

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Nonprescription Drugs Advisory Committee (NDAC) Meeting
Hilton Washington DC North/Gaithersburg, The Ballrooms
620 Perry Parkway, Gaithersburg, Maryland
May 2, 2014

DRAFT QUESTIONS TO THE COMMITTEE

1. **DISCUSSION:** Discuss the efficacy data for montelukast sodium, including data regarding the relief of ocular allergy symptoms.
2. **DISCUSSION:** Discuss the safety profile for montelukast sodium for the over-the-counter (OTC) setting. Include discussion on:
 - a. *neuropsychiatric events,*
 - b. *adequacy of proposed labeling regarding neuropsychiatric events ,*
 - c. *potential for off-label use and consequences of such use, and*
 - d. *pediatric use.*
3. **VOTE:** Has the safety of OTC use of montelukast sodium for relief of allergy symptoms, considering potential off-label use, been adequately demonstrated?
 - a. *If not, what further data should be obtained?*
4. **DISCUSSION:** Discuss the proposed Drug Facts Label and Consumer Package Insert.
5. **VOTE:** Is the risk/benefit profile of montelukast sodium supportive of OTC use in adults for the nasal indication “temporarily relieves these symptoms due to hay fever or other upper respiratory allergies”?
 - a. *If yes, do you have additional comments or recommendations for labeling?*
 - b. *If not, what further data should be obtained?*