cc: Original NDA 20-958
HFD-180/Div. File
HFD-180/P.Levine

Drafted: 2/2/00
Initialed by: K.Johnson 02/28/00
S.Doddapaneni 03/14/00
Final: 03/17/00
Filename: Pepcid 20958- Telecon020200.doc

TELECON

CSO/Folkendt

MEMORANDUM OF TELECON

DATE: December 4, 1998

APPLICATION NUMBER: NDA 20-958; famotidine/antacid combination chewable tablet

BETWEEN:

Name: George Latyszonek; Director, Regulatory Affairs
Phone: 215-233-7152
Representing: Johnson & Johnson • Merck

AND

Name: Michael Folkendt
Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECTS: Request for additional statistical information and analyses.

At the request of the statistical reviewer (see attached e-mail message), Dr. M. Rashid, and approval of the statistical team leader, Dr. A.J. Sankoh, I transmitted verbatim to Mr. Latyszonek the following request for additional statistical information and analyses:

1. The method used to determine the sample size in protocol 106;

2. Subgroup analyses (efficacy) tables by male, female, age >65, age <65, white, non-white for each primary endpoint for the three pivotal studies 106, 109 and 110.

In addition, at Dr. Sankoh's request, I reminded Mr. Latyszonek that the requested subgroup analyses are required components of an NDA.

After consulting the statistician, Mr. Latyszonek, in a subsequent phone conversation, stated that he expect to be able to submit the requested information by December 11, 1998.

In response to Mr. Latyszonek inquiry whether there were any statistical issues concerning the pivotal studies and whether or not an additional study may be need for this application, I stated that I am not able to comment the approvability of the application until all reviews are complete.

/S/ 12/4/98

Michael Folkendt
Regulatory Project Manager

CSO/Folkendt

MEMORANDUM OF TELECON

DATE: October 22, 1998

APPLICATION NUMBER: NDA 20-958; famotidine/antacid combination chewable tablet

BETWEEN:

Name: George Latyszonek; Director, Regulatory Affairs
Phone: 215-233-7152
Representing: Johnson & Johnson • Merck

AND

Name: Michael Folkendt
Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECTS: 1) Proposed trade name "Pepcid —— ' is unacceptable.
2) NDA is not planned to be discussed at an advisory committee meeting.
3) Request for additional desk copies.

BACKGROUND:

NDA 20-958, submitted on February 20, 1998, provides for a famotidine/antacid combination chewable tablet with a proposed trade name "Pepcid —— ' for the treatment of heartburn. On October 21, 1998, a team meeting was held to discuss this application and the progress of the reviews.

Concerning the proposed trade name "Pepcid —— ' on September 3, 1998, the CDER Labeling and Nomenclature Committee found the proposed trade name unacceptable for the following reasons: (1) there is a high potential for look-alike/sound-alike confusion between the proposed trade name and Pepcid . — (2) "CFR 210.6(b) states that the labeling may be considered misleading if the designation of such drug includes or suggests one or more, but not all ingredients. In this case, Pepcid — certainly identifies the famotidine component, but not the antacid component." And (3) — as an adjective is overly promotional in that it suggests first in rank, leading, or chief. In the 10/21/98 team meeting, the team rejected reason (1) above because the proposed drug product will be marketed as an OTC tablet while Pepcid Premixed Injection is a 50 mL plastic bag used primarily in hospitals. However the team unanimously agreed with the CDER Labeling and Nomenclature Committee that the proposed trade name is unacceptable because of reasons (2) and (3) above.

Concerning whether or not this application will be scheduled to be discussed at an advisory committee meeting, the team agreed that, at this time, there does not appear a need to take this application to the advisory committee.

THE CALL:

I called Mr. Latyszonek to inform him that the proposed trade name was found unacceptable for the two reasons stated above and that there are no plans, at this time, for this NDA to be discuss at an advisory committee meeting. I also requested, at Dr. Katz's request, a desk copy of the summary volume for the NDA and of the color mock-up labeling, including the diskettes of the PDF file, for the drug product.

Mr. Latyszonek acknowledged that there is currently no advisory committee meeting planned for this application. He also stated that the requested desk copies should arrive in the Division by the middle of next week. Concerning the proposed trade name, although he expressed disagreement with the stated reasons for finding the proposed trade name unacceptable, he stated they would propose a new trade name shortly.

In addition to the above topics, Mr. Latyszonek inquired whether they could submit the updated stability data now. He said that they were told in the pre-NDA meeting that they could not if it were submitted after the first four months after the NDA was submitted. I told him that he could send in the updated stability data now. However, depending upon where in the review cycle the Chemistry review is, it may not be reviewed in this review cycle.

He also inquired on the status of the reply to their chemistry questions submitted on 6/30/98 to their IND for OTC Pepcid. I told him I will have to check on its status and I will get back to him.

Finally, Mr. Latyszonek inquired about a recent request received from the Division of OTC Drug Products concerning another application where they were asked to change the storage statement from "Store up to 30° C (86° F)" to "Store between 20° C-25° C (68° F-78° F)" despite the fact that they have stability data at 30° C and the fact that it was not a condition in the approvable letter (i.e., producing new labeling requirements as a condition of approval for the efficacy supplemental). I stated that I did not know anything about the above request. I stated that I'm no longer the project manager of supplemental applications for approved OTC drug products and that he should discuss this matter with the Division of OTC Drug Products. I also reminded him that if the matter could not be resolved at the Division level, that he should follow the dispute resolution process.

He thanked me and the call was then concluded. /S/ 12/4/98

Michael Folkendt
Regulatory Project Manager

cc:
Archival NDA 20-958
HFD-180/Div. File
HFD-180/Michael Folkendt
HFD-180/E.Duffy
HFD-180/W.M.Adams
HFD-180/H.Gallo-Torres
HFD-180/L.Talaraico
HFD-560/A.Rothschild
HFD-560/L.Katz

Drafted: MF/October 23,1998
Finaled: 12/4/98
filename: 20958-102298-telecon.doc

TELECON

Folkendt

MEMORANDUM OF TELECON

DATE: June 22, 1998

APPLICATION NUMBER: NDA 20-958; Pepcid —— (famotidine/antacid combination) Chewable Tablets

BETWEEN:

Name: George Latyszonek; Director, Regulatory Affairs
Phone: 215-233-7152
Representing: Johnson & Johnson Merck Consumer Pharmaceuticals Co.

AND

Name: Michael Folkendt
Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: Information requested by DSI

The attached "BIMO REVIEW COPY", listing information an applicant should sent (in duplicate) directly to the Division of Scientific Investigation (DSI) either prior to or at the time of submission of an NDA or an efficacy supplement, was recently distributed to the Project Management staff. None of this information has, as yet, been sent to DSI by the firm.

I call Mr. Latyszonek and requested that he send directly to DSI, as soon as possible, two copies of the "BIMO Review Copy" as described in the attachment and a copy of the cover letter for this "BIMO Review Copy" to this Division. Because of the number of items on the list, it was agreed that I sent the attachment to Mr. Latyszonek via fax.

/S/ - 6/22/98

Michael Folkendt
Regulatory Project Manager

cc:
Archival NDA 20-958
HFD-180/Div. File
HFD-180/Michael Folkendt
HFD-180/J.Senior

TELECON

2 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

CSO Folkendt

MEMORANDUM OF TELECON

DATE: May 8, 1998

APPLICATION NUMBER: 20-958; Non-prescription Pepcid® — [famotidine, 10 mg/antacid (calcium carbonate, 800 mg; magnesium hydroxide, 165 mg) combination] Chewable Tablets

BETWEEN:

Name: George Latyszonek; Director, Regulatory Affairs
Phone: 215-233-7152
Representing: Johnson & Johnson•Merck

AND

Name: Michael Folkendt
Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: Request for additional Information

BACKGROUND: On March 31, 1998, a 45-day filing meeting was held concerning this application. In that meeting, it was decided that the application would be filed on April 21, 1998. However, there were numerous request of the firm for additional information (see 45-day filing meeting minutes and Memoranda dated April 7 and 16, 1998).

This telephone conversation is a follow up to a April 1, 1998 telephone conversation where Mr. Latyszonek was informed that the application will be filed on April 21, 1998 but there will be numerous requests.

THE CALL: After consolidating and finalizing all the requests (see attachment) and at the request of the reviewers, I called Mr. Latyszonek to discuss the requests. It was agreed in that telephone conversation that, because the list is lengthy and time was short, the attached list of requests would be faxed to him.

