

# 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

## AGENDA

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*The committee will discuss new drug application 204781, DOTAREM (gadoterate meglumine injection), submitted by Guerbet, LLC. The proposed indication is for magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adults and pediatric patients (from neonates to 17 years of age) to detect and visualize areas with disruption of the blood brain barrier (specialized tissues that help protect the brain) and/or abnormal vascularity.*

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8:00 a.m.	Call to Order and Introduction of Committee	<b>Robert F. Mattrey, MD</b> Chairperson, MIDAC
8:05 a.m.	Conflict of Interest Statement	<b>Diane P. Goyette, RPh, JD</b> Designated Federal Officer, MIDAC
8:10 a.m.	FDA Introductory Remarks	<b>Dwaine Rieves, MD</b> Director Division of Medical Imaging Products (DMIP) Office of Drug Evaluation-IV (ODE-IV) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	<b>GUEST SPEAKER PRESENTATION</b>	
	Use of Gadolinium Contrast in Children Under Two Years of Age	<b>Louis-Gilbert Vezina, MD</b> Director, Program in Neuroradiology Children's National Medical Center Professor of Radiology and Pediatrics The George Washington University School of Medicine and Health Sciences
9:00 a.m.	Clarifying Questions from the Committee	
9:15 a.m.	<b>BREAK</b>	
9:30 a.m.	<b>SPONSOR PRESENTATIONS</b>	<b>Guerbet, LLC</b>
	Dotarem Introduction	<b>Corina Harper</b> Guerbet LLC
	Gd-Based Contrast Agents for CNS Imaging: Essential Medical Needs	<b>Kenneth Maravilla, MD</b> Professor of Radiology and Neurological Surgery Director of MR Research Laboratory University of Washington

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**AGENDA (cont.)**

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**SPONSOR PRESENTATIONS (CONT.)**

MRI Post Contrast Imaging in  
Pediatric Neuroradiology

**Donna Roberts, MD**  
Assistant Professor of Radiology  
Medical University of South Carolina

NSF, GBCA, and Renal Disease  
Patients

**Emanuel Kanal, MD, FACR, FISMRM, AANG**  
Professor of Radiology and Neuroradiology  
Director of Magnetic Resonance Services  
University of Pittsburgh

Dotarem Efficacy

**Jing Hao, MD**  
Guerbet LLC

Dotarem Safety

**Pierre Desche, MD**  
Guerbet LLC

Efficacy and Safety in Pediatric  
Population < 2 Years Of Age

**Pierre Desche, MD**

Conclusion

**Corina Harper**

10:45 a.m. Clarifying Questions from the Committee

11:00 a.m. **FDA PRESENTATIONS**

Dotarem Injection (Gadoterate  
Meglumine) Efficacy, Safety, Use in  
Children < 2 years

**Barbara A. Stinson, DO**  
Medical Officer  
DMIP, ODE-IV, OND, CDER, FDA

Dotarem Dose Selection

**Gene Williams, PhD**  
Clinical Pharmacology Team Leader  
Division of Clinical Pharmacology V  
Office of Clinical Pharmacology (OCP)  
Office of Translational Sciences (OTS)  
CDER, FDA

11:45 a.m. Clarifying Questions from the Committee

12:00 p.m. **LUNCH**

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**AGENDA (cont.)**

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- 12:45 p.m. Open Public Hearing Session
- 1:45 p.m. Charge to the Committee
- 2:00 p.m. Questions to the Committee/Committee  
Discussion
- 3:00 p.m. **ADJOURNMENT**