CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 019919 (S002)

Trade Name: ROWASA 500 MG SUPPOSITORY

Generic Name: MESALAMINE

Sponsor: SOLVAY PHARMACEUTICALS, INC.

Approval Date: 08/08/97

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 019919 (S002)

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter	X			
Final Printed Labeling				X
Medical Review(s)				X
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				X
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)				X
Administrative Document(s)				X
Correspondence	X			

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 019919 (S002)

APPROVAL LETTER

NDA 19-919/S-002

Solvay Pharmaceuticals, Inc.
Attention: J. Greg Perkins, Ph.D.
901 Sawyer Road
Marietta, GA 30062

AUG - 8 1997

Dear Dr. Perkins:

Please refer to your supplemental new drug application dated January 19, 1996, received January 23, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rowasa® (mesalamine) 500 mg Suppository.

We acknowledge receipt of your submission dated February 10, 1997. The User Fee goal date for this application is August 11, 1997.

The supplemental application provides for

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Melodi McNeil, Regulatory Health Project Manager, at (301) 443-0483.

Sincerely yours,

Eric P mm 8/8/97

Eric P. Duffy, Ph.D.
Chemistry Team Leader
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Original NDA 19-919/S-002
HFD-180/Div. Files
HFD-180/CSO/M.McNeil
HFD-180/Ysern
HFD-820/ONDC Division Director
HFD-92/DDM-DIAB
DISTRICT OFFICE

Drafted by: mm/August 8, 1997/c:\wpfiles\cso\n\19919708.ap
final: August 8, 1997

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 019919 (S002)

APPROVABLE LETTER

NDA 19-919/S-002

Solvay Pharmaceutical
Attention: J. Greg Perkins, Ph.D.
901 Sawyer Road
Marietta, Georgia 30062

JUL 2 2 1996

Dear Dr. Perkins:

Please refer to your January 19, 1996 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rowasa® (mesalamine) Suppository, 500 mg.

The supplemental application provides for

We have completed the review of this supplement application. Before this supplement may be approved, we would like to clarify the following information:

1. Please explain why there is a

2. Please provide rationale

3. The will be reviewed and the holder will be notified of any deficiencies noted.

Within 10 days after the date of this letter, you are required to amend this supplemental application , notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw this application .

Should you have any questions, please contact:

Melodi McNeil
Consumer Safety Officer
Telephone: (301) 443-0483

Sincerely yours,

Eric P. Duffy 6/24/96

APPEARS THIS WAY
ON ORIGINAL

Eric P. Duffy, Ph.D.
Acting Chemistry Team Leader
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
NDA 19-919/S-002
HFD-180 Division File
DISTRICT OFFICE
HFD-181/ CSO/MMcNeil
HFD-80
HFD-232
HFD-820/YYChiu
HFD-180/MYsern M.Y 6/24/96
R/D init:EDuffy/6-17-96
MY/dob DRAFT 6-18-96/**F/T 6-24-96**/WP: c:/wpfiles/chem/S/19919002.AMY

APPEARS THIS WAY
ON ORIGINAL

APPROVABLE

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 019919 (S002)

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW #2	1. Organization: FDA	2. NDA Number: 19-919
3. Name and Address of Applicant (City & State): Solvay Pharmaceuticals 901 Sawyer Road, Marietta, Georgia 30062		4. AF Number: AUG - 8 1997
		5. Supplement(s)
6. Name of Drug: Rowasa® Suppositories,	7. Nonproprietary Name: Mesalamine (USAN)	Numbers: SCM/AC/ 002 — Dates: Feb 11, 1997
8. Supplement Provides for:		9. Amendments and Other (Reports, etc.) Dates:
10. Pharmacological Category: For the treatment of active mild to moderate ulcerative proctitis	11. How Dispensed: RX X__ OTC __	12. Related IND/NDA/DMF(s): NDA 19-919
13. Dosage Form: rectal Suppositories	14. Potency: 500 mg/ suppository	
15. Chemical Name and Structure: 5-amino-2-hydroxy-benzoic acid: C_7H_7N MW:153.13		16. Records and Reports: Current ___ Yes ___ No; Reviewed ___ Yes ___ No

17. Comments: See Review Notes

cc: NDA 19-919/SC-002
HFD-180/Div File
HFD-181/CSO
HFD-820/JGibbs
HFD-180/MYsern
R/D init by:E Duffy/8-6-97 EDuffy 8/8/97
MY/dob **F/T 8-7-97**/WP: c:\wpfiles\chem\s\19919002.2my

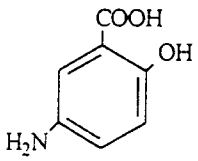
18. Conclusions and Recommendations: This supplement provides the responses to the FDA correspondence dated July 22, 1996 pertaining to this supplement.

