

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020902

CHEMISTRY REVIEW(S)

Folkendt

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

NDA 20-902 CHEMISTRY REVIEW #3

JUN 16 1999

DATE: May 25, 1999

FROM: Joseph Sieczkowski, Ph.D. [redacted] 6-16-1999
ONDC II/HFD-180

SUBJECT: AL NDA-20-902, Pepcid® AC Gelcap/Labeling requirements
(FR Vol. 64, Number 51, 3/17/99).

TO: NDA-20-902

This labeling amendment dated May 17, 1999 was made to comply with the Agency's final rule on Over-The-Counter Human Drugs: Labeling Requirements (FR Vol. 64, #51, 3/17/99). The labeling was provided on paper and in PDF electronic format. The paper labeling version (AL 5/17/99) was reviewed by chemistry.

The following labeling information was submitted: Diskettes with labeling (Attachment (ATT) 1), Package Insert (ATT 2), Blister Card (ATT 3), Bottle Carton (ATT 4), Bottle Label (ATT 5), Blister Carton (ATT 6), Sample Pouch (ATT 7) and Dispensit (ATT 8).

Labeling items reviewed: Trade name, generic name, distributor's name and address, provision for Lot No. and expiration date, storage statement and inactive ingredients list.

CONCLUSIONS:

All chemistry aspects of the drug product labeling appeared satisfactory.

CC:

- NDA 20-902
- HFD-180/Div.File/NDA 20-902
- HFD-181/CSO/M.Folkendt
- HFD-180/L.Talarico
- HFD-180/E.Duffy
- HFD-180/J.Sieczkowski [redacted]

R/D init: E.Duffy/

dob DRAFT 6-9-99/F/T 6-9-99\Word: n:\wordfiles\chem\N\20902906.3JS

6/16/99

Folkendt

MAY 10 1999

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

NDA 20-902 CHEM REVIEW: #2 REVIEW DATE: April 22, 1999

SUBMISSION TYPE	DATES						
	DOCUMENT	CDER	ASSIGNED	REVIEW	NUM	LETTER	ST
ORIGINAL	09/30/97	09/30/97	10/14/97	-	-	-	-
AMENDMENT	12/8/97	12/10/97	12/24/97	-	-	-	-
BC Vol. 2.1							
AMENDMENT	06/24/98	06/29/98	07/9/98	09/1/98	#1	09/30/98	AE
BC Vol. 5.1							
AMENDMENT	12/18/98	12/22/98	01/1/99	04/22/99	#2	-	-
AZ Vol. 6.1							

NAME & ADDRESS OF APPLICANT: Johnson & Johnson Merck
7050 Camp Hill Road
Fort Washington, PA 19034

DRUG PRODUCT NAME:
Proprietary: Pepcid® AC Acid Controller™ Gelcaps
Nonproprietary/USAN: famotidine tablets
Code Name/#: YM-11170, L-643,341-00T, MK-0208
Chem.Type/Ther.Class: CAS Registry Number: 76824-35-6

ANDA SUITABILITY PETITION/DES PATENT STATUS:
See Remarks/Comments, Item 2.

PHARMACOLOGICAL CATEGORY:
H₂ receptor antagonist.

INDICATION:
Treat or prevent: Heartburn, Acid indigestion, Sour stomach

DOSAGE FORM: Tablet (Gelcap-gelatin film coated tablet).

STRENGTH: 10mg

ROUTE OF ADMINISTRATION: Oral

HOW DISPENSED: Rx XXX OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:
See USP 23.

SUPPORTING DOCUMENTS:

NDA 19-462 Famotidine drug substance and tablets.
NDA 20-325 Famotidine 10mg film coated tablets.