CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020745

CHEMISTRY REVIEW(S)

REQUEST FOR TRADEMARK REVIEW

To: Labeling and Nomenclature Committee
Attention: Dan Boring, Chair (HFD-530), 9201 Corporate Blvd, Room N461

From: Division of Gastrointestinal and Coagulation Drug Products	**HFD-180**
Attention: Michael Folkendt, Project Manager	**Phone:** (301) 443-0487
Date: February 12, 1997 /S/ 2/12/97	
Subject: Request for Assessment of a Trademark for a Proposed New Drug Product	
Proposed Trademark: Zantac® 75 EFFERdose®	**NDA/ANDA#** 20-745
Established name, including dosage form: ranitidine hydrochloride Effervescent Tablets for OTC use.	
Other trademarks by the same firm for companion products: Zantac 75® Tablets for OTC use; Zantac EFFERdose Tablets and Granuales (150mg) for PRESCRIPTION USE Plus a number of other dosage forms for the prescription product	
Indications for Use (may be a summary if proposed statement is lengthy): For the treatment of episodic heartburn.	
Initial Comments from the submitter (concerns, observations, etc.): -none-	

Note: Meetings of the Committee are scheduled for the 4th Tuesday of the month. Please submit this form at least one week ahead of the meeting. Responses will be as timely as possible.

cc: Original 20-745; HFD-180/division file; HFD-180/M.Folkendt; HFD-180/J.Sieczkowski

Rev. December 95

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ON ORIGINAL

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ON ORIGINAL

716

REQUEST FOR TRADEMARK REVIEW

To: Labeling and Nomenclature Committee
Attention: Dan Boring, Chair (HFD-530), 9201 Corporate Blvd, Room N461

From: Division of Gastrointestinal and Coagulation Drug Products	**HFD-180**
Attention: Michael Folkendt	**Phone:** (301) 443-0487
Date: October 28, 1996	
Subject: Request for Assessment of a Trademark for a Proposed New Drug Product	
Proposed Trademark: Zantac 75 RapiDose	**NDA/ANDA#** NDA 20-745
Established name, including dosage form: ranitidine hydrochloride Effervescent Tablets	
Other trademarks by the same firm for companion products: Zantac 75 for the OTC 75 mg tablets Zantac 150 & Zantac 300 for the 150 and 300 mg prescription tablets Zantac 150 GELdose & Zantac 300 GELdose for 150 and 300 mg prescription capsules Zantac 150 EFFERdose Tablets and Granules for prescription Zantac for prescription syrup.	
Indications for Use (may be a summary if proposed statement is lengthy): Alternate dosage form for OTC use for the treatment of heartburn.	
Initial Comments from the submitter (concerns, observations, etc.):	

Note: Meetings of the Committee are scheduled for the 4th Tuesday of the month. Please submit this form at least one week ahead of the meeting. Responses will be as timely as possible.

cc: Original NDA 20-745; HFD-180/division file; HFD-180/M.Folkendt; HFD-180/J.Sieczkowski

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Consult #716 (HFD-180)

ZANTAC 75 Rapidose ranitidine hydrochloride effervescent tablets

The proprietary name ZANTAC 75 is already in use and was not considered by the Committee. The descriptive nomenclature "Rapidose" was evaluated and found to be misleading because the "rapid" of this term refers to how quickly the tablet dissolves. Consumers might be misled into believing the medication goes to work more quickly, when that may not be true.

The Committee finds the proposed proprietary name unacceptable.

/S/ 1/7/97
(, Chair
CDER Labeling and Nomenclature Committee

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ON ORIGINAL

Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Review of Chemistry, Manufacturing, and Controls

MAY - 7 1997

NDA 20-745 **CHEM REVIEW :** #1 **REVIEW DATE:** January 30, 1997

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	02 JUL 1996	05 JUL 1996	22 JUL 1996
AMENDMENT [BC]	10 OCT 1996	15 OCT 1996	-
BC	10 DEC 1996	13 DEC 1996	26 DEC 1996
BC	19 DEC 1996	20 DEC 1996	02 JAN 1997

NAME & ADDRESS OF APPLICANT:

APPEARS THIS WAY
ON ORIGINAL

Glaxo Wellcome
P.O. Box 13398
Five Moore Drive
Research Triangle Park, North Carolina 27709

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DRUG PRODUCT NAME

Proprietary: Zantac® 75 EFFERdose® Tablets/Zantac® 75 RapiDose® Tablets.

