

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020103, S015

CHEMISTRY REVIEW(S)

DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls Supplement

NDA#: 20-103 SUPPLEMENT#: SE1-015 CHEM REVIEW#: 1 REVIEW DATE: 8/18/99

SUBMISSION TYPE	DOCUMENT		DATES		NUM	LETTER	ST
	CDER	ASSIGNED	REVIEW				
ORIGINAL	8/28/98	8/31/98					

SUPPLEMENT PROVIDES FOR: New indication: prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin.

NAME & ADDRESS OF APPLICANT: Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

DRUG PRODUCT NAME:

Proprietary:

Nonproprietary/USAN:

Code Name/#:

Chem. Type/Ther. Class:

Zofran Tablets, 24 mg
ondansetron hydrochloride dihydrate
GR38032F

PHARMACOLOGICAL CATEGORY: 5-HT₃ Receptor Antagonist

INDICATION: Anti-emetic

DOSAGE FORM: Tablet

STRENGTH: 24 mg

ROUTE OF ADMINISTRATION: Oral

HOW DISPENSED: Rx OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

1,2,3,9-Tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one, hydrochloride, dihydrate.

C₁₈H₁₉N₃O · HCl · 2H₂O

Mol. wt. = 365.86

For molecular structure see USAN 1997, pg. 516.

SUPPORTING DOCUMENTS:

DMF Number	Item referenced	Holder	Status	Review Date	Letter Date
[REDACTED]					

RELATED DOCUMENTS (if applicable): N/A

CONSULTS: None

REMARKS/COMMENTS:

The following statement is provided to establish the categorical exclusion of the drug product from environmental assessment requirements. It is provided in Appendix V to volume 1 (pg. 254) of NDA 20-103/SCF-016, a supplement which provides for the new 24 mg tablet strength.

The proposed action is subject to the categorical exclusion listed in 21 CFR Part 25.31(b). Glaxo Wellcome has reviewed market forecasts, indications and dosage information [REDACTED]

[REDACTED] Glaxo Wellcome does not have knowledge of any extraordinary circumstances that might cause this action to have a significant affect on the quality of the human environment.


Categorical exclusion as requested was granted for NDA 20-103/SCF-016. Accordingly, there are no CMC concerns with NDA 20-103/SE1-015.

APPEARS THIS WAY ON ORIGINAL

CONCLUSIONS & RECOMMENDATIONS:


This application may be approved.

/s/


Raymond P. Frankewich, Ph.D.
Review Chemist, HFD-180

8/19/99

/s/


Eric P. Duffy, Ph.D.
Chemistry Team Leader, HFD-180

8/19/99

CC:
NDA #20-103/SE1-015
HFD-180/LTalarico
HFD-180/Div File/NDA #20-103
HFD-180/EDuffy
HFD-180/RFrankewich
HFD-181/KJohnson
R/D Init by:
RPF/dob F/T\Word: n:\wordfiles\chem\S\20103015.1RPF

APPEARS THIS WAY ON ORIGINAL