

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

NDA 20-902 CHEM REVIEW #1 REVIEW DATE: September 1, 1998

SUBMISSION TYPE	DOCUMENT		DATES			ASSIGNED	REVIEW	NUM	LETTER	ST
	CDER		CDER							
ORIGINAL	30	SEP 97	30	SEP 97	14	OCT 97				
AMENDMENT BC Vol. 2.1	08	DEC 97	10	DEC 97	24	DEC 97				
AMENDMENT BC Vol. 5.1	24	JUN 98	29	JUN 98	09	JUL 98				

SEP 29 1998

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

DRUG PRODUCT NAME:

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

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

PHARMACOLOGICAL CATEGORY:

H₂ receptor antagonist (prevention and treatment of heartburn).

INDICATION:

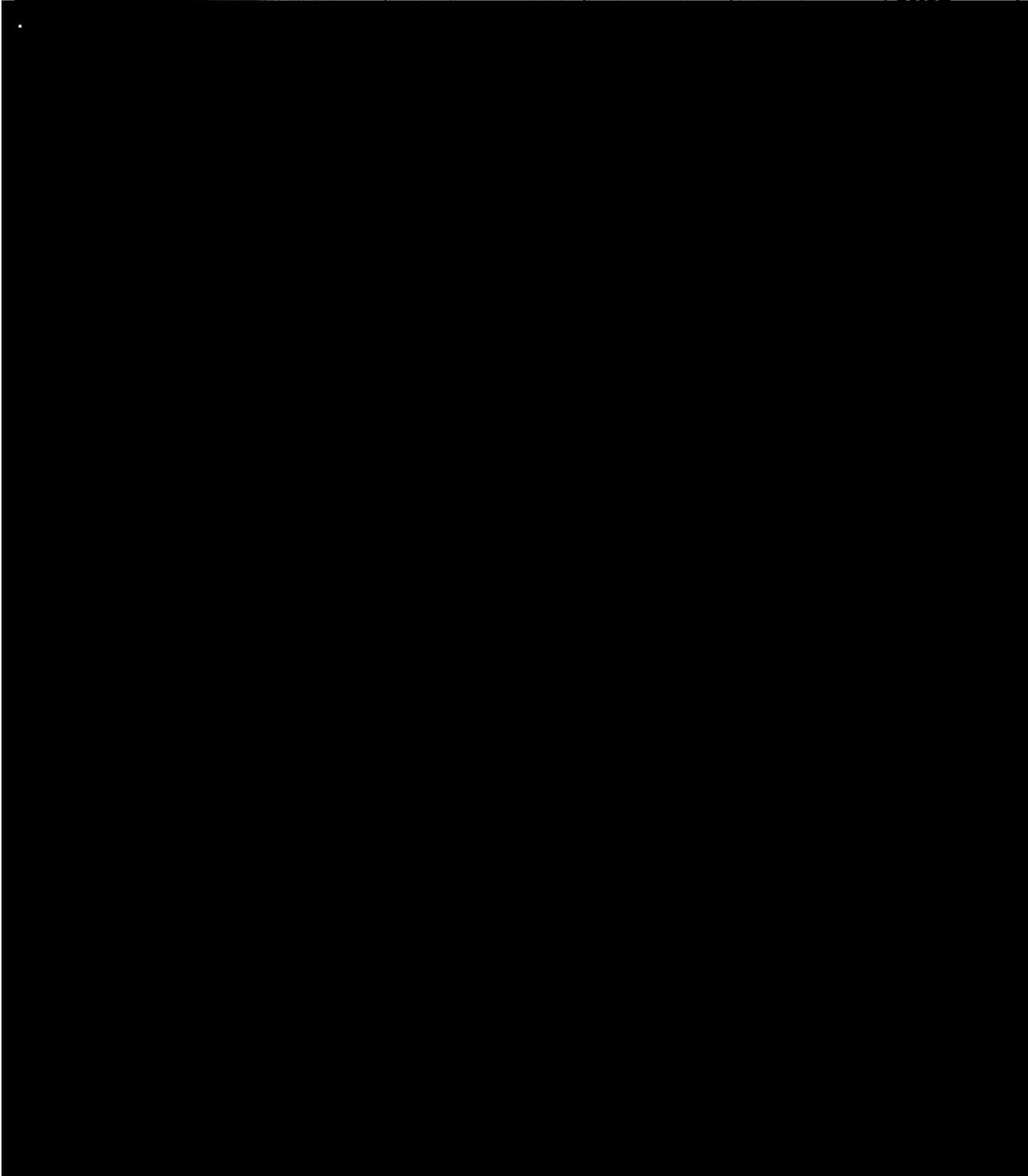
DOSAGE FORM: Tablet (Gelcap-gelatin film coated tablet)
STRENGTH: 10 mg
ROUTE OF ADMINISTRATION: ORAL
HOW DISPENSED: Rx XXX OTC