A rationale for establishing and maintaining a specification is provided.

19. Reviewer

Name: Maria Elena Ysern, MSc.	Signature: Maria Elena Ysern	Date Completed: March 24, 1997

Form FDH 2266 (7/75) ALT R

CHEMIST'S REVIEW #1	1. Organization: HFD-180	2. NDA Number: 19-919
3. Name and Address of Applicant (City & State): Solvay Pharmaceuticals, Inc. 901 Sawyer Road Marietta, GA 30062		4. AF Number: JUN 20 1996 5. Supplement(s)
6. Name of Drug: Rowasa® Suppository	7. Nonproprietary Name: Mesalamine	Numbers: SCM 002 Dates: 1/19/96
8. Supplement Provides for: The supplement provides information		9. Amendments and Other (Reports, etc.) Dates:
10. Pharmacological Category: Treatment of active mild to moderate ulcerative proctitis.	11. How Dispensed: RX X OTC _	12. Related IND/NDA/DMF(s)
13. Dosage Form: Suppositories	14. Potency: 500 mg	
15. Chemical Name and Structure: 5-amino-2-hydroxy-benzoic acid; $C_7H_7NO_3$; M.W.= 153.13 		16. Records and Reports: Current __ Yes __ No Reviewed __ Yes __ No

17. Comments: See Review Notes

cc: NDA 19-919
HFD-180/Div File
HFD-181/CSO/MMcNeil
HFD-180/SFredd
HFD-180/MYsern
R/D init by:EDuffy/6-17-97 Eric P. Duffy 6/20/96
MY/dob **F/T 6-18-96**/WP: c:\wpfiles\chem/S/19919002.1MY

18. Conclusions and Recommendations: A letter requesting additional information should be sent to the company.

19. Reviewer

Name:	Signature	Date Completed:
Maria Elena Ysern, MSc.	Maria Elena Ysern	June 4, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 019919 (S002)

CORRESPONDENCE

MEMORANDUM OF TELECON

DATE: February 2, 1996

APPLICATION NUMBER: NDA 19-919/S-002
Rowasa (mesalamine) 500 mg Suppository

BETWEEN:

Name: Theresa Cheung
Phone: (770) 578-5910
Representing: Solvay Pharmaceuticals, Inc.

AND

Name: Melodi McNeil, CSO
Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: Supplemental

BACKGROUND: Supplement -002, submitted January 19, 1996, provides for an

The cover letter also referred to to be initiated in February, 1996, with results to be submitted in the second quarter of 1996 as an amendment to the supplement. Given the July 21, 1996 due date, Dr. Gibbs voiced his concern as to whether review of this information is required for an action, and as such could affect the filing of the supplement, or if these are the first 3 production batches available for examination by the District Office prior to their release for distribution. Information about these lots are not required to be reviewed before an action can be taken on the supplement. Per Dr. John Gibbs, a telephone call was made to clarify the situation.

TODAY'S PHONE CALL: Ms. Theresa Cheung verified that the supplemental process validation studies mentioned at the bottom of page three of the firm's cover letter are those which will be available to be inspected by the District Office prior to distribution.

CONCLUSION: Since the supplemental application appears, on its face, to be complete, it will be filed.

Melodi McNeil
Consumer Safety Officer

cc: Original NDA 19-919/S-002
HFD-180/Div. File
HFD-180/Melodi McNeil
HFD-180/M. Ysern

rd init:K. Johnson 2/5/96, 2/12/96
J. Gibbs 2/13/96
Final:February 13, 1996

TELECON

APPEARS THIS WAY
ON ORIGINAL