

III. The sponsor should consider the following labeling recommendations.

- A. Regarding the storage statement. The sponsor should consider adding a space before and after the "-" between the Centigrade and the Fahrenheit temperatures for consumer readability.
- B. Although the sponsor stated that the statement of identity on the principal display panel has been increased, we would prefer that it be in a size more related to the proprietary name.
- C. We recommend that, for consumer readability, that the point type size of the immediate bottle label be increased to at least a 6-point type.
- D. Regarding the package insert, for safety reasons, under the section "How to use PEPCID AC Gelcaps," the sponsor should include the age range, [REDACTED]

The Agency notes that if any additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

The comments and recommendations above may be conveyed to the sponsor.

[REDACTED] /SI
 7/22/99
 Gloria Chang, R.Ph.
 Interdisciplinary Scientist, HFD-560

[REDACTED] /SI
 7/22/99
 Helen Cothran, B.S.
 Team Leader, HFD-560

[REDACTED] /SI
 Date signed 7/23/99
 Linda M. Katz, M.D., M.P.H.
 Deputy Director, HFD-560

Attachments

**14 Pages Redacted
Draft Labeling**

Johnson & Johnson MERCK

July 16, 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)
Labeling

Dear Dr. Talarico:

Reference is made to the New Drug Application cited above, submitted on September 30, 1997, the approvable letter of June 21, 1999, and our submission of July 2, 1999, which provided a complete response to the approvable letter.

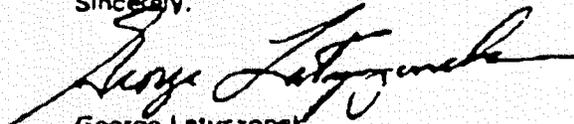
We also refer to a telephone conversation on July 15, 1999, between Michael Folkendt (FDA) and George Latyszczek (JJMCP) during which we were requested to provide the graphics specifications for the labeling included in our July 2, 1999 submission.

Attached are the specifications for each of the cartons included in our approvable letter response. The type size meets or exceeds the requirements set forth in the labeling final rule for over-the-counter human drugs.

We consider the filing of this New Drug Application to be a confidential matter, and request the Food and Drug Administration not make its contents, nor any future communications in regard to it, public without first obtaining the written permission of Merck & Co., Inc.

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

Sincerely,



George Latyszczek
Director Regulatory Affairs

:jxs
Attachment

cc: Charles Ganley, MD, HFD-560, Room S-205

MEMORANDUM

Folkendt

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

JUN 15 1999

DATE: June 16, 1999
FROM: Director,
Division of OTC Drug Products (HFD-560)

SUBJECT: Labeling Review
Pepcid AC Gelcaps (Gelatin Coated Tablets)
NDA 20-902

TO: Director,
Division of Gastrointestinal and Coagulation Drug Products
(HFD-180)

Attached is OTC's review of the draft labeling submitted by Merck Research Laboratories for the subject NDA.

/s/

Charles J. Ganley, M.D.

APPEARS THIS WAY ON ORIGINAL