marketing.

2. The sponsor should be advised that when the application (NDA # 20-801) requesting to change the trade name of the drug from "Pepcid AC Acid Controller" to [redacted] is approved, a labeling supplement for the subject product must be submitted to reflect the trade name change. For consistency and readability, the sponsor should use the same trade name throughout the labeling.

3. The tablet (Gelcap) image on the front panel of the carton package and under the subsection "Product Benefits" on the front page of the package insert for the carton, 70-count bottles and Pouch Dispenser is acceptable provided that the term "Gelcaps" is defined. (See Agency recommendations in I.A.1.)

4. Based on the submitted labeling, the Pouch Dispenser, Pouch, and Dispenser for Pouch package insert are for consumer use only, and not for professional use. Previous NDA submission (NDA 20-801) for Pepcid AC Acid Controller tablets contains labeling for professional use samples. If professional use only samples of Pepcid Acid Controller Gelcaps are intended to be distributed, the labeling may need revisions.

5. It is suggested that the labeling be revised so that it is in compliance with the February 27, 1997 Proposed Labeling Requirements for OTC Drug Products (Attachment 3). We also suggest that the sponsor refer to the prototype proposed draft label for (Attachment 2). Additional format and wording changes from the currently approved label are included in the prototype label. The sponsor, however, should be reminded that the proposed Labeling Requirements for OTC Drug Products and the prototype label are subject to change pending finalization of the final rule.

/S/ [redacted]

Gloria Chang, R.Ph.
Interdisciplinary Scientist, HFD-560

/S/ [redacted]

Helen Cothran, B.S.
Team Leader, HFD-560

/S/ [redacted]

Rosemarie Neuner, M.D., M.P.H.
Medical Officer, HFD-560

/S/ [redacted]

Linda M. Katz, M.D., M.P.H.
Deputy Director, HFD-560

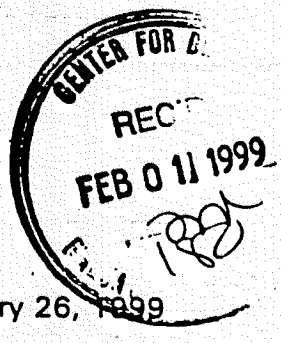
Date Signed 9/5/98

Attachments

APPEARS THIS WAY ON ORIGINAL

83 Pages Redacted
Draft Labeling

Johnson & Johnson ○ MERCK
CONSUMER PHARMACEUTICALS CO.



NEW CORRESP

January 26, 1999

Lilia Talarico, MD, Director
Division of Gastrointestinal and Coagulation
Drug Products, HFD-180, Room 6B-45
Office of Drug Evaluation III (CDER)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

NDA 20-902: PEPCID AC GELCAP
(Nonprescription famotidine 10 mg)

PATENT AND EXCLUSIVITY INFORMATION

Dear Dr. Talarico:

Please refer to the New Drug Application cited above which was deemed approvable on September 30, 1998. Attached hereto is supplemental patent and exclusivity information applicable to this NDA.

If there are any questions, please call me at (215) 273-7152 or in my absence, Edwin Hemwall at (610) 397-2306.

Sincerely,

George Latyszonek
Director, Regulatory Affairs

mhg
Attachments

DUPLICATE

Johnson & Johnson

OFFICE OF
GENERAL COUNSEL

ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, N.J. 08933-7003

Ph: 732-524-2641
Fx: 732-524-5866

January 20, 1999

Re: Pepcid AC® Acid Controller™ Gelcap
NDA 20-902 Famotidine
Time Sensitive Patent Information
Submitted in accordance with
21 CFR §314.53(d)(1) and 21 CFR §314.60

Dear:

Pursuant to the provisions of 21 USC §355(b)(1), please find supplemental patent information for the product PEPCID AC® Acid Controller™ Gelcaps under NDA 20-902.

The undersigned declares that U.S. Patent No. 5,854,267, which expires June 2, 2015 covers a method of use of product PEPCID AC® Acid Controller™ Gelcaps (famotidine), with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the product. The product is currently pending approval under Section 505 of the Federal Food, Drug and Cosmetic Act.

The undersigned requests publication of the above patent information.

Respectfully submitted,

Kenneth J. Dow
Registered Patent Attorney
Registration No. 32,890

Encs.

NDA: 20-902
Famotidine
Item 13: Patent Information

PATENT AND EXCLUSIVITY INFORMATION

1.	Active Ingredient	Famotidine	
2.	Strengths	10 mg	
3.	Trade Names	PEPCID AC® Acid Controller™ Gelcaps	
4.	Dosage form Route of Administration	Caplet Oral	
5.	Applicant Firm Name	Johnson & Johnson•Merck Consumer Pharmaceutical Co.	
6.	NDA Number	20-902	
7.	Approval Date		
8.	Exclusivity-Date First A-NDA Could be Submitted	3 years from NDA approval date	
9.	Applicable Patent Number*		Expiration
		5,854,267	June 2, 2015
		5,677,794	May 2, 2015
		4,283,408	Oct. 15, 2000
		4,820,524	Feb. 20, 2007

US005854267A

United States Patent [19]

Berlin et al.

[11] Patent Number: 5,854,267

[45] Date of Patent: Dec. 29, 1998

[54] METHOD FOR PREVENTING HEARTBURN

[75] Inventors: Roger Berlin, Haverford, Pa.; Thomas N. Gates, Bonita Springs, Fla.; Thomas Simon, Berwyn, Pa.