/S/ 1/29/99

Michael Folkendt
Regulatory Project Manager

cc: Original 20-958
HFD-180/Div. File
HFD-180/Michael Folkendt

drafted: mf/May 8, 1998
finaled: 1/29/99

TELECON

Labeling Review

NDA 20-958

Drug Product:	Pepcid Complete Chewable tablets
Active Ingredients:	Famotidine 10 mg, Calcium hydroxide 800mg, Magnesium hydroxide 165 mg
Indications:	relieves heartburn associated with acid indigestion and sour stomach
Sponsor:	Merck Research Laboratories
Date of Submission:	December 17, 1999
Amendment:	May 25, 2000
Type of Submission:	Original NDA
Reviewer:	Linda M. Katz, M.D., M.P.H.
Date of Review:	June 16, 2000

Background:

This review evaluates the proposed mock-up labeling for the package insert, 6-count carton label, 30-count bottle label, dispensit carton label, sample and trade pouch label (Attachment 1) provided in the December 17, 1999. The comments provided in this review also reflect discussion from the labeling day on May 31, 2000. On May 25, 2000, the sponsor submitted additional labeling: package insert text, immediate 50-count bottle with fold-out labeling, dispensit carton label, consumer sample pouch, 15-count carton label, and trade pouch label, as well as new graphic design elements (Attachment 2).

The review consists of specific reviewer's comments, see below, which reflect the discussion from the labeling day, as well as prototype Principal Display Panel (PDP) (Attachment 3), Drug Facts labeling (Attachment 4) and package insert (Attachment 5), which contain modifications in the text.

I. Reviewer's General Labeling Comments: Applicable to all labeling

A. The sponsor should be reminded that all labeling from both submissions need to be in compliance with the OTC labeling format requirements in 21 CFR 201.66. The sponsor did not submit the format specifications (i.e., font, type size, etc) for the labeling submitted on 5/25/00.

B. The PDP for all of the packages should be modified to include the active ingredients under the Statement of Identify (SOI) to avoid any consumer confusion that may be incurred as a result of the chosen tradename. In addition, the SOI should be increased such that it is prominently displayed. The statement " ——— should be changed to read: "Contains Calcium." The statement " ——— should replace "dual action" as a more consumer friendly statement.

C. The sponsor is reminded that use of "NEW" on the PDP must be removed after 6 months of marketing.

D. The sponsor needs to revise the following statements which are above the Drug Facts labels in the May 25, 2000 submission:
   (1) Under the antacid roll illustration, revise to read "The neutralizing benefits of antacids"
   (2) Under the Pepcid AC illustration, revise to read "The acid reducing benefits of Pepcid AC"
   (3) Under the Pepcid Complete illustration, revise to read "Combined in a single chewable tablet"

II. **30-count and 50-count tablet bottle label (immediate container) with the attached fold-out labeling**

A. **Drug Facts label** - Under the "Other information" section, the bulleted statements need to be aligned in accordance with 21 CFR 201.66(d)(4).
B. **Package Insert** - The sponsor needs to revise the package insert section as follows:
   (1) The section with the heading "How to use PEPCID COMPLETE" needs to be added.
   (2) The order of the sections in the 50-count package insert is not consistent with the other inserts provided for review for other package sizes in these submissions.
   (3) The section under the heading "PROVEN EFFECTIVE IN CLINICAL STUDIES" will need to be modified pending Agency's validation of statistical methods. (See Attachment 5.)
   (4) The consumer questionnaire survey form and coupon offers may be attached to the package insert, but the act of removing the coupons, etc., should not remove information from the approved package insert labeling. The sponsor should be reminded that the consumer questionnaire survey form, the "Free Pepcid Complete Offer" section, and/or coupons offers are not considered part of the labeling.

III. **6-count and 15-count tablet carton and pouch label**

Principal Display Panel (PDP) for Carton and Pouches -

(1) For clarity, sponsor should revise [redacted] on 15-count carton label to read "Individually wrapped pouches." For consistency, the sponsor should consider adding "Individually wrapped pouches" to the 6-count tablet PDP.

IV. **Sample pouches**

(1) The Drug Facts label is in the modified labeling format and needs to be in accordance with the formatting requirements in 21 CFR 201.66 (d)(10).
(2) Under the top "***Drug Facts*** (continued)" label section, the sponsor needs to add a right justified arrow pointing down to the next labeling box after the "Keep out of reach of children" section of label.

(3) Under heading "***Drug Facts*** (continued)", delete the phrase "Warnings (continued)"
(4) The sponsor needs to add the heading " ***Drug Facts*** (continued)" right before the ***Directions*** section, separating the headings with a hairline.
(5) Under the ***Other information*** heading, the sponsor needs to add as the first bulleted statement: ▪ **each tablet contains:** calcium xx mg, magnesium xx mg.
(6) The statement "Not for Retail Sale" needs to be added to the consumer sample pouches.

3. **Package Insert**: Revise the package insert statement on the side panels of the dispensit carton that reads: [redacted] to read "What Consumers Should Know About:." The sponsor should be reminded that the section that reads "Proven effective in clinical studies" should be modified pending the Agency's validation of the statistical methods.

Reviewer's Recommendations. The above comments can be conveyed to the sponsor. The sponsor should also be reminded that format for all labeling including the 5/25/00 submitted labeling must be in accordance with 21 CFR 201.66 (d).

/S/ date 6/19/00
Linda M. Katz, M.D., M.P.H.
Deputy Director, HFD-560

Attachments

6/20/00
/S/

NDA 20-958
HFD560 Division File
HFD-560/ Keravich/Ganley/Cothran/ChangG/Katz / Segal
HFD180/Kacuba

4 page(s) of revised draft labeling has been redacted from this portion of the review.

CSO/Folder

Division of Over-the-Counter Drug Products

Labeling Review

FEB - 8 1999

NDA#: 20-958
TYPE OF SUBMISSION: Original New Drug Application
SPONSOR: Merck Research Laboratories
DRUG PRODUCT: Pepcid —— (Chewable Tablet)
INDICATION: For relief of heartburn, acid indigestion, and sour stomach
ACTIVE INGREDIENTS: Famotidine 10 mg, calcium carbonate 800 mg, and magnesium hydroxide 165 mg per tablet
SUBMISSION DATE: February 20, 1998
REVIEWER: Melvin Lessing
REVIEW DATE: January 22, 1999
Project Manager: Al Rothschild

Background:
This original NDA was filed to obtain approval for a new OTC product that is a combination of an acid reducer (H2 blocker) with two antacid ingredients. This review is of black and white copies of the 30-tablet cartons for blisters and pouches, the 30-tablet dispenser, the package inserts for blisters and pouches, the bottle overwrap, the 5-panel bottle label, the child resistant sample pouch, the non-child resistant sample pouch, the single dose foil pouch and the blister matte. The sponsor's proposed labeling is Attachment 1.

Reviewer's Comments and Recommendations on the Pepcid —— NDA Labeling

The following recommendations should be conveyed to the sponsor before this application can be approved:

A. CARTONS, DISPENSER, BOTTLE OVERWRAP, 5 PANEL BOTTLE LABEL, PACKAGE INSERTS, BLISTER MATTES, SAMPLE POUCHES, AND SINGLE DOSE FOIL POUCH

1. The sponsor is using the product name "Pepcid —— " which CDER's Nomenclature Committee and this Division consider to be unacceptable. The name is misleading because it identifies the acid reducer component, but does not identify the antacid component. Further, the name ——— " implies "first in rank, leading, or chief" and, thus, is promotional. Therefore, the sponsor is advised to submit a new name to the Agency.

2. We recommend that the statement of identity be revised. Because there is no established name for this combination of ingredients, we suggest the following:

Acid Reducer and Antacid

3. On the front panel of the carton for the pouches and blisters, front panel of sample pouches, front panel of dispenser, and panel 1 of the 5 panel bottle, to be consistent with the use of this product, the phrase

B. CARTONS, DISPENSER, BOTTLE OVERWRAP, 5 PANEL BOTTLE LABEL, PACKAGE INSERTS, AND SAMPLE POUCHES

1. We suggest that the sponsor consider the label heading and subheadings and use of upper and lower case letters as proposed in the February 27, 1997 Proposed Labeling Requirements for OTC Drug Products (62 FR 9024). Note that in the proposal, the heading "**Warnings**" precedes the "**Directions.**" We also suggest that the sponsor consider revising the text and format of the labeling to reflect the proposed draft prototype label (Attachment 2). 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 proposed rule.

2. The **Active ingredient** section of the cartons, dispenser, bottle overwrap, sample pouches, and panel 2 of the 5 panel bottle label needs to state the purpose of each of the three ingredients. To conform with the February 27, 1997 Proposed Labeling Requirements for OTC Drugs (62 FR 9024) and with the draft prototype label (Attachment 2), this section should be revised as follows:

Active ingredients (in each tablet)	**Purpose**
Famotidine 10 mg	Acid reducer
Calcium carbonate 800 mg	Antacid
Magnesium hydroxide 165 mg	Antacid

3. Revise the heading "**Uses**" to "**Use.**" To be consistent with other acid reducer drug products and to conform with the February 27, 1997 Proposed Labeling Requirements for OTC Drugs (62 FR

9024), revise the "**Use**" section in all labeling to denote heartburn as the primary symptom, with other symptoms as secondary symptoms, to read: "for relief of heartburn associated with acid indigestion and sour stomach."