Nonproprietary/USAN: ranitidine hydrochloride effervescent tablets, 75 mg.

Code Name/#: AH 19065 for ranitidine hydrochloride/Zantac® OTC for Zantac® 75 EFFERdose Tablets.

Chem.Type/Ther.Class: Histamine H_2 Receptor Antagonist.

ANDA Suitability Petition/DESI/Patent Status:

Patents: 4,128,658 July 25, 1997
4,521,431 June 4, 2002
5,102,665 June 23, 2009

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PHARMACOLOGICAL CATEGORY/INDICATION:
Relief from heartburn, acid indigestion, and sour stomach.

DOSAGE FORM: Effervescent Table (white to pale yellow <<Z75>> on one face

STRENGTH: 75 mg

ROUTE OF ADMINISTRATION: Oral

HOW DISPENSED: _____ Rx XXX OTC

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

Generic Name: ranitidine hydrochloride

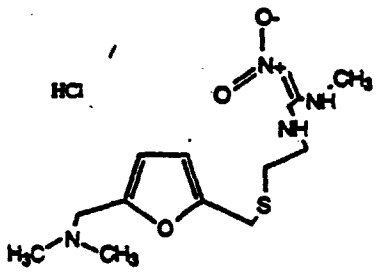
Chemical Name: N-[2-[[[5-[(dimethylamino)methyl]-2-furanyl]methyl]thio]ethyl]-N'-methyl 2-nitro-1,1-ethenediamine, hydrochloride

CAS Number: 066357-35-5

Molecular Formula: $C_{13}H_{22}N_4O_3S \cdot HCl$

Molecular Weight: 350.87

Structure:



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Physical Description: white to pale yellow, granular substance

SUPPORTING DOCUMENTS:

NDA 18-703 Zantac® Tablets
NDA 20-520 Zantac® 75 Tablets (for over-the-counter use)

RELATED DOCUMENTS: (if applicable):

NDA 20-251 Zantac® 150 EFFERdose® Tablets, 150 mg.

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CONSULTS:

1. Statistics (Expiration dating): Submitted 18 October 1996 for review.
2. Nomenclature: Submitted on 28 OCT 1996 to Nomenclature Committee.
3. Biopharmaceutics: Original Submission sent for review for bioequivalence.
4. EER dated September 3, 1996.

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REMARKS/COMMENTS:

1. EER noted at Acceptable, dated 1/15/97.
2. The Nomenclature Committee noted that the proposed proprietary name "Zantac® 75 RapiDose" is not acceptable, Review date 1/7/97; CDER date 1/13/97.
3. The "Clinical Pharmacology and Biopharmaceutics Review" dated 1/17/97 recommends the acceptance of the proposed

4. The statistics consult has not been received to this date and it is not expected that the proposed drug product expiry date will be shortened by the statistics consult review.
5. Addendum February 20, 1997: The Statistical Review and Evaluation Stability Study dated February 6, 1997 by Moh-Jee Ng noted that the 18 months of stability data for the Zantac® 75 EFFERdose supports an expiration dating period of 24 months for storage between 2°C/AMBH and 30°C/60% RH.

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CONCLUSIONS & RECOMMENDATIONS:
Based on the submitted chemistry, manufacturing and controls information submitted for Zantac® 75 EFFERdose® Tablets the application should be approved. A request should be made of Glaxo Wellcome to provide a methods validation package in a single document

The CSO should submit the EA Review and FONSI to Nancy B. Sager, Environmental Scientist, HFD-357 for a concurrence on the adequacy of the EA information submitted and the FONSI.

/S/

APPEARS THIS WAY
ON ORIGINAL

Joseph Sieczkowski, Ph.D. 2-20-97
Review Chemist, HFD-180

/S/ 3/7/97
Eric P. Duffy, Ph.D.
Chemistry Team Leader, HFD-180

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cc: Original: NDA 20-745
HFD-180/Division File
HFD-180/CSO/MFolkendt
HFD-80
HFD-92
HFD-232
HFD-820/ONDC/Div.Dir
HFD-180/JSieczkowski
R/D init: EDuffy/
dob DRAFT 1-30-97/**F/T 2-12-97**\WP: c:\wpfiles\chem\S\20745701.1js

APPROVAL