

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 020752**

**CHEMISTRY REVIEW(S)**

*Jo/Kendt*

**DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS**

Review of Chemistry, Manufacturing, and Controls

1. NDA: 20-752 2. CHEM REVIEW: #3 3. REVIEW DATE: May 21, 1998

**4. APPLICATION HISTORY**

<u>DOCUMENT TYPE</u>	<u>DATE</u>	<u>COMMENT</u>	MAY 21 1998
Original	01-Aug-96		
BC	13-Sep-96	Change in in-process control	
BC	04-Oct-96	Address of testing site	
BC	28-Feb-97	Minor changes	
BC	12-May-97	Imprint Waiver Request	
BL	13-Jun-97	Labeling	
Review #1	16-Jul-97	Information Requested	
Letter	31-Jul-97	Not Approvable	
AC	26-Nov-97	Response to letter	
Review #1	11-May-98	Information Requested	
Letter	12-May-98	IR Letter	

APPEARS THIS WAY  
ON ORIGINAL

**ITEM REVIEWED**

<u>DOCUMENT TYPE</u>	<u>DATE</u>	<u>COMMENT</u>
BC	11-May-98	Aspartame information
AC	13-May-98	Response to letter
Telecon	19-May-98	Discussion of comments from review #3
AC	20-May-98	Response to telecon

**5. NAME & ADDRESS OF APPLICANT:**

Merck Research Laboratories  
Sumneytown Pike  
BLA-20  
West Point, PA 19486

APPEARS THIS WAY  
ON ORIGINAL

**6. DRUG PRODUCT NAME:**

Proprietary: PEPCID RPD® Wafers  
Nonproprietary/USAN: famotidine  
Chem.Type/Ther.Class: 3S

7. PHARMACOLOGICAL CATEGORY: proton pump inhibitor

8. INDICATION: treatment of duodenal ulcer, GERD and ZES

9. DOSAGE FORM: Tablet, orally disintegrating (Applicant proposed "Rapidly dissolving wafer")

10. STRENGTH: 20 mg and 40 mg

APPEARS THIS WAY  
ON ORIGINAL

11. ROUTE OF ADMINISTRATION: oral

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secret and/or

confidential

commercial

information



MAY 11 1998

**DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG  
PRODUCTS**

Review of Chemistry, Manufacturing, and Controls

1. NDA: 20-752 2. CHEM REVIEW: #2 3. REVIEW DATE: March 20, 1998

**4. APPLICATION HISTORY**

<u>DOCUMENT TYPE</u>	<u>DATE</u>	<u>COMMENT</u>
Original	01-Aug-96	
BC	13-Sep-96	Change in in-process control
BC	04-Oct-96	Address of testing site
BC	28-Feb-97	Minor changes
BC	12-May-97	Imprint Waiver Request
BL	13-Jun-97	Labeling
Review #1	16-Jul-97	Information Requested
Letter	31-Jul-97	Not Approvable
AC	26-Nov-97	Response to letter

APPEARS THIS WAY  
ON ORIGINAL

**5. NAME & ADDRESS OF APPLICANT:**

Merck Research Laboratories  
Sumneytown Pike  
BLA-20  
West Point, PA 19486

APPEARS THIS WAY  
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10. STRENGTH: 20 mg and 40 mg

11. ROUTE OF ADMINISTRATION: oral

APPEARS THIS WAY  
ON ORIGINAL

12. HOW DISPENSED:  Rx  OTC

13. CHEMICAL IDENTIFICATION: See USP 23, Page 651

APPEARS THIS WAY  
ON ORIGINAL

NDA 20-752  
PAGE 3

**18. CONCLUSIONS & RECOMMENDATIONS:** The application is  
Approvable.

**/S/**

5/7/98

Arthur B. Shaw, Ph.D.  
Review Chemist HFD-180

APPEARS THIS WAY  
ON ORIGINAL

**/S/**

5/11/98

Eric P. Duffy, Ph.D.  
Chemistry Team Leader, HFD-180

cc:  
NDA 20-752  
HFD-180/LTalarico  
HFD-180/Division File/NDA 20-752  
HFD-181/CSO  
R/D Init by: EDuffy/5-5-98  
ABS/dob **F/T 5-7-98**/WP: c:\wpfiles\chem\N\20752801.2AS

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ON ORIGINAL

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**DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS**

Review of Chemistry, Manufacturing, and Controls

1. NDA: 20-752 2. CHEM REVIEW # 1 3. REVIEW DATE: July 15, 1997

**4. APPLICATION HISTORY**

<u>Type of Document</u>	<u>Date of Document</u>	<u>Comment</u>	
Original	01-Aug-96		JUL 16 1997
Amendment BC	13-Sep-96	Change in-process control	
Amendment BC	04-Oct-96	Address of testing site	
Amendment BC	28-Feb-97	Minor changes	
Amendment BC	12-May-97	Imprint Waiver Request	
Amendment BL	13-Jun-97	Labeling	

**5. NAME & ADDRESS OF APPLICANT:**

Merci Research Laboratories  
Sumneytown Pike  
BLA-20  
West Point, PA 19486

APPEARS THIS WAY  
ON ORIGINAL

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APPEARS THIS WAY  
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11. ROUTE OF ADMINISTRATION: lingual

12. HOW DISPENSED:  Rx  OTC

13. CHEMICAL IDENTIFICATION:

APPEARS THIS WAY  
ON ORIGINAL

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commercial

information

18. CONCLUSIONS & RECOMMENDATIONS: The applicant should be sent an Information Request letter.

**/S/**

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Arthur B. Shaw, Ph.D.  
Review Chemist HFD-180

7/16/97

APPEARS THIS WAY  
ON ORIGINAL

**/S/**

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Eric P. Duffy, Ph.D.  
Chemistry Team Leader, HFD-180

7/16/97

cc:  
NDA 20-752  
HFD-180/  
HFD-180/Division File/NDA 20-752  
HFD-181/CSO  
R/D Init by:EDuffy/7-16-97  
ABS/dob **F/T 7-16-97**\WP: c:\wpfiles\chem\N\20752609.1AS

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