

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-301

MEDICAL REVIEW(S)

CLINICAL REVIEW

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Established Name mesalamine
Trade Name Apriso
Therapeutic Class Locally acting aminosalicylate
Applicant Salix Pharmaceuticals, Inc.

Priority Designation S

Formulation 0.375 g delayed-release capsules
Dosing Regimen 1.5 g (four 0.375 g capsules)
once daily
Indication Maintenance of remission of
Ulcerative Colitis (UC)
Intended Population Adults ages 18 years and older
currently in remission from UC

Table of Contents

1	EXECUTIVE SUMMARY	5
1.1	RECOMMENDATION ON REGULATORY ACTION	5
1.2	RECOMMENDATION ON POSTMARKETING ACTIONS	5
1.2.1	Risk Management Activity	5
1.2.2	Required Phase 4 Commitments	5
1.2.3	Other Phase 4 Requests	5
1.3	SUMMARY OF CLINICAL FINDINGS	5
1.3.1	Brief Overview of Clinical Program	5
1.3.2	Efficacy	6
1.3.3	Safety	7
1.3.4	Dosing Regimen and Administration	8
1.3.5	Drug-Drug Interactions	8
1.3.6	Special Populations	8
2	INTRODUCTION AND BACKGROUND	10
2.1	PRODUCT INFORMATION	10
2.2	CURRENTLY AVAILABLE TREATMENT FOR INDICATION	11
2.3	AVAILABILITY OF PROPOSED ACTIVE INGREDIENT IN THE UNITED STATES	11
2.4	IMPORTANT ISSUES WITH PHARMACOLOGICALLY RELATED PRODUCTS	11
2.5	PRESUBMISSION REGULATORY ACTIVITY	11
2.6	OTHER RELEVANT BACKGROUND INFORMATION	12
3	SIGNIFICANT FINDINGS FROM OTHER REVIEW DISCIPLINES	13
3.1	CMC (AND PRODUCT MICROBIOLOGY, IF APPLICABLE)	13
3.2	ANIMAL PHARMACOLOGY/TOXICOLOGY	13
4	DATA SOURCES, REVIEW STRATEGY, AND DATA INTEGRITY	13
4.1	SOURCES OF CLINICAL DATA	13
4.2	TABLES OF CLINICAL STUDIES	14
4.3	REVIEW STRATEGY	14
4.4	DATA QUALITY AND INTEGRITY	15
4.5	COMPLIANCE WITH GOOD CLINICAL PRACTICES	15
4.6	FINANCIAL DISCLOSURES	16
5	CLINICAL PHARMACOLOGY	16
5.1	PHARMACOKINETICS	17
5.2	PHARMACODYNAMICS	17
5.3	EXPOSURE-RESPONSE RELATIONSHIPS	17
6	INTEGRATED REVIEW OF EFFICACY	18
6.1	INDICATION	18
6.1.1	Methods	18
6.1.2	General Discussion of Endpoints	18
6.1.3	Study Design	20
6.1.4	Efficacy Findings	21
6.1.5	Clinical Microbiology	25
6.1.6	Efficacy Conclusions	26
7	INTEGRATED REVIEW OF SAFETY	26
7.1	METHODS AND FINDINGS	26
7.1.1	Deaths	27

