CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-958

PHARMACOLOGY REVIEW

Folkert

NDA 20,958 REVIEW # 1

Sponsor & Address: Merck Research Laboratories
West Point, PA

Date of Submission: February 20, 1998

Date of HFD-180 Receipt: February 23, 1998 JUL 30 1998

Date of Review: July 30, 1998

Product Name: PEPCID®

Generic Name: Famotidine/Antacid Combination

Dosage Form: Chewable Tablet 1780 mg

Pharmacologic Category: Histamine H_2-receptor antagonist

COMPONENT	ROLE	MG/TABLET
Sugar		
Magnesium Stearate ✓		
Dextrates ✓		
Monohydrate ✓		
Hydroxypropyl Methylcellulose ✓		
Cellulose Acetate ✓		
Hydroxypropyl Cellulose ✓		

Red	Oxide ✓	
Total Tablet Weight (mg)		**1780**

(1) Used in the manufacture of tablets, but removed during the manufacturing process.

starch NF and a trace quantity of sodium lauryl sulfate NF.

Indications: For treatment and prevention of heartburn, acid indigestion and sour stomach.

Related NDAs: NDA 19,462 (PEPCID Tablets, Merck)
NDA 20,325 (PEPCID AC Film-Coated Tablets, Merck)
NDA 20,801 (PEPCID AC Chewable Tablets, Merck)
NDA 20,902 (PEPCID AC Gelcaps, Merck)

REVIEW AND EVALUATION OF PHARMACOLOGY AND TOXICOLOGY DATA
Original Summary

SUMMARY AND EVALUATION:

This NDA provides for a chewable tablet of famotidine/antacid combination as an OTC therapy for the prevention and treatment of upper gastrointestinal symptoms of heartburn, acid indigestion and sour stomach. Pepcid is a well established approved therapeutic entity. Tablet, suspension and injectable forms of PEPCID have been approved for use in the treatment of active duodenal ulcer, active benign gastric ulcer and pathological hypersecretory conditions and in the maintenance therapy for duodenal ulcer patients after healing the ulcer. It was also

approved for short term treatment of gastroesophageal reflux disease. Since the drug has already been found to be safe and is the subject of 5 approved NDAs with extensive clinical exposure and is permitted to be used concomitantly with antacids, there is no need for additional preclinical studies. Approval of this NDA is recommended by Pharmacology.

/S/ 7/30/98
Jasti B. Choudary, B.V.Sc., Ph.D.

cc:
NDA
HFD-180
HFD-181/CSO
HFD-180/Dr. Choudary

JBC/hw/7/30/98
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