

FOOD AND DRUG ADMINISTRATION (FDA)

Office of the Commissioner (OC)

Joint Meeting of the Pediatric Advisory Committee (PAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, MD

September 27, 2019

FINAL QUESTIONS

1. **DISCUSSION:** Discuss the neuropsychiatric safety findings presented for montelukast.
2. **DISCUSSION:** Discuss the current labeling for montelukast, including:
 - a. Current Warnings and Precautions
 - b. Request for Medication Guide and Boxed Warning
3. **DISCUSSION:** Discuss your recommendations for communication strategies
 - a. Target audience
 - b. Target organizations
 - c. Modalities of communication