[73] Assignees: Merck & Co., Inc., Rahway; Mc Neil-PPC, Inc., Skillman, both of N.J.

[21] Appl. No.: 459,182

[22] Filed: Jun. 2, 1995

(Under 37 CFR 1.47)

[51] Int. Cl.[6] A61K 31/425

[52] U.S. Cl. 514/370

[58] Field of Search 514/370

[56] References Cited

U.S. PATENT DOCUMENTS

4,283,408 8/1981 Hirata et al. 424/270

FOREIGN PATENT DOCUMENTS

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Primary Examiner—Phyllis G. Spivack

Attorney, Agent, or Firm—Richard S. Parr; Melvin Winokur

[57] ABSTRACT

A method for preventing heartburn episodes in a patient susceptible to suffering heartburn episodes following ingestion of heartburn-inducing food or beverage, comprising administering to the patient, 30 minutes prior to consumption by the patient of the food or beverage, a composition comprising an amount of famotidine of 10 mg.

1 Claim, 3 Drawing Sheets

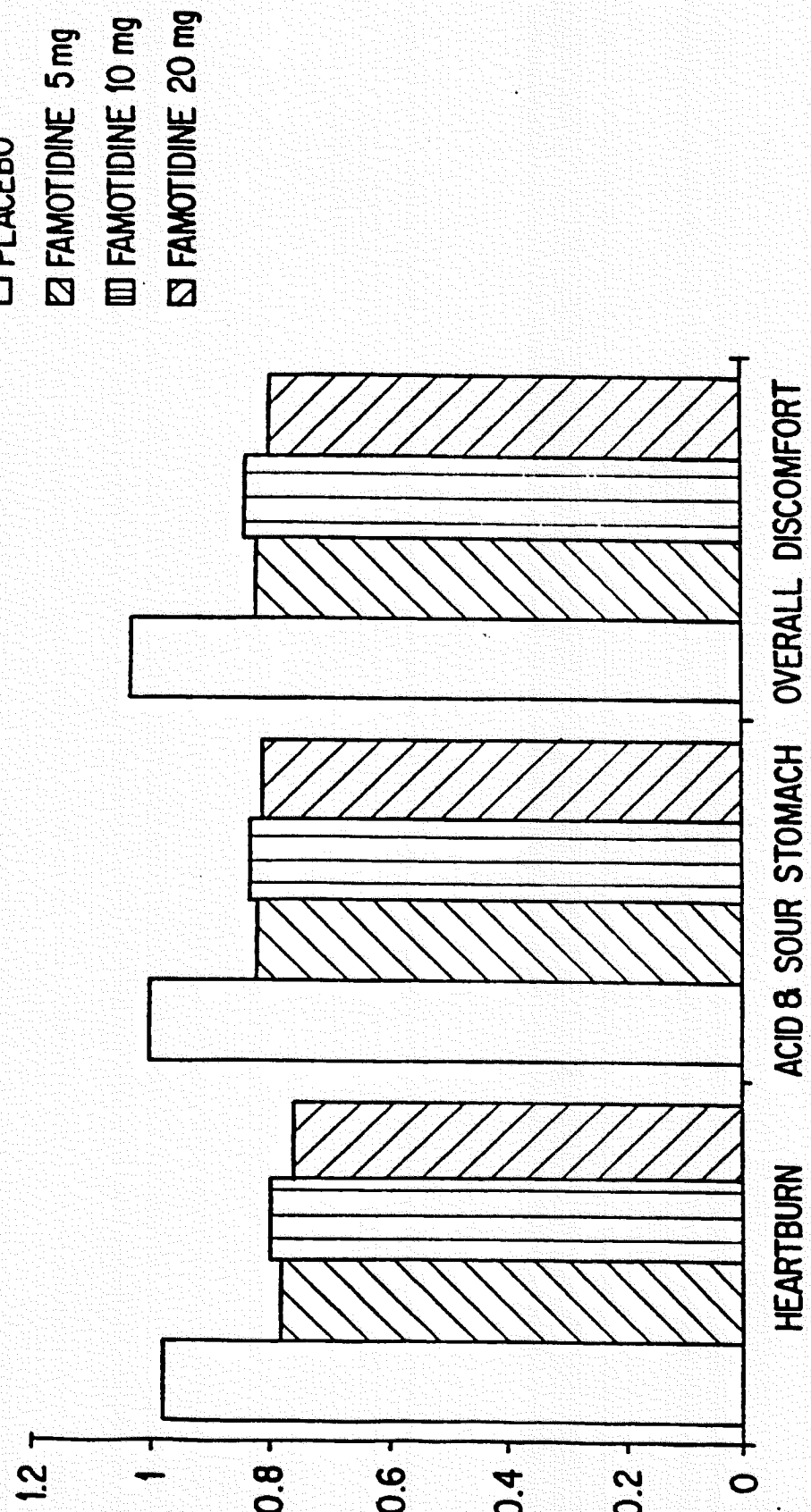
PLACEBO
FAMOTIDINE 5mg
FAMOTIDINE 10 mg
FAMOTIDINE 20 mg
1.2
1
0.8
0.6
0.4
0.2
0
HEARTBURN
ACID & SOUR STOMACH
OVERALL DISCOMFORT

FIG. 2