FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Cardiovascular and Renal Drugs Advisory Committee
CDER Advisory Committee Conference Room, Room 1066
5630 Fishers Lane - Rockville, MD
February 24, 2005

AGENDA

The committee will discuss supplemental new drug applications (sNDAs) S-022, S-024, S-025 to approved new drug application (NDA) 20-838, ATACAND® (candesartan cilexetil) Tablets (4 mg, 8 mg, 16 mg, and 32 mg), AstraZeneca LP, for the use in the treatment of patients with congestive heart failure.

8:00	Call to Order and Introductions	**Steven E. Nissen, M.D. (Chair)**
	Conflict of Interest Statement	**LT Cathy Groupe, B.S.N.** Executive Secretary Cardiovascular and Renal Drugs Advisory Committee
8:15	Welcome and Comments	**Norman Stockbridge, M.D., (Acting) Director** Division of Cardiovascular and Renal Drug Products
	Sponsor Presentation	
8:30	Regulatory Overview	**Cindy Lancaster, M.S., M.B.A, J.D.** AstraZeneca LP
8:45	Background and Rationale	**James B. Young, M.D.** Cleveland Clinic Foundation
		John J.V. McMurray, M.D. University of Glasgow
9:00	Efficacy	**Mark A. Pfeffer, M.D., Ph.D.** Brigham and Women's Hospital Boston
9:15	Safety	**James Hainer, M.D., M.P.H.** AstraZeneca LP
9:30	Benefit/Risk Summary	**James B. Young, M.D.** Cleveland Clinic Foundation
9:45	Discussion	**Marc A. Pfeffer, M.D., Ph.D.** Brigham and Women's Hospital Boston
10:00	Break	
10:15	**Questions from the Committee**	
12:00	Lunch	
1:00	**Open Public Hearing**	
2:00	**Committee Discussion and Questions**	
3:00	Break	
3:15	**Committee Discussion and Questions (continued)**	
5:00	**Adjournment**	