

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Cardiovascular and Renal Drugs Advisory Committee
Hilton Washington DC North/Gaithersburg
Gaithersburg Maryland**

**AGENDA
April 26, 2006
8:00 A.M. – 12:00 P.M.**

The committee will discuss the agency's draft recommendations for relabeling of antihypertensive drugs for outcome claims, as a follow-up to the committee's meeting on June 15, 2005, where the committee discussed class labeling of antihypertensive drugs based on the proximity of their data to outcome trials

8:00	Call to Order and Introductions	Thomas G. Pickering, M.D., D.Phil. Acting Committee Chair Cardiovascular and Renal Drugs Advisory Committee
	Conflict of Interest Statement	LCDR Cathy Groupe, B.S.N. Executive Secretary Cardiovascular and Renal Drugs Advisory Committee
8:10	Introduction and Background	Norman Stockbridge, M.D., Ph.D. Director Division of Cardiovascular and Renal Products FDA Center for Drug Evaluation and Research
8:15		Open Public Hearing
8:45	<u>FDA Presentation:</u>	
	Guidance for Industry Labeling for Outcome Claims for Drugs to Treat Hypertension (Draft Guidance)	Norman Stockbridge, M.D., Ph.D.
9:00		Committee Discussion
10:00		Break
10:15		Continuation of Committee Discussion
10:45		Questions to the Committee
12:00		Adjournment