

# 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

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*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.*

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8:00	Call to Order Introduction of Committee	<b>Robert A. Harrington, M.D.</b> Acting Chair, CRDAC
	Conflict of Interest Statement	<b>Mimi Phan, Pharm.D., R.Ph.</b> Acting Designated Federal Officer, CRDAC
8:10	Opening Remarks	<b>Gerald Dal Pan, M.D., M.H.S.</b> Director, Office of Surveillance and Epidemiology (OSE) FDA
8:15	FDA Overview	<b>George Shashaty, M.D.</b> Medical Officer, FDA Division of Medical Imaging and Hematology Products Office of Oncology Drug Products
8:30	Guest Speaker	
8:50	Guest Speaker	
9:00	Guest Speaker	
9:20	Break	
9:35	Sponsor Presentation	<b>Bayer Pharmaceuticals</b>
10:35	FDA Presentation	<b>Rita Ouellet-Hellstrom, Ph.D.</b> Epidemiologist, FDA, OSE  <b>Mark Levenson, Ph.D.</b> Statistical Reviewer, Division of Biometrics, FDA  <b>Chris Holland, M.S.</b> Statistical Reviewer, Division of Biometrics, FDA
11:35	Questions to the Presenters	
12:00 p.m.	Lunch	

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- 1:00 p.m. Open Public Hearing
- 2:00 p.m. Questions to the CRDAC/DSaRM and Discussion
- 3:30 p.m. Break
- 3:45 p.m. Questions to the CRDAC/DSaRM and Discussion (continued)
- 5:00 p.m. Adjourn