

Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Cardiovascular and Renal Drugs Advisory Committee
December 10, 2008
Hilton Washington DC/Silver Spring, Maryland Ballroom
8727 Colesville Road, Silver Spring MD

Draft Agenda

8:00 a.m.	Call to Order Introduction of Committee	Robert A. Harrington, MD, FACC Acting Chair, CRDAC
	Conflict of Interest Statement	Elaine Ferguson, MS, RPh Designated Federal Official, CRDAC

The committee will discuss new drug application (NDA) 22-349, IMAGIFY (perflubutane polymer microspheres) injectable suspension, Acusphere Inc., proposed for use as an ultrasound imaging agent indicated for patients with stable chest pain being evaluated for inducible ischemia for the detection of coronary artery disease based on assessment of myocardial perfusion and wall motion.

8:05 a.m.	FDA Opening Remarks	Rafel (Dwayne) Rieves, MD Director Division of Medical Imaging and Hematology Products, CDER, OND, OODP
8:15 a.m.	<u>Sponsor Presentations</u> Introductory Remarks	Michael R. Slater Acusphere, Inc.
	Use of Ultrasound Contrast for the Detection of Myocardial Ischemia	Michael H. Picard, MD, FACC, FASE Director, Clinical Echocardiography Massachusetts General Hospital
	AI-700 Imaging	Professor R. Senior MD, DM, FRCP, FESC, FACC Consultant Cardiologist & Director of Cardiac Research, Northwick Park Hospital, London
	AI-700 Clinical Efficacy	Richard C. Walovitch, PhD Acusphere, Inc.
	AI-700 Clinical Safety	Howard C. Dittrich, MD, FACC Clinical Professor of Medicine University of California, San Diego
	Innate Immune Response and Complement Activation	John D. Lambris, PhD Dr. Ralph and Sallie Weaver Professor of Research Medicine Department of Pathology & Laboratory Medicine, University of Pennsylvania
	...Continue AI-700 Clinical Safety	Howard C. Dittrich, MD, FAAC
	Concluding Remarks	Richard C. Walovitch, PhD Acusphere, Inc.
10:15 a.m.	<u>Break</u>	

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| 10:30 a.m. | FDA Presentation – Clinical and Statistical review of the application, and FDA introduction to questions | Scheldon Kress, MD
Medical Officer
Division of Medical Imaging and Hematology Products,
CDER, OND, OODP

Anthony Mucci, Ph.D
Statistical Reviewer
Division of Biostatistics, CDER, OB, OTS |
| 11:30 a.m. | Questions to presenters | |
| 12:00 p.m. | Lunch | |
| 1:00 p.m. | Open Public Hearing | |
| 2:00 p.m. | FDA Questions to the committee | |
| 2:30 p.m. | Break | |
| 3:30 p.m. | Discussion of questions to the committee | |
| 4:30 p.m. | Adjourn | |