4. The "**Directions**" section on all labeling, including the "How to use Pepcid ——— section of the package insert, dispenser, and panel 2 of the 5 panel bottle label, must be revised to ——— Also, for consistency in labeling, the heading "How to use Pepcid ——— should be changed to "Directions.

5. To be consistent with labeling for other acid reducer products, the "**Directions**" section on all labeling, including the "How to Use Pepcid ——— section of the package insert, dispenser, and panel 2 of the 5 panel bottle label, should be revised to read: "to **relieve** symptoms, chew 1 tablet ———

6. Revise the sentence ——— in the "**Directions**" section on all labeling, including the "How to Use Pepcid ——— section of the package insert, dispenser, and panel 2 of the 5 panel bottle label, revised to read: "Do not — more than 2 tablets in 24 hours." (See Attachment 2-prototype label.)

7. In the "**Warnings**" section on all labeling, including the ——— section of the package insert and the dispenser, add the following as the first warning statement: "**Allergy** ——— : Do not use if you are allergic to famotidine or other acid reducers."

8. We also recommend that the heading "**Warnings**" be used to designate the warning information on the package insert and on the right front panel of the dispenser.

9. Consumers should be warned not to use this Pepcid product with other Pepcid products in order to avoid potential overdosing. Therefore, the sponsor needs to add the warning "**Do not use** with other famotidine products or acid reducers" in the "**Warnings**" section on all labeling, including the ——— section of the package insert and the dispenser.

10. The label needs to include additional warnings. A warning referring individuals with peptic ulcer disease or other serious gastrointestinal conditions to consult their physicians before

taking OTC heartburn medication would be medically sound to keep these patients under the active care of their physicians. Also,

12. In the "**Warnings**" section on all labeling, including the "Know when to see your doctor" section of the package inserts and the dispenser, the "**pregnancy-nursing warning**" must be placed right before the "**Keep out of reach...**" warning statement.

14. Because it is referred to as the "package insert" in the "Read the Label" section on the carton and dispenser, include the title "Package Insert" on the front panel of the package insert to make it easier for the consumer to identify the package insert.

1 page(s) of revised draft labeling has been redacted from this portion of the review.

/S/

Melvin Lessing, P.D., M.S.
Interdisciplinary Scientist (HFD-560)

/S/

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

/S/

Andrea Leonard-Segal, M.D.,
Medical Officer (HFD-560)

/S/

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

2/8/99

Attachments

cc:
NDA 20-958
HFD-180: Folkendt
HFD-105: Bowen
HFD-560: Katz/Cothran/Segal/Chang/Robinson/Rothschild/T4Binder
/Lessing
HFD-560: Division File
Doc. ID: 20-958.wpd

n:\team4\labeling\20.958

CONSULTATION RESPONSE
Office of Post-Marketing Drug Risk Assessment
(OPDRA; HFD-400)

DATE RECEIVED: 2/25/2000	DUE DATE: 4/28/2000	OPDRA CONSULT #: 00-0075

TO:

Lilia Talarico, M.D.
Director, Division of Gastro-Intestinal and Coagulation Drug Products
(HFD-180)

THROUGH:

Paul Levine
Project Manager
(HFD-180)

PRODUCT NAME:	MANUFACTURER:
Pepcid Complete (famotidine, calcium carbonate, and magnesium hydroxide chewable tablets) NDA #: 20-958	Merck Research Laboratories

SAFETY EVALUATOR: Lauren Lee, Pharm.D.

OPDRA RECOMMENDATION:

OPDRA does not object to the use of the proprietary name, Pepcid Complete. See the checked box below.

☐ FOR NDA/ANDA WITH ACTION DATE BEYOND 90 DAYS OF THIS REVIEW
This name must be re-evaluated approximately 90 days prior to the expected approval of the NDA. A re-review of the name prior to NDA approval will rule out any objections based upon approvals of other proprietary names/NDA's from the signature date of this document. A re-review request of the name should be submitted via e-mail to "OPDRAREQUEST" with the NDA number, the proprietary name, and the goal date. OPDRA will respond back via e-mail with the final recommendation.

☑ FOR NDA/ANDA WITH ACTION DATE WITHIN 90 DAYS OF THIS REVIEW
OPDRA considers this a final review. However, if the approval of the NDA is delayed beyond 90 days from the date of this review, the name must be re-evaluated. A re-review of the name prior to NDA approval will rule out any objections based upon approvals of other proprietary names/NDA's from this date forward.

☐ FOR PRIORITY 6 MONTH REVIEWS
OPDRA will monitor this name until approximately 30 days before the approval of the NDA. The reviewing division need not submit a second consult for name review. OPDRA will notify the reviewing division of any changes in our recommendation of the name based upon the approvals of other proprietary names/NDA's from this date forward.

/S/ 5/1/2000 /S/ 5/1/00

Jerry Phillips, R.Ph.
Associate Director for Medication Error Prevention
Office of Post-Marketing Drug Risk Assessment
Phone: (301) 827-3242
Fax: (301) 480-8173

Peter Honig, MD
Director
Office of Post-Marketing Drug Risk Assessment
Center for Drug Evaluation and Research
Food and Drug Administration

Office of Post-Marketing Drug Risk Assessment
HFD-400; Rm. 15B-03
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE RECEIVED: February 25, 2000

NDA#: 20-958

NAME OF DRUG: Pepcid Complete (famotidine, calcium carbonate, and magnesium hydroxide chewable tablets)

NDA HOLDER: Merck Research Laboratories

*****NOTE: This review contains proprietary and confidential information that should not be released to the public.*****

I. INTRODUCTION:

This OPDRA consult is in response to a February 25, 2000 request by the Division Gastro-Intestinal and Coagulation Drug Products, to review the proposed proprietary drug name, Pepcid Complete, regarding potential name confusion with other proprietary/generic drug names. Container label and container labeling were not submitted for review of possible interventions in minimizing medication errors.

The proposed name, Pepcid ——, was first reviewed by the Labeling and Nomenclature Committee (LNC) on September 3, 1998 and was found to be unacceptable due to the potential for confusion with Pepcid —— the lack of representation of the antacid component in the name, and the promotional/fanciful aspect of the name.

In a letter dated January 18, 1999, the sponsor submitted a new proposed proprietary name, Pepcid Complete.

PRODUCT INFORMATION

Pepcid Complete comprises of famotidine (10 mg) and antacid [calcium carbonate (800 mg) and magnesium hydroxide (165 mg)] in a chewable tablet formulation. *Famotidine is a competitive inhibitor of histamine H_2–receptors and inhibits gastric secretion.* Pepcid Complete is indicated for the treatment of heartburn associated with acid ingestion and sour stomach. Pepcid Complete is proposed for over-the-counter (OTC) use. Pepcid is the proprietary name for the famotidine family of prescription drug products (20 mg, 40 mg) which includes tablets, oral suspension, orally disintegrating tablets, injection, and premixed injection dosage forms. Pepcid AC is the proprietary name for the non-prescription famotidine family of products which currently include tablets and chewable tablets. There is no approved drug product containing famotidine/antacid combination in a single tablet.

II. RISK ASSESSMENT

A. EXPERT PANEL DISCUSSION

[The expert panel consists of members of OPDRA's medication error Safety Evaluator Staff and a representative from the Division of Drug Marketing, Advertising and Communications (DDMAC)].

Product Name	Generic name; strength	Usual Dose
Pepcid AC Acid Controller (otc)	Famotidine tablets (10 mg); chewable tablets (10 mg); gelcaps (10 mg)	**Oral:** Duodenal ulcer: Acute therapy: 40 mg/day at bedtime. 20 mg twice/day is also effective.
Pepcid (Rx)	Famotidine tablets (20 mg & 40 mg); powder for oral suspension (40 mg per 5 mL when reconstituted); injection (10 mg per mL); injection, premixed (20 mg per 50 mL in 0.9% NaCl)	Maintenance therapy: 20 mg once a day at bedtime. Benign gastric ulcer: Acute therapy: 40 mg orally once a day at bedtime. Pathological hypersecretory conditions: Individualize dosage. The adult starting dose is 20 mg every 6 hours; some patients may require a higher starting dose. GERD: 20 mg twice daily for up to 6 weeks. For esophagitis including erosions and ulcerations and accompanying symptoms due to GERD, 20 or 40 mg twice daily for up to 12 weeks. Heartburn, acid indigestion and sour stomach (otc only): Relief: 10 mg (1 tablet) with water. Prevention: 10 mg 1 hour before eating a meal that is expected to cause symptoms. Can be used up to twice daily (up to 2 tablets in 24 hrs). **Parenteral:** In some hospitalized patients with pathological hypersecretory conditions or intractable ulcers, or in patients unable to take oral medication, give famotidine IV 20 mg every 12 hours. Doses and regimen for GERD are not established.
Pepcid RPD (Rx)	Famotidine tablets, orally disintegrating (20 mg & 40 mg)	

*LA = Look-alike
*SA = Sound-alike

1. According to the expert panel, the proposed proprietary name, Pepcid Complete, does not adequately represent the inclusion of the antacid component in the name, and therefore, is objectionable. The panel also objected to a previously submitted name, ——— due to similar reasons.

