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
1:00 P.M. – 5:00 P.M.

The committee will discuss the safety implications for the use of placebo in studies of drugs to treat antihypertension. The largest database is from the "Placebo in Hypertension Adverse Reaction Meta-Analysis" (PHARM) Study, a meta-analysis of more than 80,000 patients in placebo-controlled trials of antihypertensive medication submitted in NDAs.

1:00	Call to Order and Introductions	**William R. Hiatt, M.D.** Committee Chair Cardiovascular and Renal Drugs Advisory Committee
	Conflict of Interest Statement	**LCDR Cathy Groupe, B.S.N.** Executive Secretary Cardiovascular and Renal Drugs Advisory Committee
1:05	Introduction and Background	**Norman Stockbridge, M.D., Ph.D.** Director Division of Cardiovascular and Renal Products FDA Center for Drug Evaluation and Research
1:15		**Open Public Hearing**

FDA Presentations:

1:30	Placebo-Controls in Short-Term Clinical Trials of Hypertension	**Sana M. Al-Khatib, M.D., M.H.S.** Electrophysiologist Department of Medicine – Division of Cardiology Duke University Medical Center
2:00	A Report on the PHARM Study	**Raymond Lipicky, M.D.** Principal Investigator Lipicky Consulting
2:30	Serious Clinical Events in the PHARM Study	**Dennis Mangano, Ph.D., M.D.** Principal Scientist/Founder/CEO Ischemia Research and Education Foundation
3:00		**Committee Discussion**
3:30		**Break**
3:45		**Questions to the Committee**
5:00		**Adjournment**