FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Arthritis Advisory Committee (AAC)
and the Drug Safety and Risk Management Advisory Committee (DSaRM)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
April 24-25, 2018

AGENDA

The committees will be asked to discuss supplemental new drug application (NDA) 20998 for Celebrex (celecoxib) capsules submitted by Pfizer, Inc., which includes the results from the PRECISION (Prospective Randomized Evaluation of Celecoxib Integrated Safety vs. Ibuprofen Or Naproxen) trial, a cardiovascular outcomes randomized controlled trial that compared celecoxib to ibuprofen and naproxen, and determine whether the findings of the trial change FDA's current understanding of the safety of these three NSAIDs. In order to interpret some of the PRECISION findings, the committee will also consider the clinical implications of the drug interactions between each of these three NSAIDs and aspirin in patients taking aspirin for secondary prevention of cardiovascular disease.

Day 1: Tuesday, April 24, 2018

8:00 a.m.	Call to Order and Introduction of Committee	**Richard A. Neill, MD** Acting Chairperson, AAC
8:05 a.m.	Conflict of Interest Statement	**Jennifer Shepherd, RPh** Acting Designated Federal Officer, AAC
8:10 a.m.	FDA Introductory Remarks	**Judith A. Racoosin, MD, MPH** Deputy Director for Safety Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**FDA PRESENTATION**	
	Regulatory History of the Interaction Between Aspirin and Other Nonprescription NSAIDs	**Jenny Lee Kelty, MD** Medical Officer Division of Nonprescription Drug Products (DNDP) Office of Drug Evaluation IV (ODE-IV) OND, CDER, FDA
8:30 a.m.	**APPLICANT PRESENTATIONS**	**Pfizer, Inc.**
	Aspirin and NSAIDs studied in PRECISION: Aspirin-NSAID Interactions	**Milton L. Pressler, MD** Vice President, Clinical Development Pfizer Inc. New York, NY

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Background on Celecoxib, Ibuprofen, Naproxen Interaction with Aspirin	**Jack Cook, PhD** Vice President, Clinical Pharmacology Pfizer Inc. Groton, CT
	Concluding Remarks	**Milton L. Pressler, MD**
8:55 a.m.	**INDUSTRY PRESENTATION**	**Bayer HealthCare**
	A Review of Naproxen/Aspirin Pharmacodynamic Interaction Data from the Kontakt Study	**Paul Gurbel, MD** Director, Inova Center for Thrombosis Research and Drug Development, Inova Heart and Vascular Institute **Alberto Parades-Diaz, MD** Director, Global Medical Affairs Analgesics Bayer HealthCare
9:15 a.m.	Clarifying Questions	
9:35 a.m.	**FDA PRESENTATIONS**	
	Aspirin-NSAID Interactions	**Martin Rose, MD, JD** Medical Officer and Clinical Team Leader Division of Cardiovascular and Renal Products (DCRP) Office of Drug Evaluation I (ODE-I) OND, CDER, FDA
	Aspirin-Naproxen Drug Interaction	**Sudharshan Hariharan, PhD** Team Leader Division of Clinical Pharmacology-1 (DCP-1) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS), CDER, FDA
10:20 a.m.	**BREAK**	
10:35 a.m.	**FDA PRESENTATION**	
	Regulatory History: NSAID-associated Cardiovascular Thrombotic Events	**Judith A. Racoosin, MD, MPH**

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10:50 a.m.	**APPLICANT PRESENTATIONS**	**Pfizer, Inc.**
	Introductive and Perspective on PRECISION	**Milton L. Pressler, MD** Vice President, Clinical Development Pfizer Inc. New York, NY
	The PRECISION Trial Prospective Randomized Evaluation of Celecoxib Integrated Safety versus Ibuprofen or Naproxen	**Steven E. Nissen, MD** Professor and Chairman, Cardiovascular Medicine Cleveland Clinic, Cleveland, OH
	Rheumatologist's Perspective Implications for OA/RA Patient Management	**Stanley B. Cohen, MD** Clinical Professor of Rheumatology UT Southwestern Medical School, Dallas, TX
	Concluding Remarks Contribution of PRECISION to Guide the Safe and Appropriate Use of Celecoxib and its Comparators	**Milton L. Pressler, MD**
12:20 p.m.	Clarifying Questions	
12:40 p.m.	**LUNCH**	
1:40 p.m.	**FDA PRESENTATIONS**	
	Clinical Assessment of the PRECISION Trial	**Anjelina Pokrovnichka, MD** Medical Officer DAAAP, ODE-II, OND, CDER, FDA
	Statistical Assessment of the PRECISION Trial	**Bo Li, PhD** Statistical Reviewer Division of Biometrics VII Office of Biostatistics (OB), OTS, CDER, FDA
3:10 p.m.	Clarifying Questions	
3:30 p.m.	**BREAK**	
3:45 p.m.	**INDUSTRY PRESENTATIONS**	**Consumer Healthcare Products Association**
	OTC Industry Perspective and Educational Efforts	**Barbara A. Kochanowski, PhD** Sr. Vice President, Regulatory & Scientific Affairs Consumer Healthcare Products Association

	INDUSTRY PRESENTATIONS (CONT.)	**Johnson & Johnson Consumer Inc.**
	OTC Ibuprofen: Cardiovascular Safety and Consumer Use	**Edwin Kuffner, MD** Chief Medical Officer Johnson & Johnson Consumer Inc
4:15 p.m.	Clarifying Questions	
5:00 p.m.	**ADJOURNMENT**	

Day 2: Wednesday, April 25, 2018

8:00 a.m.	Call to Order and Introduction of Committee	**Richard A. Neill, MD** Acting Chairperson, AAC
8:05 a.m.	Conflict of Interest Statement	**Jennifer Shepherd, RPh** Acting Designated Federal Officer, AAC
8:30 a.m.	**OPEN PUBLIC HEARING**	
9:30 a.m.	Charge to the Committee	**Judith A. Racoosin, MD, MPH** Deputy Director for Safety DAAAP, ODE-II, OND, CDER, FDA
9:40 a.m.	Questions to the Committee/Committee Discussion	
10:30 a.m.	**BREAK**	
10:45 a.m.	Questions to the Committee/Committee Discussion	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	