

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	Acting Chair, AAC
	Conflict of Interest Statement	Nicole Vesely, Pharm.D. Designated Federal Official, AAC
8:45 a.m.	Opening Remarks	

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.	Introductory Presentations
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>
11:35 a.m.	<i>Questions from the Committee to the Sponsor</i>
12:00 p.m.	Lunch
1:00 p.m.	<u>FDA Presentation</u>
1:50 p.m.	<i>Questions from the Committee to the FDA</i>
2:00 p.m.	Open Public Hearing
3:00 p.m.	<i>Questions to the AAC and AAC Discussion</i>
4:30 p.m.	Adjourn