FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC)

AGENDA

November 29, 2006

8:00 a.m.	Call to Order Introduction of Committee	**Joan Bathon, M.D.** Acting Chair, AAC
	Conflict of Interest Statement	**Johanna Clifford, M.Sc., RN** Designated Federal Official, AAC
8:15 a.m.	Opening Remarks	**Bob Rappaport, M.D., Director** Division of Anesthesia, Analgesia & Rheumatology Products (DAARP), CDER, FDA

The committee will discuss the safety and efficacy of the non-steriodal anti-inflammatory drug (COX-2 inhibitor) drug application NDA 20-998, Supplement 021, trade name, CELEBREX (celecoxib), Pfizer, Inc. for the proposed indication of the relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA) in patients two years and older.

FDA Presentation

8:30 a.m.	Introduction of Juvenile Rheumatoid Arthritis & State of the Art Treatment Armamentarium	**Carolyn Yancey, M.D., Medical Officer** DAARP, CDER, FDA
	Cardiovascular Risk and NSAIDS	**Sharon Hertz, M.D., Deputy Director** DAARP, CDER, FDA
9:30 a.m.	**Sponsor Presentation**	***Pfizer, Inc.***
	Juvenile Rheumatoid Arthritis: Clinical Overview	**Daniel J. Lovell, M.D., MPH** Cincinnati Children's Hospital Medical Center
	Celecoxib in the Treatment of Juvenile Rheumatoid Arthritis	**Simon Lowery, M.D.** Pfizer, Inc.
10:30 a.m.	Risk/Benefit Profile of Celebrex for Use in JRA	**Jeffrey Siegel, M.D., Medical Team Leader** DAARP, CDER, FDA
11:00 a.m.	*Break*	
11:15 p.m.	Open Public Hearing	
12:15 p.m.	*Lunch*	
1:15 p.m.	*Questions from the Committee*	
2:15 p.m.	Break	
2:30 p.m.	*Questions to the AAC and AAC Discussion*	
5:00 p.m.	*Adjourn*	