DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	**Clinical Pharmacology Tracking/Action Sheet for Formal/Informal Consults**

From: **Arun Agrawal, Ph.D.**	**To: DOCUMENT ROOM (LOG-IN and LOG-OUT) Please log-in this consult and review action for the specified IND/NDA submission**

REVIEW DATE: 02/03/2012	IND No.	NDA 20-829/S-059, NDA 20-830/S-061, and NDA 21-409/S-036	SUBMISSION DATE : 09/30/2011	

NAME OF DRUG: Montelukast Sodium NDA 20-829: Singulair tablets NDA 20-830: Singulair chewable tablets NDA 21-409: Singulair oral granules	PRIORITY CONSIDERATION	Date of informal/FormalConsult:	

NAME OF THE SPONSOR: Merck

TYPE OF SUBMISSION

CLINICAL PHARMACOLOGY RELATED ISSUE

☐ PRE-IND	☐ DISSOLUTION/IN-VITRO RELEASE	☐ FINAL PRINTED LABELING
☐ ANIMAL to HUMAN SCALING	☐ BIOAVAILABILITY STUDIES	☒ LABELING REVISION
☐ IN-VITRO METABOLISM	☐ IN-VIVO WAIVER REQUEST	☐ CORRESPONDENCE
☐ PHASE I PROTOCOL	☐ SUPAC RELATED	☐ DRUG ADVERTISING
☐ PHASE II PROTOCOL	☐ CMC RELATED	☐ ADVERSE REACTION REPORT
☐ PHASE III PROTOCOL	☐ PROGRESS REPORT	☐ ANNUAL REPORTS
☐ DOSING REGIMEN CONSULT	☐ SCIENTIFIC INVESTIGATIONS	☐ FAX SUBMISSION
☐ PK/PD- POPPK ISSUES	☐ MEETING PACKAGE (EOP2/Pre-NDA/CMC/Pharmacometrics/Others)	☐ OTHER *(SPECIFY BELOW):*
☐ PHASE IV RELATED		

REVIEW ACTION

☒ NAI (No action indicated)	☐ Oral communication with Name: [ ]	☐ Formal Review/Memo (attached)
☐ E-mail comments to:	☐ Comments communicated in meeting/Telecon. see meeting minutes dated: [ ]	☒ See comments below
☐ Medical ☐ Chemist ☐ Pharm-Tox ☐ Micro ☐ Pharmacometrics ☐ Others (Check as appropriate and attach e-mail)		☐ See submission cover letter
		☐ OTHER *(SPECIFY BELOW)*:

REVIEW COMMENT(S)

☐ **NEED TO BE COMMUNICATED TO THE SPONSOR** ☐ **HAVE BEEN COMMUNICATED TO THE SPONSOR**

COMMENTS/SPECIAL INSTRUCTIONS:

Merck submitted a Prior Approval Supplement (PAS) on 05/26/2011, to modify the product labeling for Singulair line of products, in response to a request from FDA dated 04/28/2011, in which FDA requested that information from the pediatric exercise-induced bronchoconstriction (EIB) study - protocol 377 [A double-blind, placebo-controlled, multicenter, crossover study to evaluate the effects of a single oral dose of montelukast, compared with placebo, on EIB in pediatric patients aged 4 to 14 years] – be added to the labeling for Singulair so as to furnish adequate information for the safe and effective use of the drug. This update in Singulair labeling did not change any information related to clinical pharmacology in the currently approved labeling and therefore, no action is indicated from clinical pharmacology viewpoint.

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/s/

ARUN AGRAWAL
02/03/2012

SURESH DODDAPANENI
02/06/2012