FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC)

AGENDA

July 29, 2008

8:30 a.m.	Call to Order Introduction of Committee	**H. James Williams, M.D.** Acting Chair, AAC
	Conflict of Interest Statement	**Nicole Vesely, Pharm.D.** Designated Federal Official, AAC
8:45 a.m.	Opening Remarks	**Jeffrey Siegel, M.D.** Clinical Team Leader, Division of Anesthesia, Analgesia and Rheumatology Products, CDER/FDA

The committee will discuss biologics license application (BLA) 125276, ACTEMRA (tocilizumab), Hoffmann-La Roche, Inc., for the proposed treatment of adult patients with moderately to severely active rheumatoid arthritis.

8:50 a.m.	**Sponsor Presentation** Introduction/Overview	**Hoffmann-La Roche, Inc.** **Jonathan Leff, M.D.** Vice President and Clinical Development Head, Inflammation Disease Biology Area
	Efficacy	**Kenneth Bahrt, M.D.** Global Medical Director, Autoimmunity
	Safety	**Joel Krasnow, M.D.** Clinical Science Leader
	Risk Mitigation/Pharmacovigilance	**Philippe Van der Auwera, M.D., Ph.D.** Global Head of Drug Safety
	Summary	**Kenneth Bahrt, M.D.** Global Medical Director, Autoimmunity
10:20 a.m.	*Questions from the Committee to the Sponsor*	
10:35 a.m.	Break	
10:50 a.m.	**FDA Presentation** Actemra (tocilizumab) for Rheumatoid Arthritis: FDA Perspective	**BLA 125276** **Sarah Okada, M.D.** Clinical Team Leader, Division of Anesthesia, Analgesia and Rheumatology Products, CDER/FDA
11:35 a.m.	*Questions from the Committee to the FDA*	
11:45 a.m.	Lunch	
12:45 p.m.	Open Public Hearing	
1:45 p.m.	*Questions to the AAC and AAC Discussion*	
3:30 p.m.	Adjourn	