2. According to DDMAC, the name would be very confusing to consumers because the word, "complete" implies a broader indication than the product's actual indication.

B. SAFETY EVALUATOR RISK ASSESSMENT

Both the Division and the expert panel make references to our previous review of the proprietary name, ——— Both ——— and Pepcid Complete are combination products that contain H_2-receptor inhibitors and antacids. In the case with ——— there were safety concerns because the ——— component was not included in the name, and serious interactions could occur when ——— is taken in combination with certain other drugs. However, from a safety perspective, the proposed name, Pepcid Complete, does not pose a similar concern. Furthermore, since the term "complete" has been used in other product names, there is insufficient evidence at this time to render the proposed name, Pepcid Complete, objectionable.

IV. RECOMMENDATIONS:

OPDRA does not object to the use of the proprietary name, Pepcid Complete.

OPDRA would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications,

please contact Lauren Lee, Pharm.D. at 301-827-3243.

/S/

Lauren Lee, Pharm.D.
Safety Evaluator
Office of Post-Marketing Drug Risk Assessment

Concur:

/S/ 5/1/2000

Jerry Phillips, RPh
Associate Director for Medication Error Prevention
Office of Post-Marketing Drug Risk Assessment

CC:

NDA: 21-958
Office Files
HFD-180; DivFiles; Paul Levine, Project Manager
HFD-180; Lilia Talarico, M.D., Division Director
HFD-042, Patricia Staub, Regulatory Review Officer, DDMAC (Electronic Only)
HFD-440; Ann Corken, Safety Evaluator, DDRE II, OPDRA
HFD-400; Jerry Phillips, Associate Director, OPDRA
HFD-400; Peter Honig, Director, OPDRA (Electronic Only)
HFD-002; Mac Lumpkin, Deputy Center Director for Review Management
(Electronic Only)

CSO | Folkendt

REQUEST FOR TRADEMARK REVIEW

To: Labeling and Nomenclature Committee
Attention: Dan Boring, Chair (HFD-530), 9201 Corporate Blvd, Room N461

From: Division of Gastrointestinal and Coagulation Drug Products		**HFD-180**
Attention:	Michael Folkendt Regulatory Project Manager	**Phone:** (301) 827-1602
Date: February 23, 1999		
Subject: Request for Assessment of a Trademark for a Proposed New Drug Product		
Proposed Trademark: Pepcid ———		**NDA 20-958**

Established name, including dosage form: Non-prescription famotidine (10 mg)/antacid [calcium carbonate (800 mg) & magnesium hydroxide (165 mg)] combination chewable tablet.

Other trademarks by the same firm for companion products:
"Pepcid" is the proprietary name for the Rx famotidine family of drug products (20 mg, 40 mg) which include Tablets, Oral Suspension, Orally Disintegrating Tablets, Injection, and Injection Premixed dosage forms. "Pepcid AC" is the proprietary name for the non-prescription famotidine family of products which currently include Tablets and chewable tablets. There is no approved drug product containing famotidine/antacid combination in a single tablet.

Indications for Use (may be a summary if proposed statement is lengthy):
Marketed OTC for the treatment of heartburn associated with acid indigestion and sour stomach.

Initial Comments from the submitter (concerns, observations, etc.):
This proposed proprietary name was first reviewed by the Labeling and Nomenclature Committee (LNC) on 9/3/98 and was found unacceptable (see attached LNC recommendation) based on the following three reasons:

1. There is a high potential for confusion with Pepcid Premixed.
2. May be considered misbranded under 21 CFR 201.6(b) because the name suggests one or more, but not all ingredients (i.e., in this case suggests famotidine but not the antacid component).
3. The adjective ——— in the proprietary name is overly promotional [see 21 CFR 201.10(c)(3)].

The review team (including representatives from OTC) rejected reason 1 because Pepcid Premixed is an injection product in a large (50 mL) bag which is only available in a hospital while the proposed drug product is intended for the OTC market place. Therefore, the potential for confusion was expected to be extremely slight.
Reasons 2 & 3 were therefore communicated with the firm. **The firm has now responded with a rebuttal (see attached letter) and requests that the proposed proprietary name be reconsidered.**

Note: Meetings of the Committee are scheduled for the 4th Tuesday of the month. Please submit this form at least one week ahead of the meeting. Responses will be as timely as possible.

cc: Archival NDA 20-958; HFD-180/division file; HFD-180 M.Folkendt; HFD-560/A.Rothschild

Application: NDA 20958/000
Stamp: ~~20-FEB-1998~~
Regulatory Due: 20-JUN-2000
Applicant: MERCK RES
BLA-30
WEST POINT, PA 19486
Priority: 4S
Org Code: 180

Action Goal:
District Goal: 21-OCT-1998
Brand Name: PEPCID COMPLETE ANTACID /FAMOTIDINE/165
Estab. Name:
Generic Name: ANTACID/FAMOTIDINE

Dosage Form: (TABLET)
Strength: 10MG FAMOTIDINE

Application Comment: THIS NDA PROVIDES FOR A COMBINATION TABLET CONTAINING FAMOTIDINE (10 MG AND AN ANTACID (800 MG CALCIUM CARBONATE & 165 MG MAGNESIUM HYDROXIDE) FOR OTC USE FOR THE TREATMENT OF HEARTBURN. (on 17-JUL-1998 by M. FOLKENDT (HFD-103) 301-827-3959)

FDA Contacts:

P. LEVINE JR	(HFD-180)	301-827-7310 ,	Project Manager
W. ADAMS	(HFD-180)	301-827-7310 ,	Review Chemist
L. ZHOU	(HFD-150)	301-594-5765 ,	Team Leader

Overall Recommendation: ACCEPTABLE on 26-AUG-1998 by J. D AMBROGIO (HFD-324) 301-827-0062
ACCEPTABLE on 16-JUN-2000 by S. FERGUSON (HFD-324) 301-827-0062

Establishment:

DMF No:
Responsibilities:
Profile:
Estab. Comment:

AADA:
R
OAI Status: NONE
(on 15-FEB-2000 by W. ADAMS (HFD-180) 301-827-7310)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	17-JUL-1998				FOLKENDTM
OC RECOMMENDATION	17-JUL-1998			ACCEPTABLE BASED ON PROFILE	FERGUSONS

Establishment: 2529821
JOHNSON AND JOHNSON MERCK CONSUMER PHARMACEUTICA
1838 COLONIAL VILLAGE LANE
LANCASTER, PA 17601

DMF No:
Responsibilities:

AADA:

Profile:
OAI Status: NONE

Estab. Comment: DRUG PRODUCT MANUFACTURE, RELEASE TESTING AND STABILITY TESTING (on 15-FEB-2000 by W. ADAMS (HFD-180) 301-827-7310)
THE FDA PROJECT MANAGER IS M. FOULKENDT, (301) 443-0487. PROFILE CLASS SHOULD BE UPDATED DURING EI: COVER QUALITY RELEASE SYSTEM.

DUE DATE IS 9/10/98.

PLEASE COMPLETE A MEMO OF CONCUR/NONCONCUR AT THE CLOSE OF THE EI AND FORWARD TO THE PRE-APPROVAL OFFICE AND COMPLIANCE BRANCH. (on 24-JUL-1998 by MKING)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	17-JUL-1998				FOLKENDTM

SUBMITTED TO DO	17-JUL-1998 10D			FERGUSONS
ASSIGNED INSPECTION	24-JUL-1998 PS			MKING
INSPECTION PERFORMED	25-AUG-1998	19-AUG-1998		DPAGANO

FDA-483 OBSERVATIONS DID NOT WARRANT A WITHHOLD RECOMMENDATION. THREE OUT OF THE FOUR 483'S ISSUED WERE CORRECTED TO THE INVESTIGATOR'S SATISFACTION PRIOR TO CLOSE OF THE INSPECTION.

DO RECOMMENDATION	25-AUG-1998	ACCEPTABLE INSPECTION	DPAGANO

FDA-483 ISSUED DID NOT WARRANT A WITHHOLD RECOMMENDATION. THREE OUT OF THE FOUR OBSERVATIONS CITED WERE CORRECTED PRIOR TO THE CLOSE OF THE INSPECTION.