7.1.2	Other Serious Adverse Events	27
7.1.3	Dropouts and Other Significant Adverse Events	30
7.1.4	Other Search Strategies.....	36
7.1.5	Common Adverse Events	36
7.1.6	Less Common Adverse Events	43
7.1.7	Laboratory Findings.....	43
7.1.8	Vital Signs	46
7.1.9	Electrocardiograms (ECGs).....	48
7.1.10	Immunogenicity	48
7.1.11	Human Carcinogenicity	48
7.1.12	Special Safety Studies.....	48
7.1.13	Withdrawal Phenomena and/or Abuse Potential.....	48
7.1.14	Human Reproduction and Pregnancy Data	48
7.1.15	Assessment of Effect on Growth.....	49
7.1.16	Overdose Experience	49
7.1.17	Postmarketing Experience.....	50
7.2	ADEQUACY OF PATIENT EXPOSURE AND SAFETY ASSESSMENTS	51
7.2.1	Description of Primary Clinical Data Sources (Populations Exposed and Extent of Exposure) Used to Evaluate Safety	51
7.2.2	Description of Secondary Clinical Data Sources Used to Evaluate Safety.....	55
7.2.3	Adequacy of Overall Clinical Experience	60
7.2.4	Adequacy of Special Animal and/or In Vitro Testing	60
7.2.5	Adequacy of Routine Clinical Testing.....	60
7.2.6	Adequacy of Metabolic, Clearance, and Interaction Workup.....	60
7.2.7	Adequacy of Evaluation for Potential Adverse Events for Any New Drug and Particularly for Drugs in the Class Represented by the New Drug; Recommendations for Further Study.....	60
7.2.8	Assessment of Quality and Completeness of Data	60
7.2.9	Additional Submissions, Including Safety Update	61
7.3	SUMMARY OF SELECTED DRUG-RELATED ADVERSE EVENTS, IMPORTANT LIMITATIONS OF DATA, AND CONCLUSIONS	61
7.4	GENERAL METHODOLOGY	62
7.4.1	Pooling Data Across Studies to Estimate and Compare Incidence	62
7.4.2	Explorations for Predictive Factors	62
7.4.3	Causality Determination	63
8	ADDITIONAL CLINICAL ISSUES	64
8.1	DOSING REGIMEN AND ADMINISTRATION	64
8.2	DRUG-DRUG INTERACTIONS	64
8.3	SPECIAL POPULATIONS.....	64
8.4	PEDIATRICS	65
8.5	ADVISORY COMMITTEE MEETING	65
8.6	LITERATURE REVIEW	65
8.7	POSTMARKETING RISK MANAGEMENT PLAN	65
8.8	OTHER RELEVANT MATERIALS	65
9	OVERALL ASSESSMENT.....	66
9.1	CONCLUSIONS	66
9.2	RECOMMENDATION ON REGULATORY ACTION	68
9.3	RECOMMENDATION ON POSTMARKETING ACTIONS	68
9.3.1	Risk Management Activity	68
9.3.2	Required Phase 4 Commitments	68
9.3.3	Other Phase 4 Requests.....	68
9.4	LABELING REVIEW.....	68
9.5	COMMENTS TO APPLICANT.....	69

10	APPENDICES	70
10.1	STUDY PROTOCOL MPUC3003.....	70
10.1.1	Protocol Summary.....	70
10.1.2	Inclusion Criteria.....	71
10.1.3	Exclusion Criteria.....	71
10.1.4	Primary Efficacy Endpoint.....	71
10.1.5	Secondary Efficacy Endpoints.....	72
10.1.6	Treatment.....	73
10.1.7	Monitoring.....	73
10.1.8	Control Procedures.....	75
10.1.9	Safety evaluation.....	77
10.1.10	Protocol Amendments.....	77
10.1.11	Statistical Methods.....	78
10.1.12	Study Results.....	78
10.2	STUDY PROTOCOL MPUC3004.....	92
10.2.1	Protocol Summary.....	92
10.2.2	Inclusion Criteria.....	93
10.2.3	Exclusion Criteria.....	93
10.2.4	Primary Efficacy Endpoint.....	93
10.2.5	Secondary Efficacy Endpoints.....	94
10.2.6	Treatment.....	95
10.2.7	Monitoring.....	95
10.2.8	Control Procedures.....	97
10.2.9	Safety evaluation.....	99
10.2.10	Protocol Amendments.....	99
10.2.11	Statistical Methods.....	100
10.2.12	Study Results.....	100
10.3	STUDY PROTOCOL MPUC3005.....	113
10.3.1	Protocol Summary.....	113
10.3.2	Inclusion Criteria.....	114
10.3.3	Exclusion Criteria.....	114
10.3.4	Efficacy Analyses.....	115
10.3.5	Safety Analyses.....	115
10.3.6	Treatment.....	115
10.3.7	Monitoring.....	115
10.3.8	Control Procedures.....	116
10.3.9	Safety Evaluation.....	117
10.3.10	Protocol Amendments.....	118
10.3.11	Statistical Methods.....	118
10.3.12	Study Results.....	118
	Adverse Events	121
10.4	LIST AND DESCRIPTION OF INVESTIGATORS.....	127
10.4.1	MPUC3003 Clinical Investigators.....	128
10.4.2	Study MPUC3004 Clinical Investigators.....	133
10.4.3	Study MPUC3005 Clinical Investigators.....	137
10.5	LINE-BY-LINE LABELING REVIEW.....	143
11	REFERENCES	144

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