

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

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON, DC/SILVER SPRING
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND

OCTOBER 23, 2008

AGENDA

The committee will discuss the clinical development of radionuclide imaging products for the detection of amyloid to assist in the diagnosis of Alzheimer's disease.

8:00 a.m.	Call to Order and Opening Remarks	Larry B. Goldstein, M.D. Acting Chair Peripheral and Central Nervous System Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	Diem-Kieu H. Ngo, Pharm.D., BCPS Designated Federal Official
8:15 a.m.	FDA Introductory Remarks	CAPT Rafel Dwaine Rieves, M.D. Director, Division of Medical Imaging and Hematology Products (DMIHP), Office of Oncology Drug Products (OODP), OND, CDER, FDA
FDA PRESENTATION		
8:30 a.m.	Overview of Potential Imaging Claims	Alexander Gorovets, M.D. Medical Officer Team Leader DMIHP, OODP, OND, CDER, FDA
8:45 a.m.	Clinical Presentation, Diagnosis and Management of Alzheimer's Disease	Madhav Thambisetty, M.D., Ph.D. Staff Clinician Section of Brain Physiology and Metabolism National Institute on Aging
9:25 a.m.	Amyloid and Amyloid Deposition in the Brain	G. William Rebeck, Ph.D. Associate Professor Department of Neuroscience Georgetown University Medical Center
9:45 a.m.	BREAK	

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AGENDA
-CONTINUED-

INDUSTRY PRESENTATION

AVID RADIOPHARMACEUTICALS

- 10:00 a.m. Introduction and Development Overview of ¹⁸F-AV-45 **Daniel Skovronsky, M.D., Ph.D.**
CEO, Avid Radiopharmaceuticals
- Clinical Utility and Reference Standard for Amyloid Imaging **Christopher Clark, M.D.**
University of Pennsylvania, Department of Neurology
Medical Director, Avid Radiopharmaceuticals
- Development Plan Proposal **Daniel Skovronsky, M.D., Ph.D.**
CEO, Avid Radiopharmaceuticals
- 10:30 a.m. Clarifying Questions to Presenters

BAYER HEALTH CARE PHARMACEUTICALS

- 10:40 a.m. Introduction and Bayer Position **Madhu Anant, M.Sc.,RAC**
Deputy Director, Global Regulatory Affairs
Bayer Health Care Pharmaceuticals
- Clinical Utility **Kenneth Marek, M.D.**
Director, Institute of Neurodegenerative Disorders
Yale University Medical School
- Phase 3 Study Design – Standard Of Truth **Cornelia Reininger, M.D. Ph.D.**
Director, Global Clinical Development
Bayer Health Care Pharmaceuticals
- Conclusion **Madhu Anant, M.Sc.,RAC**
Deputy Director, Global Regulatory Affairs
Bayer Health Care Pharmaceuticals
- 11:10 a.m. Clarifying Questions to Presenters

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GE HEALTHCARE

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| 11:20 a.m. | Product Introduction, Proposed Indication and Clinical Development Plan for GE-067 | David Brooks, M.D., D.Sc.
Head of Neurology in Clinical Development, GE Healthcare
Hartnett Professor of Neurology, Imperial College London |
| | Data to Support [11C]PIB as a Standard of Truth (SoT) | William Klunk, M.D., Ph.D.
Professor of Psychiatry and Neurology
University of Pittsburgh, Pittsburgh, PA |
| | Clinical Utility for Amyloid Imaging | Keith A. Johnson, M.D.
Assistant Professor of Neurology, Harvard University
Director of Molecular Imaging, Massachusetts General Hospital, Boston, MA |
| 11:50 a.m. | Clarifying Questions to Presenters | |
| 12:00 p.m. | FDA Summary and Considerations | Qi Feng, M.D., Ph.D.
Medical Officer
DMIHP, OODP, OND, CDER, FDA |
| 12:30 p.m. | LUNCH | |
| 1:30 p.m. | Open Public Hearing | |
| 2:30 p.m. | Clarifying Questions to Presenters | |
| 2:45 p.m. | Panel Discussion/Committee Questions | |
| 3:30 p.m. | BREAK | |
| 3:45 p.m. | Panel Discussion/Committee Questions, Continued | |
| 5:00 p.m. | ADJOURNMENT | |