

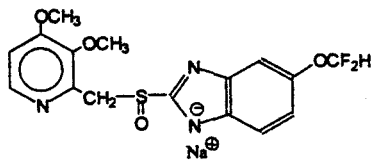
**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-987/S-007

CHEMISTRY REVIEW(S)

FEB 15 2002

CHEMIST'S REVIEW #1		1. <u>Organization:</u> HFD-180		2. <u>NDA Number:</u> 20-987	
3. <u>Name and Address of Applicant (City & State):</u> Wyeth Ayerst Laboratories P.O. Box 8299 Philadelphia, PA 19101-8299				4. <u>AF Number:</u>	
6. <u>Name of Drug:</u> PROTONIX™ Tablets				5. <u>Supplement(s)</u>	
7. <u>Nonproprietary Name:</u> pantoprazole sodium		Numbers SEI-007	Dates June 21, 2001		
8. <u>Supplement Provides for:</u> Efficacy supplement—Zollinger-Ellison syndrome				9. <u>Amendments and Other (Reports, etc.) Dates:</u>	
10. <u>Pharmacological Category:</u> Proton pump inhibitor		11. <u>How Dispensed:</u> Rx <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		12. <u>Related IND/NDA/DMF(s):</u> NDA 20-988	
13. <u>Dosage Form:</u> delayed-release tablets		14. <u>Potency:</u> 40 mg, 20 mg			
15. <u>Chemical Name and Structure:</u> Sodium-[5-(difluoromethoxy)-2-[[[(3,4-dimethoxy-2-pyridyl)-methyl]-sulfinyl]-1H-benzimidazole sesquihydrate				16. Records and Reports:	
				Current <input type="checkbox"/> Yes <input type="checkbox"/> No	
				Reviewed <input type="checkbox"/> Yes <input type="checkbox"/> No	
17. <u>Comments:</u> cc: NDA 20987/ SEI-007 HFD-180/Div File HFD-180/CPerry HFD-180/MKowblansky HFD-180/ LZhou					
18. <u>Conclusions and Recommendations:</u> The current efficacy supplement involves no new chemistry, manufacturing or control information; the currently approved product is being proposed for a new indication. Consequently, no chemistry-related labeling changes are required. The applicant appropriately requests categorical exclusion from preparation of an environmental assessment, on the basis that the estimated concentration of pantoprazole at the point of entry into the aquatic environment is below one part per billion. Consequently, from the CMC perspective, this supplement should be Approved .					
19. Reviewer					
Name: Marie Kowblansky, Ph.D.		Signature:		Date Completed: 2/12/02	

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Marie Kowblansky
2/14/02 05:34:32 PM
CHEMIST

Liang Zhou
2/15/02 02:10:06 PM
CHEMIST