

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Joint Meeting of the Cardiovascular and Renal Drugs Advisory Committee (CRDAC) and the
Drug Safety and Risk Management Advisory Committee (DSaRM)

DRAFT AGENDA

May 2, 2011

The committees will discuss safety considerations of ultrasound contrast agents (materials intended to improve the clarity of ultrasound imaging), particularly related to new information and developments since the prior Advisory Committee meeting on the same topic on June 24, 2008. The discussion will include the results of required postmarketing safety studies and data from postmarketing surveillance. Specific drugs to be discussed include: (1) New drug application (NDA) 21-064, perflutren lipid microsphere injectable suspension, Lantheus Medical Imaging, Inc.; (2) NDA 20-899, perflutren protein-type A microspheres injectable suspension, GE Healthcare; and (3) the investigational new drug (IND) application for sulfur hexafluoride microbubble injection, Bracco Diagnostics, Inc. Perflutren lipid microsphere injectable suspension and perflutren protein-type A microspheres injectable suspension are indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border (improve the clarity of imaging of specific areas of the left lower side of the heart).

8:00 a.m.	Call to Order Introduction of Committee	Milton Packer, M.D. Acting Chair, CRDAC
	Conflict of Interest Statement	Nicole Vesely, Pharm.D. Designated Federal Officer, CRDAC
8:10 a.m.	<u>FDA Presentation</u> Regulatory History of Ultrasound Contrast Agents	Ira Krefting, M.D. Deputy Director for Safety, Division of Medical Imaging Products, Office of Drug Evaluation IV, CDER
8:30 a.m.	<u>Speaker Presentation</u> Current Cardiological Applications of Contrast Echocardiography	Sanjiv Kaul, M.D. (Guest Speaker) Professor of Medicine and Radiology Head, Division of Cardiovascular Medicine Oregon Health & Science University
9:00 a.m.	<u>Industry Presentation</u> DEFINITY® Post Marketing Studies Results DEFINITY® Pharmacovigilance Safety Data Review DEFINITY® Risk/Benefit Profile	<u>Lantheus Medical Imaging, Inc.- perflutren lipid microsphere injectable suspension (Definity)</u> Mark Hibberd, M.D. Senior Medical Director, Medical Affairs Lantheus Medical Imaging, Inc. Dana Washburn, M.D. Vice President, Clinical Development & Medical Affairs Lantheus Medical Imaging, Inc. Michael Main, M.D. Cardiologist St. Luke's Mid-America Heart Institute Kansas City, MO
9:30 a.m.	<i>Break</i>	
9:35 a.m.	<u>Industry Presentation</u>	<u>GE Healthcare - perflutren protein-type A microspheres injectable suspension (Optison)</u>

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DRAFT AGENDA (continued)

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	Introduction and Optison Post-Marketing Safety Data	Paul Sherwin, M.D., Ph.D. Senior Medical Director Global Clinical Development GE Healthcare
	Post-Marketing Clinical Studies of Optison Safety	Jonathan Goldman, M.D., FACC, FASE Executive Vice President-ICON Clinical Research San Francisco, California Assistant Clinical Professor of Medicine, UCSF San Francisco, California
	Peer-Reviewed Literature on Optison Human Safety	Steven Feinstein, M.D., FACC, FESC Professor of Medicine Director-Echocardiography Lab Rush University Medical Center Chicago, Illinois
	Impact of Product Labeling on Patient Care	Steven Feinstein, M.D., FACC, FESC
	Conclusions	Paul Sherwin, M.D., Ph.D.
10:05 a.m.	<i>Break</i>	
10:20 a.m.	<u>Industry Presentation</u> Safety Profile of SonoVue [®] (Sulfur Hexafluoride Microbubbles)	<u>Bracco Diagnostics, Inc - sulfur hexafluoride microbubble injection (SonoVue)</u> Alberto Spinazzi, M.D. Senior Vice President, Group Medical and Regulatory Affairs, Bracco Diagnostics, Inc.
10:50 a.m.	Questions to Industry Presenters	
11:10 a.m.	<u>FDA Presentation</u> Retrospective Observational Database Analyses for Definity and Optison	Janelle Charles, Ph.D Mathematical Statistician, Division of Biometrics VII, Office of Biostatistics, CDER
	<u>FDA Presentation (cont.)</u> Postmarketing Studies and Surveillance of Ultrasound Contrast Agents	Ross Filice, M.D. Medical Officer, Division of Medical Imaging Products, Office of Drug Evaluation IV, CDER
11:50 a.m.	Questions to FDA Presenters	
12:10 p.m.	<i>Lunch</i>	

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DRAFT AGENDA (continued)

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- 1:10 p.m. Open Public Hearing
- 2:10 p.m. Questions to the Committees
- 3:00 pm. *Break*
- 3:15 p.m. Questions to the Committees (continued)
- 4:00 p.m. *Adjourn*

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