OC RECOMMENDATION	26-AUG-1998	ACCEPTABLE DISTRICT RECOMMENDATION	DAMBROGIOJ
SUBMITTED TO OC	15-FEB-2000		ADAMSM
OC RECOMMENDATION	15-FEB-2000	ACCEPTABLE BASED ON FILE REVIEW BASED ON PROFILE	DAMBROGIOJ

Establishment:

DMF No: ADA:
Responsibilities:

Profile: OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	17-FEB-2000				ADAMSM
OC RECOMMENDATION	17-FEB-2000			ACCEPTABLE BASED ON PROFILE	FERGUSONS

Establishment:

DMF No: AADA:
Responsibilities:

Profile: OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	17-JUL-1998				FOLKENDTM
SUBMITTED TO DO	17-JUL-1998	10D			FERGUSONS
DO RECOMMENDATION	21-JUL-1998			ACCEPTABLE BASED ON FILE REVIEW	JMARTIN1
OC RECOMMENDATION	22-JUL-1998			ACCEPTABLE	DAMBROGIOJ

		DISTRICT RECOMMENDATION	
SUBMITTED TO OC	15-FEB-2000		ADAMSM
OC RECOMMENDATION	15-FEB-2000	ACCEPTABLE	DAMBROGIOJ
		BASED ON FILE REVIEW	
		BASED ON PROFILE	

Establishment: [redacted]

DMF No: AADA:
Responsibilities: [redacted]
Profile: OAI Status: NONE
Estab. Comment: PLEASE COMPLETE PAGE TWO OF THIS ASSIGNMENT AND FORWARD TO THE PRE-APPROVAL OFFICE ALONG WITH A COPY TO COMPLIANCE BRANCH AT THE COMPLETION OF THE INSPECTION. (on 25-FEB-2000 by D. PAGANO (HFR-CE100) 215-597-4390)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	17-FEB-2000				ADAMSM
SUBMITTED TO DO	17-FEB-2000	GMP			FERGUSONS
ASSIGNED INSPECTION	25-FEB-2000	PS			DPAGANO
INSPECTION SCHEDULED	10-MAR-2000		09-MAR-2000		DPAGANO
INSPECTION PERFORMED	10-MAR-2000		09-MAR-2000		DPAGANO
DO RECOMMENDATION	10-MAR-2000			ACCEPTABLE INSPECTION	DPAGANO
AN FDA-483 WAS ISSUED HOWEVER THE PROFILE CLASS CTL IS NOT AFFECTED. THE INSPECTION TEAM CONSISTED OF DEBRA BENNETT, YVONNE WOOD AND MICHAEL GURBARG.					
OC RECOMMENDATION	13-MAR-2000			ACCEPTABLE DISTRICT RECOMMENDATION	DAMBROGIOJ

Establishment: 2510592
MERCK AND CO INC
SUMNEYTOWN PIKE BLA20
WEST POINT, PA 19486

DMF No: AADA:
Responsibilities: [redacted]
Profile: OAI Status: NONE
Estab. Comment: [redacted]

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	17-JUL-1998				FOLKENDTM
SUBMITTED TO DO	17-JUL-1998	10D			FERGUSONS
DO RECOMMENDATION	20-JUL-1998			WITHHOLD FIRM NOT READY	DPAGANO
FIRMS SECOND RESPONSE TO WARNING LETTER WAS DEEMED SATISFACTORY HOWEVER, FIRM IS NOT READY FOR A FOLLOW UP INSPECTION FOR WARNING LETTER ISSUES.					
OC RECOMMENDATION	20-JUL-1998			WITHHOLD FIRM NOT READY	EGASM

ASSIGNED INSPECTION	20-AUG-1998 PS			DPAGANO
INSPECTION PERFORMED	20-AUG-1998	18-AUG-1998		DPAGANO

THIS INSPECTION WAS INITIATED DURING THE FOLLOW-UP TO THE WARNING LETTER.

DO RECOMMENDATION	20-AUG-1998	WITHHOLD	DPAGANO

STABILITY PROGRAM

THERE IS NO DATA TO SUPPORT THE HOLD TIME FOR THE COATED ——— THIS IS A JOINT VENTURE PRODUCT AND THE INSPECTION REVEALED THAT THE PROTOCOL DIRECTED A STABILITY SAMPLE FOR THE HOLD TIME. THE FIRM ANTICIPATES HAVING STABILITY DATA WITHIN THE NEXT WEEK OR SO

DO RECOMMENDATION	25-AUG-1998	ACCEPTABLE	DPAGANO

ADEQUATE FIRM RESPONSE

FIRM PROVIDED STABILITY DATA FOR THE HOLD STUDY. PHI-DO DEEMED THE CORRECTIVE ACTION ACCEPTABLE.

OC RECOMMENDATION	26-AUG-1998	ACCEPTABLE	DAMBROGIOJ

DISTRICT RECOMMENDATION

SUBMITTED TO OC	15-FEB-2000		ADAMSM
OC RECOMMENDATION	15-FEB-2000	ACCEPTABLE	DAMBROGIOJ

BASED ON FILE REVIEW
BASED ON PROFILE

Establishment:

DMF No: AADA:
Responsibilities:
Profile: OAI Status: NONE
Estab. Comment: DET-DO WATE # 109688 HAS AN "A" PRIORITY AND A JUNE 30, 2000 DUE DATE. LAST DET-DO GMP EI DATED JULY 11-12, 1995 WAS VAI WITH ISSUES. (on 15-FEB-2000 by M. ROBINSON (HFR-CE740) 313-226-6260)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-FEB-2000				ADAMSM
SUBMITTED TO DO	15-FEB-2000	GMP			DAMBROGIOJ
ASSIGNED INSPECTION	15-FEB-2000	PS			MROBINSO
INSPECTION SCHEDULED	12-JUN-2000				MROBINSO
INSPECTION PERFORMED	16-JUN-2000		15-JUN-2000		MROBINSO

DET-DO PAI DATED 6/13-15/2000 REPORTED SOME DEVIATIONS ON A FDA-483 NOT LIKELY TO ADVERSELY AFFECT FINISHED PRODUCT QUALITY. EI WILL BE CLASSIFIED VAI.

DO RECOMMENDATION	16-JUN-2000	ACCEPTABLE	MROBINSO

INSPECTION

PAI & GMP EI 6/13-15/2000 WILL BE CLASSIFIED VAI FOR DEVIATIONS NOT LIKELY TO ADVERSELY AFFECT FINISHED PRODUCT QUALITY.

OC RECOMMENDATION	16-JUN-2000	ACCEPTABLE	FERGUSONS

DISTRICT RECOMMENDATION

Establishment:

DMF No: AADA:
Responsibilities:
Profile: OAI Status: NONE

ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	17-JUL-1998				FOLKENDTM
OC RECOMMENDATION	17-JUL-1998			ACCEPTABLE BASED ON PROFILE	FERGUSONS

Establishment:

DMF No: AADA:
Responsibilities:
Profile: CSN OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-FEB-2000				ADAMSM
SUBMITTED TO DO	15-FEB-2000	GMP			DAMBROGIOJ
ASSIGNED INSPECTION	22-FEB-2000	PS			KRODEN
INSPECTION SCHEDULED	22-FEB-2000				KRODEN
INSPECTION PERFORMED	31-MAR-2000		14-MAR-2000		KRODEN
	A GMP/PRE-APPROVAL INSPECTION WAS CONDUCTED AT THIS FACILITY REGARDING THIS APPLICATION. NO OBJECTIONABLE CONDITIONS WERE NOTED AND NO FDA-483 WAS ISSUED. BASED ON THE INSPECTIONAL FINIDNGS, KAN-DO RECOMMENDS APPROVAL OF THIS APPLICATION.				
DO RECOMMENDATION	31-MAR-2000			ACCEPTABLE INSPECTION	KRODEN
	A GMP/PRE-APPROVAL INSPECTION WAS CONDUCTED AT THIS FACILITY COVERING THIS APPLICATION. NO OBJECTIONABLE CONDITIONS WERE NOTED AND NO FDA-483 WAS ISSUED. BASED ON THE INSPECTIONAL FINDINGS, KAN-DO RECOMMENDS APPROVAL OF THIS APPLICATION.				
OC RECOMMENDATION	31-MAR-2000			ACCEPTABLE DISTRICT RECOMMENDATION	FERGUSONS

Establishment:

DMF No: AADA:
Responsibilities:
Profile: OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	17-JUL-1998				FOLKENDTM
OC RECOMMENDATION	17-JUL-1998			ACCEPTABLE BASED ON PROFILE	FERGUSONS

Establishment:

DMF No: AADA:

ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Responsibilities:
Profile: OAI Status: NONE
Estab. Comment:
301-827-7310)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	17-JUL-1998				FOLKENDTM
OC RECOMMENDATION	17-JUL-1998			ACCEPTABLE BASED ON PROFILE	FERGUSONS

Establishment:

