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)
College Park Marriott Hotel and Conference Center, General Vessey Ballroom
3501 University Blvd. East, Hyattsville, Maryland
January 11, 2019

AGENDA

The committees will discuss supplemental new drug application (sNDA) 021-856, ULORIC (febuxostat) tablets, sponsored by Takeda Pharmaceuticals, which includes the results from the postmarketing safety trial required by FDA to evaluate the cardiovascular safety of febuxostat, entitled "Cardiovascular Safety of Febuxostat and Allopurinol in Patients with Gout and Cardiovascular Morbidities (CARES)." Febuxostat is a xanthine oxidase inhibitor indicated for the chronic management of hyperuricemia in patients with gout. The committee's discussion will include the results from the CARES trial, the benefit risk assessment of febuxostat, and potential regulatory actions.

8:00 a.m.	Call to Order and Introduction of Committee	**Maria Suarez-Almazor, MD, PhD** Acting Chairperson, AAC
8:05 a.m.	Conflict of Interest Statement	**Yinghua Wang, PharmD, MPH** Designated Federal Officer, AAC
8:10 a.m.	FDA Opening Remarks	**Nikolay P. Nikolov, MD** Associate Director for Rheumatology Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Takeda Pharmaceuticals**
	Introduction and Regulatory History	**Beth-Anne Knapp** Vice President, Global Regulatory Affairs Takeda Development Centers America
	Gout: Disease Burden, Background & Treatment Landscape	**Michael A. Becker, MD** Professor of Medicine Emeritus University of Chicago
	CARES and Cardiovascular Safety of Febuxostat	**William B. White, MD** Professor of Medicine Cardiology Center University of Connecticut School of Medicine
	Efficacy of Febuxostat	**Lhanoo Gunawardhana, MD, PhD** Senior Medical Director Clinical Science, Marketed Products Takeda Development Centers America

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Benefit/Risk Assessment	**John Affinito, MD** Executive Medical Director Global Patient Safety & Evaluation, Marketed Products Takeda Development Centers America
	Clinical Perspectives	**N. Lawrence Edwards, MD, MACP, MACR** Professor and Vice Chairman Department of Medicine, University of Florida
9:45 a.m.	Clarifying Questions	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Introduction and Regulatory History	**Rosemarie Neuner, MD, MPH** Medical Officer DPARP, ODE-II, OND, CDER, FDA
	Statistical Assessment of Cardiovascular Safety of CARES	**Ya-Hui Hsueh, PhD** Statistical Reviewer Division of Biometrics VII, Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Characteristics of Febuxostat and Allopurinol Users in Real World Settings and Utilization Patterns	**Marie Bradley, PhD, MScPH, MPharm** Epidemiology Reviewer Division of Epidemiology II Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology CDER, FDA
	Clinical Considerations and Benefit-Risk Assessment	**Rosemarie Neuner, MD, MPH**
11:30 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	

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1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Charge to the Committees	**Nikolay P. Nikolov, MD**
2:05 p.m.	Questions to the Committees/ Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committees/ Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	