

OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA: 19651/ Supplement 24	Submission Date: 05/02/2013
Brand Name	Asacol®
Generic Name	Mesalamine
Reviewers	Sandhya Apparaju, Ph.D. Justin Earp, Ph.D.
Team Leaders	Sue Chih Lee, Ph.D. Nitin Mehrotra, Ph.D.
OCP Division	DCP3
OND Division	DGIEP
Sponsor	Warner Chilcott
Submission Type	Prior Approval Labeling Supplement; PLR
Formulation; Strength(s)	Delayed Release Tablets; 400 mg
Indication	Ulcerative Colitis

Recommendation: The prior approval labeling supplement for Asacol 400 mg, NDA 19-651/Supplement 24 has been found acceptable from a Clinical Pharmacology perspective.

Executive Summary: This is a companion supplement to NDA 21830/Suppl 6 under which pediatric dose ranging and efficacy studies in UC (> 5 years) were conducted using Asacol 400 mg (NDA 19-651) as the age appropriate pediatric formulation; thus labeling for Asacol has been updated in this supplement to include dosing recommendations and other relevant information (PK, safety, efficacy) from the completed pediatric UC trials.

The labeling revisions proposed under NDA 19651/Supplement 24 for Asacol 400 mg Delayed Release capsules, have been reviewed from a Clinical Pharmacology perspective. Data supporting the revisions to the pediatric sections of this label including dosing recommendations have been reviewed under the pediatric (b) (4) supplement NDA 21830/Supplement 6 for Asacol HD and deemed acceptable from a Clinical pharmacology Perspective. Please see the Clinical Pharmacology review for NDA 21830/Suppl 6 (signed 09/13/2013) in this regard. Please refer to the final approved labeling for NDA 19651.

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/s/

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10/03/2013

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