DMF No: AADA:
Responsibilities:
Profile: OAI Status: NONE
Estab. Comment: (on 15-FEB-2000 by W. ADAMS (HFD-180) 301-827-7310)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	17-JUL-1998				FOLKENDTM
OC RECOMMENDATION	17-JUL-1998			ACCEPTABLE BASED ON PROFILE	FERGUSONS

Establishment:

DMF No: AADA:
Responsibilities:
Profile: OAI Status: NONE
Estab. Comment: (on 15-FEB-2000 by W. ADAMS (HFD-180) 301-827-7310)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-FEB-2000				ADAMSM
OC RECOMMENDATION	15-FEB-2000			ACCEPTABLE BASED ON FILE REVIEW	EGASM

FUR

Establishment:

DMF No: AADA:
Responsibilities:
Profile: OAI Status: NONE
Estab. Comment:
(on 14-FEB-2000 by W. ADAMS (HFD-180) 301-827-7310)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	17-JUL-1998				FOLKENDTM
OC RECOMMENDATION	17-JUL-1998			ACCEPTABLE BASED ON PROFILE	FERGUSONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code Of Federal Regulations, 314)

Form Approved OMB No. 0910-0338.
Expiration Date: April 30, 2000
See OMB Statement on last page.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Merck & Co., Inc.	4/13/00
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE (FAX) Number** *(Include Area Code)*
(215) 273-7152	(215) 273-8315

APPLICANT ADDRESS *(Number, Street, City, State, Country, Zip Code or Mail Code, and U.S. License number if previously issued):*	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE
Sumneytown Pike P.O. Box 4, BLA-33 West Point, PA 19486	George Latyszonek, Director Regulatory Affairs, JJMCPC

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 20-958

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Famotidine/Antacid Combination	PEPCID® Complete

CHEMICAL/ BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*

DOSAGE FORM	STRENGTHS:	ROUTE OF ADMINISTRATION
Chewable Tablet	10 mg/800 mg/165 mg	Oral

(PROPOSED) INDICATION(S) FOR USE:
1. Treatment and prevention of Heartburn, acid indigestion and sour stomach

APPLICATION INFORMATION

APPLICATION TYPE *(Check one)*
☐ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCED LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug — Holder of Approved Application

TYPE OF SUBMISSION (check one)
☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☒ OTHER

REASON FOR SUBMISSION Response to request - resubmission of Response

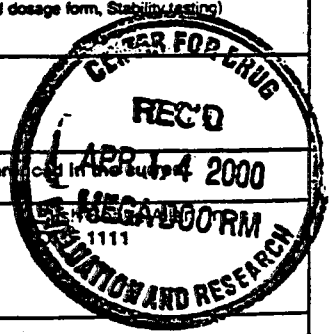
PROPOSED MARKETING STATUS (check one) ☐ PRESCRIPTION PRODUCT (Rx) ☒ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 — THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for the drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

See Attached



Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the subject application)

Merck Research Laboratories
NDA 20-801
NDA 19-462
NDA 20-325

FORM FDA 356h (4/97)

This application contains the following items: *(Check all that apply)*	
	1. Index
	2. Labeling (check one) ☐ Draft Labeling ☐ Final Printed Labeling
	3. Summary (21 CFR 314.50 (c))
	4. Chemistry Section
	A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1), 21 CFR 601.2)
	B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's request)
	C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)
	5. Nonclinical pharmacology and toxicology section (21 CFR 314.50 (d) (2), 21 CFR 601.2)
	6. Human pharmacokinetics and bioavailability section (21 CFR 314.50 (d) (3), 21 CFR 601.2)
	7. Microbiology section (21 CFR 314.50 (d) (4))
	8. Clinical data section (21 CFR 314.50 (d) (5), 21 CFR 601.2)
	9. Safety update report (21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)
	10. Statistical section (21 CFR 314.50 (d) (5), 21 CFR 601.2)
	11. Case report tabulations (21 CFR 314.50 (f) (1), 21 CFR 601.2)
	12. Case reports forms (21 CFR 314.50 (f) (1), 21 CFR 601.2)
	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A))
	15. Establishment description (21 CFR Part 600, if applicable)
	16. Debarment certification (FD&C Act 306 (k) (1))
	17. Field copy certification (21 CFR 314.5 (k) (3))
	18. User Fee Cover Sheet (Form FDA 3397)
X	19. OTHER (Specify) Hard copy of Section of Amended SNDA

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
4. In case of a prescription drug product or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on reports in 21 CFR 314.80, 314.81, 600.80 and 600.81.
7. Local, State and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
George Latyszonek	George Latyszonek, Director Regulatory Affairs, JJMCPC	4/13/00

ADDRESS (Street, City, State, and ZIP Code)	Telephone Number
Sumneytown Pike, P.O. Box 4, BLA-33 West Point, PA 19486	(215) 273-7152

(120)+ folkendt (104)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Division/Office)*: HFD-40 (DDMAC) Dr. Karen Lectner, Room 17B-04, Parklawn Building

FROM: HFD-180 (Division of Gastrointestinal and Coagulation Drug Products) Michael Folkendt, Room 6B-17 Parklawn, 827-1602

October 26, 1998	IND NO.: -	NDA NO.: 20-958	TYPE OF DOCUMENT: Use Study Results	DATE OF DOCUMENT: 2/20/98

NAME OF DRUG: Pepcid — (famotidine/antacid combination) Chewable Tablets	PRIORITY CONSIDERATION: S	CLASSIFICATION OF DRUG: 4	DESIRED COMPLETION DATE: 12/4/98

NAME OF FIRM: Merck Research Laboratories

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE/ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☒ OTHER *(SPECIFY BELOW)*: USE STUDY REPORT

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER:	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER:

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE IV STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL-BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

☐ CLINICAL	☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS: Division of OTC Drug Products has requested your comments regarding the Attached Use Study Report. Please note that the Tradename "Pepcid —" has been found unacceptable by the Tradename and Nomenclature Committee and by the Core Review Team because (1) It doesn't sufficiently distinquish itself form the current OTC Pepcid Product in that this drug product is a combination of two actives (famotidine and antacid) and (2) The word — is too promotional implying the top of a group, first, etc. If you need anything else, please contact the project manager, Michael Folkendt, by e-mail or phone at 827-1602. We are trying to meet the 10-month goal date of December 20, 1998.

cc: Original NDA 20-958
HFD-180/Div. Files
HFD-180/M.Folkendt
HFD-560/A.Rothschild
HFD-560/L.Katz

CENTER FOR DRUG EVALUATION AND RESEARCH
RECEIVED
OCT 26 1998
DDMAC

SIGNATURE OF REQUESTOR: /S/ Folkendt, 827-1602 10/26/98	METHOD OF DELIVERY (Check one): ☐ MAIL ☐ HAND
SIGNATURE OF RECEIVER: /S/	SIGNATURE OF DELIVERER: /S/

Electronic Mail Message

Sensitivity: COMPANY CONFIDENTIAL

Date: 03-Dec-1998 10:54am

From: Mushfiqur Rashid
RASHIDM
Dept: HFD-715 PKLN 6B17
Tel No: 301-827-3121 FAX 301-443-9279

TO: Michael Folkendt (FOLKENDTM)

Subject: Pepcid

Hi Mike,

I have a couple things to know from the sponsor:

1) The method used to determine the sample size in protocol 106;

2) Subgroup analyses (efficacy) tables by male, female, age >65, age <65, white, non-white for each primary endpoint for the three pivotal studies 106, 109 and 110.

Thanks.

Rashid

To: Michael Folkendt

---

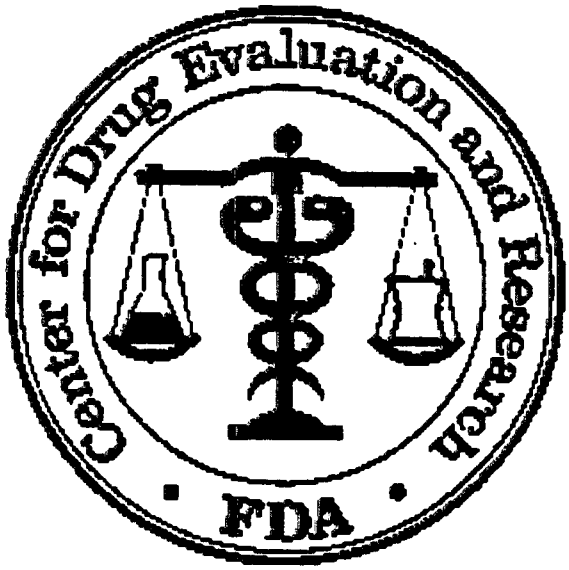
cc: Original NDA 20-958
HFD-180/Div. File
HFD-180/Michael Folkendt
HFD-180/M.Rashid
HFD-180/A.Sankoh
HFD-560/A.Rothschild
HFD-560/L.Katz

MF/December 4,1998/filename: 20958-120498-telecon.doc

TELECON

FOOD AND DRUG ADMINISTRATION
DIVISION OF GICDP
DOCUMENT CONTROL ROOM 6B-24
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857

DATE: June 20, 2000



TO:

Name: George Latyszonek

Fax No: 215-273-4123

Phone No: 215-273-7152

Location: Merck Research Laboratories

FROM:

Name: Alice Kacuba

Fax No: 301-443-9285

Phone No: 301-827-7450

Location: FDA/PKLN 6B-45/HFD-180

This fax is 8 pages long, which includes a 1 page cover letter, a 3 page action letter for NDA 20-958 and 4 pages of attachments (labeling).

