

**CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE**  
94<sup>th</sup> Meeting

**AGENDA**

*National Institutes of Health  
Building 10, Clinical Center, Jack Masur Auditorium  
9000 Rockville Pike  
Bethesda, MD.*

Thursday, October 11, 2001

9:00 a.m.	<b>Call to Order</b>	Jeffrey Borer, M.D., Acting Chair
	Conflict of Interest Statement	Joan C. Standaert, Executive Secretary
	Open Public Hearing – Scientific presentation will begin once the last open public hearing participant has spoken.	
10:00 a.m.	NDA 20-665/S-016 and NDA 21-283/S-001, <b>Diovan® (valsartan)</b> , Novartis Pharmaceuticals Corporation, for the treatment of patients with heart failure	
	<b><u>Novartis Presentations</u></b>	
	Introduction	Mathias Hukkelhoven, Ph.D. Vice-President, Regulatory Affairs Novartis Pharmaceuticals Corp.
	Clinical Efficacy Data/ Efficacy Subgroup Analyses	Jay N. Cohn, M.D. Professor of Medicine University of Minnesota Medical School Val-HeFT Study Chairman
	Safety Data	Robert Glazer, M.D. Director, Cardiovascular Clinical Research Novartis Pharmaceuticals Corp.
	Benefit:Risk Discussion	Jay N. Cohn, M.D.
11:15 a.m.	<b>Committee Discussion</b>	
	Committee Reviewer	Thomas Fleming, Ph.D. Professor and Chair University of Washington
12:00 p.m.	Lunch	
12:45 p.m.	Committee Review and Discussion/Recommendations	
3:00 p.m.	Adjourn	