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	Acting Chair, AAC
	Conflict of Interest Statement	**Nicole Vesely, Pharm.D.** Designated Federal Official, AAC
8:45 a.m.	Opening Remarks	**Bob Rappaport, M.D., Director** Division of Anesthesia, Analgesia & Rheumatology Products (DAARP), CDER, FDA

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

8:50 a.m.	**Sponsor Presentation**
10:20 a.m.	*Questions from the Committee to the Sponsor*
10:35 a.m.	Break
10:50 a.m.	**FDA Presentation**
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