

2. Regarding our comments on the consumer insert, the sponsor indicated that the rule does not apply to inserts. As a result, the sponsor will make some requested changes, and make the more significant (costly) changes at a later time.

We explained that, while the rule is not applicable to the consumer insert, to reduce confusion for the consumer, information that is the same on the label and in the insert, should look alike, as much as possible. In the sponsor's response to us, the sponsor should state which changes in the insert are being made now and which changes will be made at a later date.

3. Regarding our comments under "Stop and ask a doctor if," the sponsor preferred to retain the phrase "at the maximum dose."

We explained that if the consumer needs to take the product for 14 days, irrespective of the dose, the consumer should contact a doctor. Therefore, "at the maximum dose" should be removed.

The sponsor stated that they intend send us a letter indicating that they will withdraw the sample labels from the NDA and not distribute the pouch samples. At a later date, they may submit a supplement for pouch sample labels. Also, the sponsor will make certain changes in the insert consistent with DF. However, those changes in the insert that require significant investment, will be made at a later time. The sponsor stated that they would remove the phrase "at the maximum dose" for the "Stop and ask a doctor if" warning. Finally, the sponsor asked if their response would need to be placed in the cue for review or if the response could be reviewed immediately. We responded that unfortunately, the response would need to be placed in the cue for review but that we would make every effort to expeditiously review their response. We recommended that they call Mr. Rothschild when the response is ready to be submitted so that we could be on the look out for it and schedule the review. The sponsor indicated that the changes requested in our letter are reasonable and will respond to the remaining issues soon.

CSO/Folkendt

NDA 20-902

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

JAN 13 1999

Dear Mr. Latyszonek:

We acknowledge receipt on December 22, 1998 of your December 18, 1998 resubmission to your new drug application (NDA) for Pepcid AC® Gelcap (famotidine) Coated Tablets.

This resubmission contains additional Chemistry, Manufacturing, and Controls (CMC) information and revised draft labeling submitted in response to our September 30, 1998 action letter.

We consider this a complete class 2 response to our action letter. Therefore, the user fee goal date is June 22, 1999.

If you have any questions, contact me at (301) 827-1602.

Sincerely,

ISI

1/13/99

Michael Folkendt
Project Manager
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:

Archival NDA 20-902
HFD-180/Div. Files
HFD-180/M.Folkendt
DISTRICT OFFICE

Drafted by: mmf/January 13, 1999
final: 1/13/99
filename: 20902-ACKRS-011399.DOC

ACKNOWLEDGEMENT (AC)

Folkendt

NDA 20-902

Merck Research Laboratories
Attention: George Latyszonek
P.O. Box 4, BL A-20
West Point, PA 19486-0004

OCT - 7 1997

Dear Mr. Latyszonek:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: PEPCID[®] AC Acid Controller Gelcap

Therapeutic Classification: Standard

Date of Application: September 30, 1997

Date of Receipt: September 30, 1997

Our Reference Number: 20-902

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on November 29, 1997 in accordance with 21 CFR 314.101(a).

If you have any questions, please contact me at (301) 443-0487.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

Sincerely yours,

/s/

10/7/97

Michael Folkendt
Project Manager
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research