

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020007/S022

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW 1		1. Organization: HFD-180		2. NDA Number: 20-007	
3. Name and Address of Applicant (City & State): Glaxo Wellcome Research and Development Five Moore Drive P. O. Box 13398 Research Triangle Park, North Carolina 27709				4. AF Number: OCT 10 1996	
				5. Supplement(s)	
6. Name of Drug: Zofran Injection		7. Nonproprietary Name: Ondansetron hydrochloride		Numbers	Dates
				SE3-022	May 6, 1996
8. Supplement Provides for: the establishment of intramuscular administration as an alternative to intravenous administration in the prevention of postoperative nausea and vomiting.				9. Amendments and Other (Reports, etc.) Dates:	
10. Pharmacological Category: 5-HT Receptor Antagonist		11. How Dispensed: RX ☒ OTC ☐		12. Related IND/NDA/DMF(s)	
13. Dosage Form: Injection		14. Potency: 2 mg/mL, 2 mL single-dose vials; 2 mg/mL, 16 mL single-dose vials; 2 mg/mL, 20 mL multi-dose vials			
15. Chemical Name and Structure: See USAN 1995, pg. 485.				16. Records and Reports:	
				Current Yes ☒ No ☐	
				Reviewed Yes ☒ No ☐	
17. Comments: See 20., Review Notes cc: NDA 20-007/SE3-022 HFD-180/Div File HFD-181/CSO HFD-180/SFredd HFD-180/RFrankewich R/D init: EDuffy/ RF/dob DRAFT 10-8-96/F/T 10-9-96\Wp: c:\wpfiles\chem\s\20007022.1RF					
18. Conclusions and Recommendations: The supplement may be approved.					
19. Reviewer					
Name: Raymond Frankewich, Ph.D.		Signature: <i>[Signature]</i> TS/		Date Completed: October 1, 1996	