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

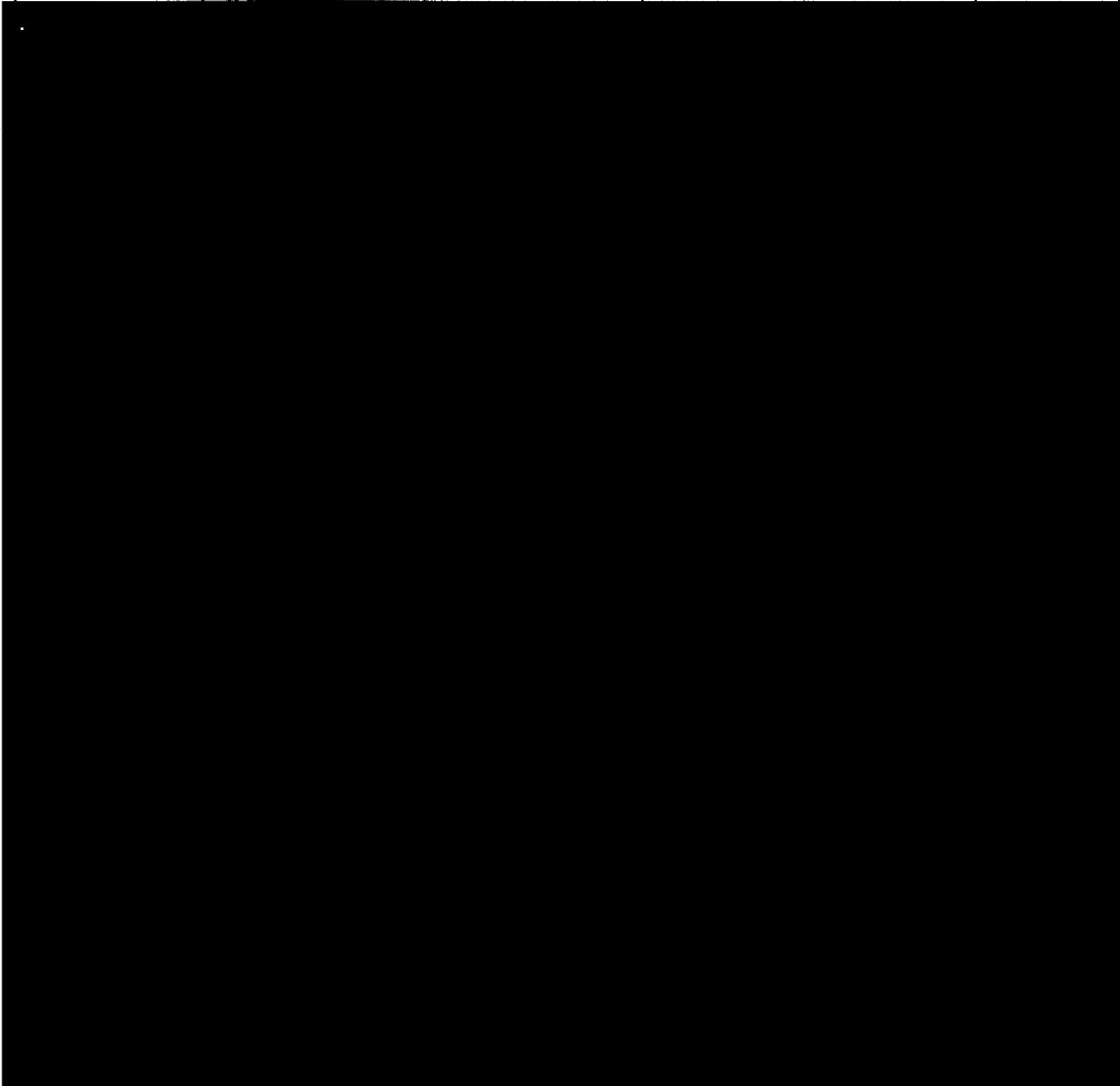
SUPPORTING DOCUMENTS:

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

DMF NUMBER	ITEM REFERENCE	HOLDER	STATUS	REVIEW	NDA/ANDA OR LETTER DATE
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CONSULTS:

1. Clinical Pharmacology and Biopharmaceutical Rev., July 27, 1998, by Michael J. Fossler.
2. Division of OTC Drug Products Labeling Review of NDA August 12, 1998 by Gloria Chang, R.Ph.

REMARKS/COMMENTS:



09/23/98