

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

**Cardiovascular and Renal Drugs Advisory Committee**

CDER Advisors and Consultants Staff Conference Room

**AGENDA**

**September 21, 2006**

The committee will discuss clinical data for aprotinin injection (trade name, TRASYLOL®), an approved product (NDA 020-304, Bayer Pharmaceuticals) with the indication for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery

8:00	Call to Order and Introductions	<b>William R. Hiatt, M.D.</b> Committee Chair Cardiovascular and Renal Drugs Advisory Committee
	Conflict of Interest Statement	<b>LCDR Cathy Groupe, B.S.N.</b> Executive Secretary Cardiovascular and Renal Drugs Advisory Committee

**FDA Presentations:**

8:10	Opening Remarks	<b>Dwaine Rieves, M.D.</b> Deputy Division Director, Division of Medical Imaging and Hematology Products, FDA
8:20	FDA Regulatory Overview	<b>Kathy M. Robie Suh, M.D., Ph.D.</b> Medical Officer, Division of Medical Imaging and Hematology Products, FDA
8:35	FDA OSE/Postmarket Reports	<b>Susan Lu, R.Ph .</b> Team Leader, Division of Drug Risk Evaluation, FDA
8:50	FDA Topics of Discussion	<b>Dwaine Rieves, M.D.</b>

**Guest Speaker Presentations:**

8:55		<b>Dennis Mangano, M.D., Ph.D.</b> Principal Scientist/Founder/CEO Ischemia Research and Education Foundation
9:40		Questions from the Committee
10:00		<b>Break</b>
10:15		<b>Keyvan Karkouti, M.D.</b> Clinical Studies Resource Centre Division of Clinical Investigations and Human Physiology Toronto General Research Institute

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**Guest Speaker Presentations (Continued):**

10:45 Questions from the Committee

**Bayer Pharmaceuticals Presentation:**

11:00 Introduction and Overview **Michael Rozycki, Ph.D.**  
Director, US Regulatory Affairs  
Bayer Pharmaceuticals Corporation

11:05 Methodological Considerations on **Robert Makuch, Ph.D.**  
the Two Recent Observational  
Studies of Aprotinin Professor of Biostatistics  
Yale University School of Public Health

11:40 Review of Clinical Data **Pamela Cyrus, M.D.**  
Vice President, US Medical Affairs  
Bayer Pharmaceuticals Corporation

11:50 Risk-Benefit Assessment **Jerrold Levy, M.D.**  
Professor and Deputy Chair for Research  
Emory University School of Medicine  
Director of Cardiothoracic Anesthesiology  
Emory University Hospital  
Department of Anesthesiology

12:00 Questions from the Committee

12:15 **Lunch**

1:00 **Open Public Hearing**

2:00 Committee Questions to Speakers

3:00 FDA Questions To the Committee

5:00 **Adjourn**