AK

TO:

Name: George Latyszonek

Fax No: 215-273-4123

Phone No: 215-273-7152

Location: Merck Research Laboratories

FROM:

Name: Alice Kacuba

Fax No: 301-443-9285

Phone No: 301-827-7450

Location: FDA/PKLN 6B-45/HFD-180

This fax is 8 pages long, which includes a 1 page cover letter, a 3 page action letter for NDA 20-958 and 4 pages of attachments (labeling).

AK

06/20/00 11:44 DGCDP/HFD-180 → 9121527341 23 NO.027 D01

DATE	S.R-TIME	DISTANT STATION ID	MODE	PAGES	RESULT
06/20	02'57"	21523831S	CALLING	08	OK 0000

ID=DGCDP/HFD-180
06/20/00 11:48

MESSAGE CONFIRMATION

DATE: Feb. 19, 1999

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and
Coagulation Drug Products, HFD-180
5600 Fishers Lane
Rockville, Maryland 20857

TO:

NAME: George Latyszonek

FAX Number: 215-273-4123

Phone Number: 215-273-7152

Location: Merck

FROM:

NAME: Michael Folkendt

FAX Number: (301) 443 - 9285

Phone Number: (301) 827 - 1602

Total Number of Pages (including this cover page): 8

COMMENTS:

The original copy of this letter will follow in the mail. Please confirm successful receipt of this fax via telephone at 301-827-1602.

- MESSAGE CONFIRMATION

02/19/99 12:36
ID=DGCDP/HFD-180

DATE	S.R-TIME	DISTANT STATION ID	MODE	PAGES	RESULT	
02/19	03'16"	2152338315	CALLING	08	OK	0000

02/19/99 12:31 DGCDP/HFD-180 → 912152734123 NO.077 P01

DATE: Feb. 19, 1999

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and
Coagulation Drug Products, HFD-180
5600 Fishers Lane
Rockville, Maryland 20857

TO:

NAME: George Latyszonek

FROM:

NAME: Michael Folkendt

[illegible] FAX [illegible] (301) 443 0286

MESSAGE CONFIRMATION

07/20/99 10:58
ID=DGCDP/HFD-180

DATE	S.R-TIME	DISTANT STATION ID	MODE	PAGES	RESULT	
07/20	02'43"	2152338315	CALLING	07	OK	0000

07/20/99 10:54 DGCDP/HFD-180 → 912152734123 NO.038 P01

DATE: July 20, 1999

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and
Coagulation Drug Products, HFD-180
5600 Fishers Lane
Rockville, Maryland 20857

TO:

NAME: George Latyszonek

FROM:

NAME: Michael Folkendt

Teleconference with Merck scheduled for July 6, 2000 from 9-9:30 to discuss the statistics issue regarding NDA 20-958, Pepcid Complete.

FDA Attendees for tcon are: for NDA 20-958, Pepcid Complete

Division of GI and Coagulation Drug Products, HFD-180

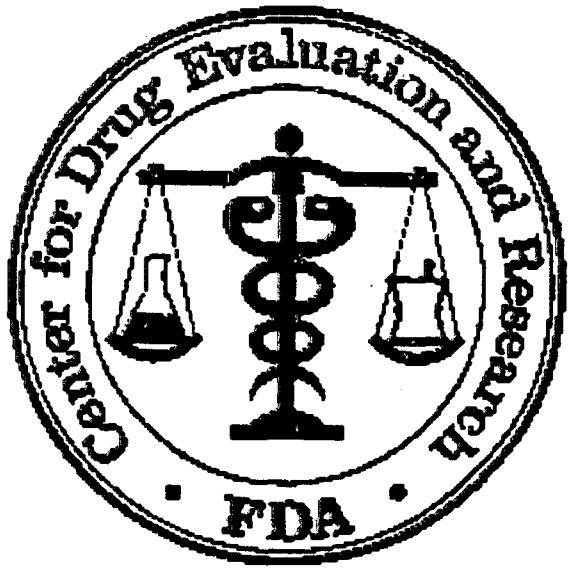
Steve Aurecchia, M.D., Deputy Director
Alice Kacuba, R.N., MSN, Regulatory Health Project Manager
Paul Levine, R.Ph., Regulatory Health Project Manager

Office of Biometrics II, HFD-715

Mike Elashoff, Ph.D., Statistics Reviewer
Tom Permutt, Ph.D., Statistics Team Leader
Ed Nevus, Ph.D., Director

FOOD AND DRUG ADMINISTRATION
DIVISION OF GICDP
DOCUMENT CONTROL ROOM 6B-24
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857

DATE: June 26, 2000



TO:

Name: George Latyszonek

Fax No: 215-273-4123

Phone No: 215-273-7152

Location: Merck Research Laboratories

FROM:

Name: Alice Kacuba

Fax No: 301-443-9285

Phone No: 301-827-7450

Location: FDA/PKLN 6B-45/HFD-180

This fax is 2 pages long, which includes a 1 page cover sheet and a 1 page that contains a list of FDA attendees for the July 6, 2000 tcon to discuss the stats issue for NDA 20-958.

AK

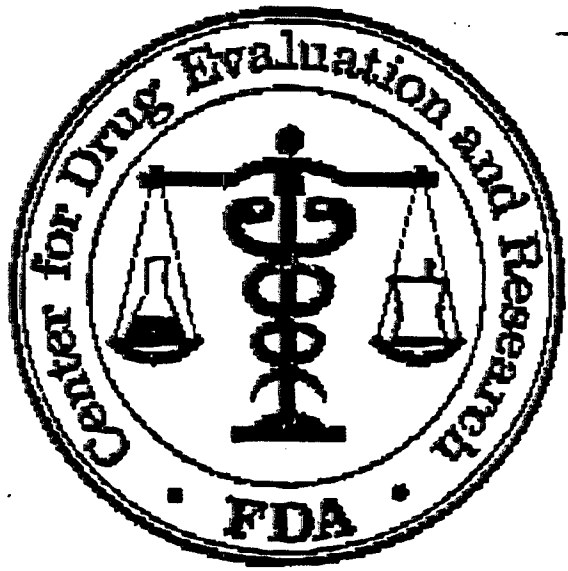
****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	0027
CONNECTION TEL	912152734123
CONNECTION ID	
ST. TIME	06/26 16:13
USAGE T	00'36
PGS. SENT	2
RESULT	OK

FOOD AND DRUG ADMINISTRATION
DIVISION OF GICDP
DOCUMENT CONTROL ROOM 6B-24
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857

DATE: June 26, 2000



TO:

Name: George Latyszonek

Fax No: 215-273-4123

Phone No: 215-273-7152

Location: Merck Research Laboratories

FROM:

Name: Alice Kacuba

Fax No: 301-443-9285

Phone No: 301-827-7450

Location: FDA/PKLN 6B-45/HFD-180

TO:	FROM:
Name: George Latyszonek	**Name: Alice Kacuba**
Fax No: (215) 273-4123	**Fax No: 301-443-9285**
Phone No: (215) 273-7152	**Phone No: 301-827-7450**
Location: Merck Research Laboratories	**Location: FDA/PKLN 6B-45/HFD-180**

This fax is 10 pages long, which includes a 1 page cover letter and a 9 page chemistry discipline review letter.

