Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Cardiovascular and Renal Drugs Advisory Committee
March 18, 2009
Marriott Conference Centers,
UMUC Inn and Conference Center by Marriott,
3501 University Blvd., East, Adelphi, MD

DRAFT Agenda

8:00 a.m.	Call to Order Introduction of Committee	**Robert A. Harrington** Chair, CRDAC
	Conflict of Interest Statement	**Elaine Ferguson, M.S.,R.Ph.** Designated Federal Official, CRDAC

The committee will discuss new drug application (NDA) 22-425, dronedarone 400 milligrams oral tablets, Sanofi Aventis, for the proposed indication in patients with a history of, or current atrial fibrillation or atrial flutter, for the reduction of the risk of cardiovascular hospitalization or death.

8:05 a.m.	FDA Opening Remarks	**Norman Stockbridge, M.D.** Director, Cardiovascular and Renal Drug Products, CDER
8:15 a.m.	**Sponsor Presentations** Introduction	**Richard Gural, Ph.D.** Sanofi-Aventis
	Unmet Medical need in Patients with Atral Fibrillation/Flutter: Rate and Rhythm Control Studies	**Gerald Naccarelli, M.D.** Hershey Medical Center
	Effect of Dronedarone on Major Cardiovascular Events: The ANDROMEDA and ATHENA Trials	**Milton Packer, M.D.** UT Southwestern Medical Center at Dallas
	Safety of Dronedarone in Atrial Fibrillation/Flutter Trials	**Paul Chew, M.D.** Sanofi-Aventis
	Benefit-Risk of Dronedarone Implications for Patients and Physicians	**John Camm, B.Sc., M.D., F.R.C.P** St. George's, University of London
	Questions to the Sponsor	
10:00 a.m.	**Break**	
10:15 a.m.	**FDA Presentations**	**Abraham Karkowsky, M.D.** Medical Officer, Cardiovascular and Renal Drug Products, CDER
11:00 a.m.	Questions to the FDA	
12:00	**Lunch**	

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1:00 p.m.	Open Public Hearing
2:00 p.m.	Questions to Sponsor and FDA Discussion of questions to committee
3:30 p.m.	**Break**
3:15 p.m.	Discussion of questions to committee (continued)
5:00 p.m.	Adjourn