES)**
30 mg PREVACID (lansoprazole delayed-release capsules), 500 mg BIAXIN (clarithromycin tablets), and 500 mg TRIMOX (amoxicillin capsules)

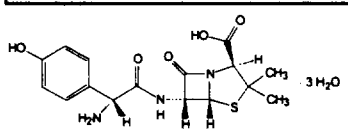
**15. CHEMICAL NAME**



2-[[[3-methyl-4-(2,2,2-tri-fluoroethoxy)-2-pyridyl]-methyl]sulfinyl] benzimidazole
$C_{16}H_{14}F_3N_3O_2S$



6-*O*-methylerythromycin
$C_{38}H_{69}NO_{13}$



(2*S*,5*R*,6*R*)-6-[(*R*)-(−)-2-amino-2-(*p*-hydroxyphenyl) acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate
$C_{16}H_{18}N_3O_5S \cdot 3\ H_2O$

**16. MEMORANDA**
N/A

**17. COMMENTS**

This supplemental application provides for formulation and packaging changes related to the reformulation of BIAXIN® (clarithromycin tablets) by its manufacturer, Abbott Laboratories. Abbott submitted formulation changes to NDA 50-662 in SCF-025. Although there were bioequivalence problems associated with the 250-mg tablets, there were no such problems with the 500-mg tablets, and SCF-025 was eventually approved (for the 500-mg tablets only) on 10/22/99.

TAP's packaging changes associated with the smaller, reformulated BIAXIN 500-mg tablets mainly concern a decrease in the size of the blister cavity and the changes [redacted] required to accomplish this. The blister materials and foil backing described in SCP-003 will be used. The first batch of product made with reformulated 500-mg BIAXIN tablets and resized packaging will be placed into the long term stability program. No deficiencies were noted.

**18. CONCLUSIONS AND RECOMMENDATIONS**
Recommend: **APPROVAL.**

**19. REVIEWER**

| NAME | SIGNATURE | DATE COMPLETED |
|---|---|---|
| John Smith | | 10/22/99 |

**20. CONCURRENCE:** HFD-590/NSchmuff

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|---|---|---|---|---|---|---|
| DISTRIBUTION | X | Original Jacket | X | JSmith | X | MO/RHopkins |
| | X | Division File | X | NSchmuff | X | CSO/JFritsch |