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

DRAFT 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 (GBCA) Magnetic Resonance Imaging (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	**Michelle Fedowitz, MD** Associate Director for Labeling DMIP, ODE IV, OND, CDER, FDA
8:00 a.m.	**GUEST SPEAKER PRESENTATION**	
	Pathophysiology of Gadolinium-based Contrast Agents and the 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**	Bayer HealthCare Pharmaceuticals, Inc.
	Presence of Gadolinium (Gd) in the brain and body	**Thomas Balzer, MD** Vice President, Medical & Clinical Affairs Radiology Radiology R&D Bayer HealthCare Pharmaceuticals, Inc.
8:45 a.m.	**INDUSTRY PRESENTATIONS**	Bracco Diagnostics Inc.
	Gadolinium Retention in Brain and Body Tissues: Safety Considerations	**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 Gadolinum 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
	Gadolinium-Based Contrast Agents US Sales Data 2006-2016	**Patty Greene, PharmD** Drug Utilization Analyst Division of Epidemiology II OPE, OSE, CDER, FDA
	Epidemiologic Studies on the Safety of Gadolinium-Based Contrast Agents	**Steve Bird, PhD, PharmD** Team Lead, Division of Epidemiology I OPE, OSE, CDER, FDA

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DRAFT 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**	

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