FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Cardiovascular and Renal Drugs Advisory Committee
Sheraton College Park, Beltsville, MD

DRAFT AGENDA
December 11, 2007

The committee will discuss new drug application (NDA) 22-034, vernakalant hydrochloride injection, 20 milligrams per milliliter, Astellas Pharma U.S., Incorporated, for the proposed indication of use for conversion of atrial fibrillation to normal sinus rhythm

8:00	Call to Order and Introductions	**William R. Hiatt, M.D.** Committee Chair Cardiovascular and Renal Drugs Advisory Committee
	Conflict of Interest Statement	**LCDR Cathy A. Miller, M.P.H., R.N.** Designated Federal Official Cardiovascular and Renal Drugs Advisory Committee
8:05	Introduction and Background	**Norman Stockbridge, M.D., Ph.D.** Director, Division of Cardiovascular and Renal Products FDA Center for Drug Evaluation and Research
8:10	**FDA Guest Speaker Presentation:**	
	Cardioversion for Atrial Fibrillation	**Christopher B. Granger, M.D.** Cardiologist Duke University School of Medicine Durham, North Carolina
9:30	**Astellas Pharma US, Inc. Presentation:**	
	Introduction	**Donald L. Raineri, Pharm.D.** Senior Director, Regulatory Affairs Astellas Pharma US, Inc. Deerfield, Illinois
	Clinical Overview of Atrial Fibrillation	**Edward L.C. Pritchett, M.D.** Consulting Professor of Medicine Duke University Medical Center Durham, North Carolina
	Mechanism of Action	**Greg Beatch, Ph.D.** Vice President, Scientific Affairs Cardiome Pharma Corp. Vancouver, B.C., Canada

Astellas Pharma US, Inc. Presentation (Continued):

	Toxicology & Clinical Pharmacology	**James Keirns, Ph.D.** Senior Director, Biopharmaceutical Sciences Astellas Pharma US, Inc. Deerfield, Illinois
	Clinical Efficacy and Safety	**Therese M. Kitt, M.D.** Senior Director, Medical Sciences Astellas Pharma US, Inc. Deerfield, Illinois
	Risk/Benefit Summary	**Jeremy N. Ruskin, M.D.** Director, Cardiac Arrhythmia Services Massachusetts General Hospital Boston, Massachusetts
10:45		Question/Discussion from the Committee

FDA Division of Cardiovascular and Renal Drug Products Presentation:

11:00	Division presentation	**Ellis Unger, M.D.** Deputy Director Division of Cardiovascular and Renal Drug Products CDER, FDA
11:30		**Questions/Discussion from the Committee**
12:00		**Lunch**
1:00		**Open Public Hearing**
3:00		**Questions to the Committee**
5:00		**Adjournment**

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AGENDA
December 12, 2007

The committee will discuss new drug application (NDA) 22-123, PULZIUM® (tedisamil sesquifumarate) IV solution 2 milligrams per milliliter, Solvay Pharmaceuticals, Incorporated, for the proposed indication of use for conversion of atrial fibrillation or atrial flutter to normal sinus rhythm

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8:00	Call to Order and Introductions	**William R. Hiatt, M.D.** Committee Chair Cardiovascular and Renal Drugs Advisory Committee
	Conflict of Interest Statement	**LCDR Cathy A. Miller, M.P.H., R.N.** Designated Federal Official Cardiovascular and Renal Drugs Advisory Committee
	Introduction and Background	**Norman Stockbridge, M.D., Ph.D.** Director, Division of Cardiovascular and Renal Products FDA Center for Drug Evaluation and Research
8:10	**Solvay Pharmaceuticals Sponsor Presentation:**	
	Introduction	**Victor Raczkowski, M.D., M.S.** Vice President US Regulatory Affairs Solvay Pharmaceuticals
	Unmet Medical Need	**Peter R. Kowey, M.D**. President, Main Line Health Heart Center William Wikoff Smith Chair in Cardiovascular Research Professor of Medicine and Clinical Pharmacology Jefferson Medical College of Thomas Jefferson
	Efficacy and Safety	**Matthias Straub, M.D.** Vice President, Global Clinical Development Solvay Pharmaceuticals
	Risk Minimization Plan	**Earl Sands, M.D.** Vice President and Chief Medical Officer U.S. Research & Development Solvay Pharmaceuticals

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Solvay Pharmaceuticals Sponsor Presentation (Continued):

	Risk Benefit	**Peter R. Kowey, M.D.**
	Conclusions	**Victor Raczkowski, M.D., M.S.**
9:45		**Break**
10:00		**Questions from the Committee**

FDA Division of Cardiovascular and Renal Drug Products Presentation:

10:30	Division presentation	**Thomas Marciniak, M.D.** Medical Team Leader Division of Cardiovascular and Renal Drug Products CDER, FDA
11:30		**Questions from the Committee**
12:00		**Lunch**
1:00		**Open Public Hearing**
2:00		**Discussion**
3:00		**Questions to the Committee**
5:00		**Adjournment**