FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC)

Proposed AGENDA

April 12, 2007

8:00 a.m.	Call to Order Introduction of Committee	**Dennis Turk, Ph.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 new drug application (NDA) 21-389/21-772, ARCOXIA (etoricoxib), Merck & Co., Inc., proposed treatment for the relief of signs and symptoms of osteoarthritis.

FDA Presentation

8:30 a.m.	History of Cardiovascular Findings from NSAID Studies	**Sharon Hertz, M.D., Deputy Director** DAARP, CDER, FDA
9:00 a.m.	**Sponsor Presentation**	***Merck Co., Inc.***
	Introduction	Zak Huang, M.D. Director, Regulatory Affairs, Merck Research Labs (MRL)
	Unmet Medical Need in OA	Grant Cannon, M.D. Professor of Medicine University of Utah, Division of Rheumatology
	Efficacy & Safety Summary	Sean Curtis, M.D. Executive Director, Clinical Research, MRL
10:00 a.m.	FDA Presentation of Etoricoxib Application	Robert Shibuya, M.D. DAARP, CDER, FDA
11:00 a.m.	An Epidemiologic Perspective on Etoricoxib	David Graham, M.D., MPH Office of Surveillance and Epidemiology, CDER, FDA
11:15 a.m.	*Break*	
11:30 p.m.	Open Public Hearing	
12:30 p.m.	*Lunch*	
1:30 p.m.	Questions from the Committee	
2:30 p.m.	*Break*	
2:45 p.m.	Questions to the AAC and AAC Discussion	
5:00 p.m.	*Adjourn*	