

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Medical Imaging Drugs Advisory Committee (MIDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland

February 14, 2013

QUESTIONS TO THE COMMITTEE

1. **DISCUSSION:** Considering the potential for efficacy and safety to vary among patients of different ages, do the data support Gadoterate:
 - a. Efficacy?
 - b. Safety?

2. Is the “risk to benefit” assessment favorable for the use of Gadoterate in CNS magnetic resonance imaging among:
 - a. **VOTE:** Adults;
 - b. **VOTE:** Pediatric patients aged ≥ 2 years of age;
 - c. **VOTE:** Pediatric patients < 2 years of age.

3. **DISCUSSION:** If the response is “no” or inconclusive regarding any of the patient groups in Question 2, what additional information is needed to form a favorable “risk to benefit” assessment?