

**Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Medical Imaging and Radiopharmaceutical Drug Products (DMIRDP)**

**Public Meeting  
“Radioactive Drugs for Certain Research Uses”**

**November 16, 2004**

**Advisors and Consultants Conference Room 1066  
5630 Fishers Lane  
Rockville, MD 20857**

- 8:00 AM Welcome and Opening Remarks  
George Q. Mills, MD, MBA, Director, DMIRDP
- 8:15 AM RDRC vs. IND  
Lynn Panholzer, PharmD, Regulatory Project Manager, DMIRDP
- RDRC: Examples of Appropriate Studies  
Jerry Collins, PhD, Director, Laboratory of Clinical Pharmacology,  
Office of Research and Testing
- RDRC: No Clinically Detectable Pharmacological Effect  
Sally Loewke, MD, Deputy Director, DMIRDP
- RDRC Radiation Dose Limits  
Orhan Suleiman, MS, PhD, FAAPM, Senior Science Policy Advisor,  
Office of Drug Evaluation III
- Pediatric Studies Under an RDRC  
Sara F. Goldkind, MD, MA, Bioethicist, Office of Pediatric Therapeutics,  
Office of the Commissioner
- 9:15 AM **BREAK**
- 9:30 AM Public Presentations (related to the above topics)
- Mathew L. Thakur, PhD, Society of Nuclear Medicine  
Eric J. Hall, D.Phil., DSc., Chair, RDRC, Professor of Radiation  
Biophysics, Columbia University Medical Center  
Wayne L. Thompson, Department of Radiology,  
University of Tennessee Medical Center  
Henry D. Royal, MD, University of St. Louis,  
Mallinckrodt Institute of Radiology  
Michael J. Gelfand, MD, Children’s Hospital, Cincinnati, Ohio  
Kim A. Williams, MD, President, American Society of Nuclear Cardiology,  
Chair, RDRC, Professor of Medicine and Radiology, University of  
Chicago

10:45 AM Public Comment Period

11:15 AM **LUNCH**

1:30 PM Quality and Purity Standards in the Production of Radioactive Drugs Under RDRC  
Eldon Leutzinger, PhD, Chemistry Team Leader, DMIRDP

RDRC and the Safety of Women of Childbearing Potential  
Sally Loewke, MD, Deputy Director, DMIRDP

RDRC: Membership and Administrative Issues  
Richard Fejka, MS, BCNP, Nuclear Pharmacist, DMIRDP

2:00 PM Public Presentations (related to above topics)

Henry D. Royal, MD, University of St. Louis,  
Mallinckrodt Institute of Radiology  
Mathew L. Thakur, PhD, Society of Nuclear Medicine  
Terence Beven, MD, FACNP, American College of Nuclear Physicians

2:30 PM **BREAK**

2:45 PM Public Presentations (other RDRC topics)

Gary T. Smith, MD, RDRC Chair, University of Tennessee Medical Center  
Colin Garner, PhD, DSc, FRCPath, CEO, Xceleron Ltd., U.K.  
Michael Chansler, VP, Business Development, Accium BioSciences  
Andrew Taylor, MD, Emory University School of Medicine

3:30 PM Public Comment Period

4:30 PM **ADJOURN**