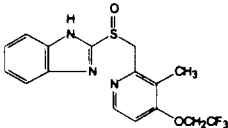
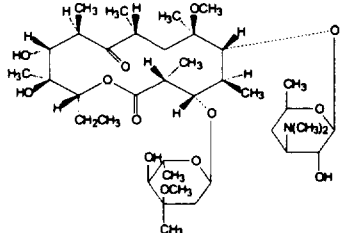
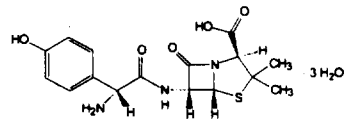


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

50-757 / S-003

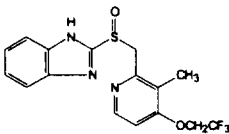
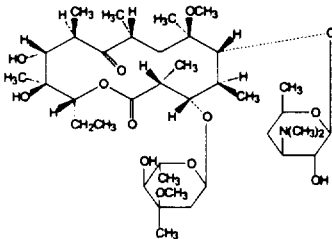
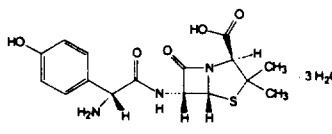
CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW # 1		1. ORGANIZATION HFD-590	2. NDA NUMBER 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 ☒ R ☐ 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 BIAVIN (clarithromycin tablets), and 500 mg TRIMOX (amoxicillin capsules)	
15. CHEMICAL NAME		16. MEMORANDA N/A	
 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]-methyl]sulfinyl] benzimidazole C₁₆H₁₄F₃N₃O₂S		 6-O-methylerythromycin C₃₈H₆₉NO₁₃	
		 (2S,5R,6R)-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 C₁₆H₁₈N₃O₅S • 3 H₂O	
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 John Smith	SIGNATURE		DATE COMPLETED 08/19/99
20. CONCURRENCE: HFD-590/NSchmuff			
DISTRIBUTION	☒ Original Jacket	☒ JSmith	☒ MO/RHopkins

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
50-757 / S-004

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW # 1		1. ORGANIZATION HFD-590	2. NDA NUMBER 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] R 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		16. MEMORANDA N/A	
 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]-methyl]sulfinyl]benzimidazole C₁₆H₁₄F₃N₃O₂S		 6-O-methylerythromycin C₃₈H₆₉NO₁₃	
		 (2S,5R,6R)-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 C₁₆H₁₈N₃O₅S · 3 H₂O	
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 John Smith		SIGNATURE	DATE COMPLETED 10/22/99
20. CONCURRENCE: HFD-590/NSchmuff			
DISTRIBUTION	X	Original Jacket	X
	X	Division File	X
		JSmith	X
		NSchmuff	X
		MO/RHopkins	
		CSO/JFritsch	