

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC)

AGENDA

November 24, 2008

8:30 a.m.	Call to Order Introduction of Committee	Kathleen O'Neil, M.D. Acting Chair, AAC
	Conflict of Interest Statement	Nicole Vesely, Pharm.D. Designated Federal Official, AAC
8:45 a.m.	Opening Remarks	Jeffrey Siegel, M.D. Clinical Team Leader, Division of Anesthesia, Analgesia and Rheumatology Products, CDER/FDA

The committee will discuss new drug application (NDA) 21856, ULORIC (febuxostat), Takeda Pharmaceuticals North America, Inc., for the proposed treatment of hyperuricemia in patients with gout.

8:50 a.m.	Clinical Overview of Gout	John Cush, M.D. Director of Clinical Rheumatology Baylor Research Institute Baylor University Medical Center
9:10 a.m.	Interpretation of Safety Data in Clinical Trials	Milton Packer, M.D. The Gayle and Paul Stoffel Distinguished Chair in Cardiology Department of Clinical Sciences University of Texas Southwestern Medical School
9:40 a.m.	<i>Questions from the Committee to Speakers</i>	
9:50 a.m.	Break	
10:05 a.m.	<u>Sponsor Presentation</u> Introduction	<u>Takeda Pharmaceuticals North America, Inc.</u> Nancy Joseph-Ridge, M.D. President Takeda Global Research and Development Center, Inc (US)
	Gout: Disease Burden and Unmet Patient Needs	Michael A. Becker, M.D. Professor of Medicine Emeritus The University of Chicago
	Febuxostat Development Program (Efficacy and Safety)	Nancy Joseph-Ridge, M.D. President Takeda Global Research and Development Center, Inc (US)

~~Evaluation of Adjudicated~~
Cardiovascular Events in the
Febuxostat Program

~~William B. White, M.D.~~

Professor of Medicine and Chief,
Division of Hypertension and Clinical Pharmacology
Pat and Jim Calhoun Cardiology Center
Director, Clinical Trials Unit
University of Connecticut School of Medicine –
Farmington

Risk/Benefit and Conclusion

Nancy Joseph-Ridge, M.D.

President
Takeda Global Research and Development Center, Inc
(US)

11:35 a.m. *Questions from the Committee to the Sponsor*

12:00 p.m. Lunch

1:00 p.m. **FDA Presentation**
Febuxostat (Uloric) for
Hyperuricemia in Gout

NDA 21856
Jane Gilbert, M.D., Ph.D.
Medical Officer, Division of Anesthesia, Analgesia and
Rheumatology Products, CDER/FDA

1:50 p.m. *Questions from the Committee to the FDA*

2:00 p.m. Open Public Hearing

3:00 p.m. *Questions to the AAC and AAC Discussion*

4:30 p.m. Adjourn