# FOOD AND DRUG ADMINISTRATION

## Center for Drug Evaluation and Research

*Cardiovascular & Renal Drugs Advisory Committee (CRDAC) in Joint Session with the*

*Drug Safety & Risk Management Advisory Committee (DSaRM)*

## AGENDA

**September 12, 2007**

---

*The committee will discuss updated information on the risks and benefits of aprotinin injection (Trasylol®, Bayer Pharmaceuticals) to reduce perioperative blood loss and the need for blood transfusion in certain patients undergoing coronary artery bypass grafting.*

---

| | | |
|---|---|---|
| 8:00 | Call to Order<br>Introduction of Committee | **Robert A. Harrington, M.D.**<br>Acting Chair, CRDAC |
| | Conflict of Interest Statement | **Mimi T. Phan, Pharm.D., R.Ph.**<br>Acting Designated Federal Officer, CRDAC |
| 8:10 | Opening Remarks | **Gerald Dal Pan, M.D.**<br>Director, Office of Surveillance and Epidemiology (OSE), CDERFDA |
| 8:15 | Trasylol (Aprotinin) NDA 20-304<br>Overview | **George Shashaty, M.D.**<br>Medical Officer, Division of Medical Imaging and Hematology Products (DMIHP),<br>Office of Oncology Drug Products (OODP),<br>CDER, FDA |
| 8:30 | Coronary Artery Bypass | **Paul Corso, M.D.**<br>Director, Cardiovascular Surgery<br>Washington Hospital Center<br>Washington, DC |
| 8:50 | A Propensity Score Comparison of Aprotinin vs. Tranexamic Acid<br>Updated Analysis of a Large, Single Center Cardiac Surgery Database | **Keyvan Karkouti, M.D., F.R.C.P.C., M.Sc.**<br>Clinical Studies Resource Centre<br>Division of Clinical Investigations and Human Physiology Toronto General Research Institute |
| 9:00 | Safety of Aprotinin vs. Epsilon Aminocaproic Acid vs. Tranexamic Acid | **Dennis Mangano, M.D., Ph.D.**<br>Principal Scientist/Founder/CEO<br>Ischemia Research and Education Foundation |
| 9:30 | Break | |

**SPONSOR PRESENTATION**

| | | |
|---|---|---|
| 9:45 | Bayer Introduction | **Kemal Malik, M.D.**<br>Head of Global Development and a Member of the Board of Management for Bayer HealthCare Pharmaceuticals |
| | Safety of Aprotinin vs. Aminocaproic Acid During CABG Surgery | **Sebastian Schneeweiss, M.D., Sc.D.**<br>Associate Professor<br>Department of Epidemiology<br>Harvard, School of Public Health |
| | Trasylol® (aprotinin injection)<br>Review of Clinical Data with a Focus on Specific Safety Events | **Pamela Cyrus, M.D.**<br>Vice President, US Medical Affairs<br>Bayer Pharmaceuticals Corporation |

# FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research

*Cardiovascular & Renal Drugs Advisory Committee (CRDAC) in Joint Session with the*
*Drug Safety and Risk Management Advisory Committee (DSaRM)*

## AGENDA
**September 12, 2007**

| | | |
|---|---|---|
| | Aprotinin Studies: Weight of Evidence | **Robert W. Makuch, Ph.D.**<br>Professor, Biostatistics<br>Yale, School of Public Health |
| | Trasylol® (aprotinin injection)<br>Risks and Benefits from a Surgeon's Perspective | **Peter K. Smith, M.D.**<br>Professor and Division Chief<br>Thoracic and Cardiovascular Surgery<br>Duke University Medical Center |

**FDA PRESENTATION**

| | | |
|---|---|---|
| 10:45 | Aprotinin: Observational Studies | **Rita Ouellet-Hellstrom, Ph.D., M.P.H.**<br>OSE, Division of Drug Risk Evaluation (DDRE)<br>CDER, FDA |
| 11:05 | Statistical Review of the Observational Studies of Aprotinin Safety Part I: Methods, Mangano and Karkouti Studies | **Mark Levenson, Ph.D.**<br>Statistical Reviewer, Office of Biostatistics, Division of Biometrics VI, CDER, FDA |
| | Statistical Review of the Observational Studies of Aprotinin Safety Part II: The i3 Safety Study | **Chris Holland, M.S.**<br>Statistical Reviewer, Office of Biostatistics, Division of Biometrics VI, CDER, FDA |
| 11:45 | *Questions to the Presenters* | |
| 12:00 p.m. | Lunch | |
| 1:00 p.m. | **Open Public Hearing** | |
| 2:00 p.m. | *Committee Discussion* | |
| 3:30 p.m. | Break | |
| 3:45 p.m. | *Committee Discussion and Questions to the CRDAC/DSaRM* | |
| 5:00 p.m. | Adjourn | |