Joint Meeting of the
Arthritis Advisory Committee
and the Drug Safety and Risk Management Advisory Committee
Hilton, 620 Perry Parkway, Gaithersburg, MD
February 16, 17, and 18, 2005

Agenda

Wednesday, February 16, 2005

8:00	Call to Order Conflict of Interest Statement	Alastair J. J. Wood, M.D., Chair Kimberly Littleton Topper, M.S. Executive Secretary
8:10	Welcome	Steven Galson, M.D., M.P.H. Acting Director, Center for Drug Evaluation and Research (CDER)
8:20	Regulatory History	Jonca Bull, M.D. Director, Office of Drug Evaluation V, CDER
8:30	Gastrointestinal Effects of NSAIDs and COX-2 Specific Inhibitors	Byron Cryer, M.D. University of Texas Southwestern Medical School
9:00	Mechanism Based Adverse Cardiovascular Events and Specific Inhibitors of COX-2	Garret A. FitzGerald, M.D. University of Pennsylvania School of Medicine
9:30	Committee Questions to Speakers	
9:50	Break	

Vioxx (rofecoxib)

Sponsor Presentation:

10:00	Rofecoxib	Ned S. Braunstein, M.D. Senior Director Merck Research Laboratories

FDA Presentation:

10:45	Vioxx Cardiovascular Safety	Lourdes Villalba, M.D. Medical Officer, CDER
11:30	Committee Questions to Speakers	
12:15	Lunch	

Celebrex (celecoxib)

Sponsor Presentation:

1:00	Introduction	Joseph M. Feczko, M.D. Senior Vice President, Pfizer Global Research and Development, and President, Worldwide Development

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Wednesday, February 16, 2005 (cont.)

	Cardiovascular Safety and Risk/Benefit Assessment of Celecoxib	Kenneth M. Verburg, Ph.D. Vice President, Inflammation and Immunology, Clinical Research and Development, Pfizer Global Research and Development
	FDA Presentation:	
1:45	COX-2 CV Safety: celecoxib	James Witter, M.D., Ph.D. Lead Medical Officer, CDER
	NIH and Investigator Presentation:	
2:15	Celecoxib in Adenoma Prevention Trials:	
	The APC Trial (Prevention of Sporadic Colorectal Adenomas with Celecoxib)	Ernest Hawk, M.D., MPH Director, Office of Centers, Training, & Resources NCI/OD/NIH
	The PreSAP Trial (Prevention of Colorectal Sporadic Adenomatous Polyps)	Bernard Levin, M.D M.D. Anderson Cancer Center The University of Texas
2:35	Committee Questions to Speakers	
3:15	Break	

Bextra (valdecoxib) and parecoxib

3:30	***Sponsor Presentation:***	
	Cardiovascular Safety and Risk/Benefit Assessment of Valdecoxib and Parecoxib	Kenneth M. Verburg, Ph.D.
	Closing	Joseph M. Feczko, M.D.
	FDA Presentation:	
4:00	COX-2 CV Safety: valdecoxib – parecoxib	James Witter, M.D., Ph.D.

Naproxen

	Sponsor Presentation:	
4:30	Bayer and Roche Joint Presentation on Naproxen	Leonard M. Baum, R.Ph. Vice President, Regulatory Affairs Bayer HealthCare Consumer Care Division Martin H. Huber, M.D. Vice President, Global Head Drug Safety Risk Management, Hoffmann-La Roche, Inc.
5:10	Committee Questions to Speakers	

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Thursday, February 17, 2005

8:00	Call to Order Conflict of Interest Statement	Alastair J. J. Wood, M.D., Chair Kimberly Littleton Topper, M.S.
8:10	Interpretation of Observational Studies of Cardiovascular Risk of Non-steroidal Drugs	Richard Platt, M.D., M.S. Harvard Medical School
8:40	Review of Epidemiologic Studies on Cardiovascular Risk with Selected NSAIDs	David Graham, M.D., M.P.H. Medical Officer, CDER
9:10	Committee Questions to Speakers	

Arcoxia (etoricoxib)

Sponsor Presentation:

9:30	Etoricoxib	Sean P. Curtis, M.D. Senior Director, Clinical Research Merck Research Laboratories

FDA Presentation:

10:00	Analysis of Cardiovascular Thromboembolic Events With Etoricoxib	Joel Schiffenbauer, M.D. Medical Officer, CDER
10:15	Break	

Lumiracoxib

Sponsor Presentation:

10:30	Lumiracoxib: Introduction	Mathias Hukkelhoven, Ph.D. Senior Vice President and Global Head, Drug Regulatory Affairs Novartis Pharmaceuticals Corporation
	Gastrointestinal and Cardiovascular Safety of Lumiracoxib, Ibuprofen, and Naproxen	Patrice Matchaba, M.D. Global Medical Director Lumiracoxib Program, Novartis Pharmaceuticals Corporation

FDA Presentation:

11:00	Lumiracoxib	Lourdes Villalba, M.D. Medical Officer, CDER
11:15	Committee Questions to Speakers	
12:00	Lunch	
1:00	Open Public Hearing	
3:00	Break	
3:15	Committee Discussion	

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Friday, February 18, 2005

8:00	Call to Order Conflict of Interest Statement	Alastair J. J. Wood, M.D.,Chair Kimberly Littleton Topper, M.S.
Naproxen	***Investigator Presentation:***	
8:10	Alzheimer's Prevention Study: ADAPT (Alzheimer's Disease Anti-Inflammatory Prevention Trial)	Constantine Lyketsos, M.D. The John Hopkins Hospital
Additional Background Presentations		
8:25	Interpretation of Observed Differences in the Frequency of Events When the Number of Events is Small	Milton Packer, M.D. University of Texas Southwestern Medical School
8:55	Committee Questions to Speakers	
9:10	Clinical Trial Design and Patient Safety: Future Directions for COX-2 selective NSAIDs	Robert Temple, M.D. Director, Office of Medical Policy, CDER
9:40	Issues in Projecting Increased Risk of Cardiovascular Events to the Exposed Population	Robert O'Neill, Ph.D. Director, Office of Biostatistics, CDER
10:10	Committee Questions to Speakers	
10:30	Break	
10:40	Summary of Meeting Presentations	Sharon Hertz, M.D. Deputy Director, Div. of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products, CDER
11:10	Advisory Committee Discussion of Questions	
12:00	Lunch	
1:00	Advisory Committee Discussion of Questions	
3:00	Break	
3:15	Advisory Committee Discussion of Questions	
4:45	Meeting Wrap-up	Alastair J. J. Wood, M.D.
5:00	Adjourn	