(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /___/

If yes, explain: _____

_____

/S/ [redacted]
Regulatory Project Manager

8/5/99
Date

/S/ [redacted]
Division Director

8-5-99
Date

cc:
APPEARS THIS WAY ON ORIGINAL
Original NDA 20-902
HFD-180/Division File
HFD-180/PM/M.Folkendt
HFD-93/Mary Ann Holovac

Levine

NDA 20-902

JUL 12 1999

Merck Research Laboratories
Attention: George Latyszonek
Director, Regulatory Affairs
P.O. Box 4, BLA-20
West Point, PA 19486-0004

Dear Mr. Latyszonek:

We acknowledge receipt on July 2, 1999 of your July 2, 1999 resubmission to your new drug application (NDA) for nonprescription Pepcid AC® (famotidine) Coated (gelatin coated, capsule shaped) Tablets, 10 mg.

This resubmission contains revised draft labeling submitted in response to our June 21, 1999 action letter.

We consider this a complete class 1 response to our action letter. Therefore, the primary user fee goal date is September 2, 1999 and the secondary user fee goal date is November 2, 1999.

If you have any questions, contact me at (301) 443-8347.

Sincerely,

/S/ [redacted] 7/9/99

Paul E. Levine, Jr., R.Ph.
Regulatory Project Manager
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

MEMORANDUM OF TELEPHONE CONVERSATION

DATE: June 24, 1999
BETWEEN: Dr. Ed Hemwall
Ms. Peggy Beacham
Mr. George Latyszoneck
Johnson & Johnson Merck
610-397-2306

AND

Dr. Linda Katz
Mr. Albert Rothschild
FDA, DOTCDP

SUBJECT: 20-902 Pepcid Gelcaps. Question regarding approvable letter of June 21, 1999.

We called the sponsor in response to their request for a telecon to address some questions regarding our approvable letter of June 21, 1999.

1. Regarding our comments on the sample pouch, the sponsor explained that sample pouches are dispensed from a dispensit at pharmacies and physician's offices. The dispensit contains all required information in Drug Facts (DF) format. Further, each sample pouch has all the required information albeit not in DF format. The sponsor stated that there is no room on the label to accommodate all required information in the DF format and asked how to file for an exemption. The sponsor indicated that they do not want to hold up approval of the application while addressing the pouch labeling and, thus, would withdraw the sample pouch label from the application, at this time. They agreed to submit a letter to this effect.

   We suggested that the sponsor submit the request for exemption, as described in the regulations, in the form of a labeling supplement. If a different process is appropriate, we would let them know.