

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

Medical Imaging Drugs Advisory Committee (MIDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
September 8, 2017

AGENDA

The committee will discuss the potential risk of gadolinium retention in the brain and other body organs in patients receiving gadolinium-based contrast agents for magnetic resonance clinical imaging procedures.

7:30 a.m.	Call to Order and Introduction of Committee	Peter Herscovitch, MD, FACP, FRCPC, FSNMMI Acting Chairperson, MIDAC
7:35 a.m.	Conflict of Interest Statement	Jennifer Shepherd, RPh Designated Federal Officer, MIDAC
7:40 a.m.	FDA Introductory Remarks Gadolinium Retention following Gadolinium Based Contrast Agents MRIs: Brain and Other Organs	Ira Krefting, MD Deputy Director for Safety Division of Medical Imaging Products (DMIP) Office of Drug Evaluation-IV (ODE-IV) Office of New Drugs (OND), CDER, FDA
7:50 a.m.	FDA PRESENTATION Regulatory Safety Actions & Risk Mitigation	Michele Fedowitz, MD Associate Director for Labeling DMIP, ODE IV, OND, CDER, FDA
8:00 a.m.	GUEST SPEAKER PRESENTATION The Pathophysiology and Retention of Gadolinium	Brent Wagner, MD Associate Professor with Tenure Director, Clinical Nephrology Training Program University of Texas Health Science Center at San Antonio
8:30 a.m.	INDUSTRY PRESENTATIONS Presence of Gadolinium (Gd) in the Brain and Body	Bayer HealthCare Pharmaceuticals, Inc. Thomas Balzer, MD Vice President, Medical & Clinical Affairs Radiology Radiology R&D Bayer HealthCare Pharmaceuticals, Inc.
8:45 a.m.	INDUSTRY PRESENTATIONS Gadolinium Retention in Brain and Body Tissues: Safety Considerations	Bracco Diagnostics Inc. Alberto Spinazzi, MD Sr. Vice President, Global Medical and Regulatory Affairs Bracco Diagnostics Inc.

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9:00 a.m.	INDUSTRY PRESENTATIONS (CONT.)	GE Healthcare
	Omniscan (gadodiamide) a gadolinium-based contrast agent (GBCA) for diagnostic magnetic resonance imaging (MRI)	
	Introduction	Mark Hibberd, MD, PhD Global Head of Medical Services & Chief Medical Officer, Life Sciences GE Healthcare
	Safety of Omniscan	Robert McDonald, MD, PhD Senior Associate Consultant Division of Neuroradiology Mayo Clinic, Rochester, Minnesota
	Risk Mitigation and Conclusion	Mark Hibberd, MD, PhD
9:15 a.m.	INDUSTRY PRESENTATIONS	Guerbet
	An Overview on Gadolinium Retention after GBCA Use	Pierre Desché, MD VP of Development, Medical and Regulatory Affairs Guerbet Group
9:30 a.m.	Clarifying Questions to Presenters	
9:45a.m.	BREAK	
9:55 a.m.	FDA PRESENTATIONS	
	Adverse Events with Gadolinium Retention after Gadolinium-Based Contrast Agent Exposure: FAERS and Medical Literature Review	David Croteau, MD, FRCPC Medical Officer, Division of Pharmacovigilance I Office of Pharmacovigilance and Epidemiology (OPE) Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Epidemiologic Studies on the Safety of Gadolinium-Based Contrast Agents	Steven Bird, PhD, PharmD Team Lead, Division of Epidemiology I OPE, OSE, CDER, FDA
	Gadolinium-Based Contrast Agents US Sales Data 2006-2016	Patty Greene, PharmD Drug Utilization Analyst Division of Epidemiology II OPE, OSE, CDER, FDA

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AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

- 10:25 a.m. Gadolinium Retention: A Summary **Karen Bleich, MD**
Medical Officer
DMIP, ODE IV, OND, CDER, FDA
- Toward More Sensitive Endpoints in
Evaluating the Safety of Post-GBCA
Gadolinium Retention **Anthony Fotenos, MD, PhD**
Lead Medical Officer
DMIP, ODE IV, OND, CDER, FDA
- 10:55 p.m. Clarifying Questions for Presenters
- 11:25 p.m. **LUNCH**
- 12:25 p.m. **OPEN PUBLIC HEARING**
- 1:45 p.m. **BREAK**
- 1:55 p.m. Questions to the Committee/Committee Discussion
- 4:00 p.m. **ADJOURNMENT**