

(PROPOSED AGENDA)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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

CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE

92nd Meeting
May 24, 25, 2001
AGENDA

Thursday, May 24, 2001

8:30 a.m. Open Public Hearing:

Sidney M. Wolfe, M.D., Director, Public Citizen's Health Research Group (15 minutes)

Edward J. Parr Jr. Esq. : Comments Franz H. Messerli, M.D. (10 minutes)

9:00 a.m. Response to Citizen's petition of Lawrence D. Bernhardt and Arnold Liebman, regarding NDA 19,668, Cardura, (doxazosine), Pfizer Inc..

PRESENTATIONS:

Citizen Petitioners:

Introduction: Salvatore J. Graziano, Milberg Weiss Bershad Hynes & Lerach LLP

Dr. L. Krakoff, Englewood Hospital (20 minutes)

Published interim analyses of ALLHAT (Antihypertensive and Lipid Lowering treatment to prevent Heart Attack Trial) NIH, NHLBI.:

Jeffrey A. Cutler M.D., M.Ph, Director Clinical Application and Prevention Program, NHLBI, NIH

(20 minutes)

Pfizer's Response to ALLHAT:

Introduction

Doxazosin Data Review: Clinical Trials, Literature Review

Non-Clinical Trial Post-Approval Experience

Pfizer Comments on ALLHAT

Presenters:

Suzanne LoGalbo, R.Ph., J.D., Director/Team Leader Regulatory Affairs

Patricia Walmsley, MB, FRCPath, Senior Medical Director, Doxazosin Worldwide Team

Gretchen Dieck, Ph.D., Sr. Epidemiologist, Safety Evaluation and Epidemiology

(20 minutes)

10:00 a.m. Break

10:15 a.m. Committee Questions and Discussion:

12:15 p.m. Lunch

1:15 p.m. Committee Questions, Discussion and Recommendations:
Committee Reviewer: Thomas Fleming, Ph.D.

5:00 p.m. Adjourn

FDA Invited Guests:

Temporary Voting Members:

Dr. R. D'Agostino, Boston University

Dr. R. Fenichel, Washington, D.C.

Dr. M. Konstam, New England Medical Center

NIH Guest:

Dr. B. Davis, University of Texas, Houston HSC, Director of ALLHAT Clinical Trials Center

May 25, 2001, 9:00a.m.

Natrecor NDA-20-920 (nesiritide) for treatment of acute heart failure, Scios Inc.

Introduction: Michael Crockett, Scios Inc.

Original NDA 20-920: R. Lipicky, M.D., Director, Division of Cardiorenal Drug Products

NDA Amendment Trial Designs: D.P. Horton, M.D., Scios Inc.

VMAC Efficacy: J. B. Young, M.D., Cleveland Clinic Foundation

Natrecor Safety, D.P. Horton, M.D., Scios Inc.

Benefit/Risk Assessment: W.T. Abraham, M.D., University of Kentucky, College of Medicine

11:30 a.m.: Break

12:00p.m.: Committee Discussion and Questions:

Committee Reviewer: Ileana Pina, M.D.

FDA Invited Guests and Temporary Voting Members:

Ralph D'Agostino, Ph.D., Boston University

Marvin Konstam, M.D., New England Medical Center