06 01/00 08:34 DGCDP/HFD-180 → 9121527341 23 NO.066 D01

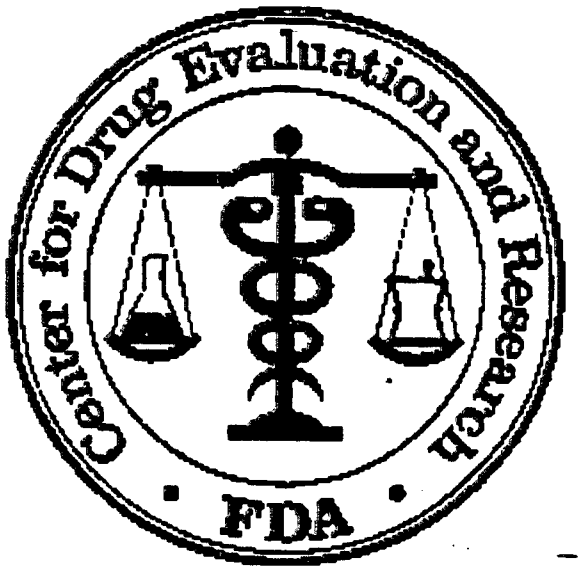
MESSAGE CONFIRMATION

06/01/00 08:39
ID=DGCDP/HFD-180

DATE	S.R-TIME	DISTANT STATION ID	MODE	PAGES	RESULT
06/01	03'29"	21523383 15	CALLING	10	OK 0000

FOOD AND DRUG ADMINISTRATION
DIVISION OF GI & COAG. DRUG PRODUCTS
DOCUMENT CONTROL ROOM 6B-24
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857

DATE: June 1, 2000



TO:

Name: George Latyszonek

Fax No: (215) 273-4123

Phone No: (215) 273-7152

Location: Merck Research Laboratories

FROM:

Name: Alice Kacuba

Fax No: 301-443-9285

Phone No: 301-827-7450

Location: FDA/PKLN 6B-45/HFD-180

This fax is 10 pages long, which includes a 1 page cover letter and a 9 page chemistry discipline review letter.

Food and Drug Administration
Division of Gastrointestinal and
Coagulation Drug Products
Document Control Room 6B-24
5600 Fisher's Lane
Rockville, MD 20857
Phone: 301-827-7310
Fax: 301-443-9285

Fax

To:	George Latyszonek	**From:**	Paul E. Levine, Jr
Fax:	215 - 273 - 4123	**Date:**	February 2, 2000
Phone:	215 - 273 - 7152	**Pages:**	2 (INCLUDING COVER PAGE)
Re:	Dissolution questions	**CC:**	

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** X **Please Reply** ☐ **Please Recycle**

Comments: Please call to verify receipt of this fax

DATE: July 20, 1999

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and
Coagulation Drug Products, HFD-180
5600 Fishers Lane
Rockville, Maryland 20857

TO:

NAME: George Latyszonek

FAX Number: 215-273-4123

Phone Number: 215-273-7464

Location: ~~J&J~~ J&J • Merck

FROM:

NAME: Michael Folkendt

FAX Number: (301) 443 - 9285

Phone Number: (301) 827 - 1602

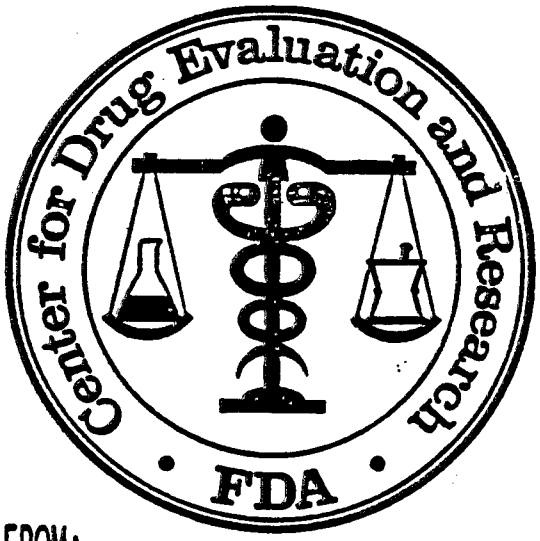
Total Number of Pages (including this cover page): 7

COMMENTS:

The original copy of this letter will follow in the mail. Please confirm successful receipt of this fax via telephone at 301-827-1602.

FOOD AND DRUG ADMINISTRATION
DIVISION OF GASTROINTESTINAL
AND COAGULATION DRUG PRODUCTS
DOCUMENT CONTROL ROOM 6B-24
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857

DATE May 8, 1998



TO:

Name George Latyszonek

Fax No. 215-233-8315

Phone No. 215-233-7152

Location Merck

FROM:

Name Michael Folkendt

Fax No. (301) 443-9285

Phone No. 301-443-0487

Total No. of Pages Including Cover 4

Comments:

Mr. Latyszonek,

As per our telephone conversation, I'm faxing you the list of Request. Please Call me if you have any questions.

Michael Folkendt

MESSAGE CONFIRMATION

05/08/98 11:12
ID=DGCDP/HFD-180

DATE	S.R-TIME	DISTANT STATION ID	MODE	PAGES	RESULT	
05/08	01'35"	2152338315	CALLING	04	OK	0000

05/08/98 11:09 DGCDP/HFD-180 → 912152338315 NO.026 D01

FOOD AND DRUG ADMINISTRATION
DIVISION OF GASTROINTESTINAL
AND COAGULATION DRUG PRODUCTS
DOCUMENT CONTROL ROOM 6B-24
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857

DATE May 8, 1998

Center for Drug Evaluation and Research
FDA

TO:

Name George Latyszonek

Fax No. 215-233-8315

Phone No. 215-233-7152

Location Merck

FROM:

Name Michael Falkendt

Fax No. (301) 443-9285

Phone No. 301-443-0487

Total No. of Pages Including Cover 4

ODE III ACTION PACKAGE TABLE OF CONTENTS

Application # 20-958 Drug Name: Pepcid Complete (famotidine, calcium carbonate 800 mg, & magnesium hydroxide 165 mg) Chewable Tablet

Applicant: Merck Research Laboratories Chem./Ther. Type: 4/S

CSO/PM: Paul Levine Phone: 301-827-7310 HFD-180

Original Application Date: 2/20/1998 Original Receipt Date: 2/20/1998

CURRENT USER FEE GOAL DATE: February 03, 2001 Date Table of Contents Completed: _____

Section A:	Administrative Information	X (completed), N/A (not applicable), or Comment
Tab A-1	Action Letter(s) Current Action: ___AP_____	X
Tab A-2	Phase 4 Commitments:	
	a. Copy of applicants communication committing to Phase 4	N/A
	b. Agency Correspondence requesting Phase 4 Commitments	N/A
Tab A-3	FDA revised Labels & Labeling and Reviews: (Separate each version/cycle with a colored sheet)	
	a. Package Insert	X
	b. Immediate Container and Carton Labels	X
Tab A-4	Original Proposed Labeling (2-20-98, 12-17-99, 5-25-00).....	X
Tab A-5	Foreign Labeling:	
	a. Foreign Marketing History.....	N/A
	b. Foreign Labeling and Review(s)	N/A
Tab A-6	Labeling and Nomenclature Committee's Tradename & OPDRA Reviews.....	X
Tab A-7	Summary Memoranda (e.g., Division Director, Group Leader, Office)	X
Tab A-8	Copy of Patent Statement	X
	Exclusivity Checklist (and any requests for exclusivity)	X
	Debarment Statements	X
Tab A-9	Correspondences, Faxes, & Telecons	X
Tab A-10	Minutes of Meetings:	
	a. End-of-Phase II meeting .....(6-24-96).....	X
	b. Pre-NDA meeting(s) .....(10-10-97).....	X
	c. Filing meeting .... (3-31-98,.....	X
	d. Other meetings ....(8-27-98 CANDA training).....	X
Tab A-11	Advisory Committee Meeting:	
	a. Questions Considered by the committee	N/A
	b. List of Attendees	N/A

c. 24 hour alert memorandum	N/A

ODE III ACTION PACKAGE TABLE OF CONTENTS (continued)

Application # 20-958 Drug Name: Pepcid Complete

Section B:	Clinical Information	X (completed), N/A (not applicable), or Comment
Tab B-1	Clinical Reviews and Memoranda	X
Tab B-2	Safety Update Reviews	X
Tab B-3	Pediatric Page	X
Tab B-4	Statistical (Clinical) Review and Memoranda	X
Tab B-5	Biopharmaceutics Review and Memoranda	X
Tab B-6	Abuse Liability Review	N/A
Tab B-7	DSI Audits	N/A
Tab B-8	Summary of Efficacy (from the summary volume of the application)	X
Tab B-9	Summary of Safety (from the summary volume of the application)	X

Section C:	Chemistry, Manufacturing, and Controls (CMC) Information	X (completed), N/A (not applicable), or Comment
Tab C-1	CMC Reviews and Memoranda	X
Tab C-2	DMF Reviews	X
Tab C-3	EA Reviews/FONSI ...(request for categorical exclusion granted in CMC review #1 (2-11-99).....	X
Tab C-4	Micro Review (validation of sterilization)	N/A
Tab C-5	Statistical Review of drug stability	N/A
Tab C-6	Inspection of facilities => Decision:_Acceptable___ Date:___6-16-00..	X
Tab C-7	Methods Validation Information	Not sent out yet

Section D:	Pharmacology/Toxicology Information	X (completed), N/A (not applicable), or Comment
Tab D-1	Pharmacology/Toxicology Reviews and Memoranda	X
Tab D-2	Carcinogenicity Review (statistical)	N/A
Tab D-3	CAC/Executive Committee Report	N/A

ADDITIONAL NOTES: