FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503) White Oak Conference Center, Silver Spring, MD September 13, 2012

DRAFT MEETING ROSTER

ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)

Kalyani Bhatt, BS, MS

Division of Advisory Committee and Consultant Management Office of Executive Programs, CDER, FDA

CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Allan Coukell, B.Sc., Pharm.

(Consumer Representative) Washington, District of Columbia

A. Michael Lincoff, M.D.

(Chairperson) Director, Cleveland Clinic Coordinating Center for Clinical Research Vice Chairman, Department of Cardiovascular Medicine and Lerner Research Institute Professor of Medicine Cleveland Clinic Cleveland, Ohio

Scott Emerson, M.D., Ph.D.

Professor of Biostatistics Department of Biostatistics University of Washington Seattle, Washington

Julia B. Lewis, M.D.

(Afternoon Session Only) Professor of Medicine Division of Nephrology Vanderbilt University Medical Center Nashville, Tennessee

Vasilios Papademetriou, M.D., F.A.C.C., F.A.H.A.

Professor of Medicine Georgetown University Chief Cardiovascular VA Medical Center Division of Cardiology Washington, District of Columbia

Philip Sager, M.D., F.A.C.C., F.A.H.A.

(Afternoon Session Only) Chair, Scientific Programs Committee, Cardiac Safety Research Consortium San Francisco, California

CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

Rob Scott, M.D.

(*Industry Representative*) Vice President Global Clinical Development Cardiovascular Therapeutic Area Head Amgen Inc. Thousand Oaks, California

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DRAFT MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) – Morning Session

<u>Diane Aronson</u> (*Patient Representative*) Boston, Massachusetts

Daniel L. Gillen, Ph.D.

Associate Professor Department of Statistics University of California Irvine, California

Linda Fried, M.D, M.P.H. Professor of Medicine Associate Professor of Epidemiology VA Pittsburgh Healthcare System Pittsburgh, Pennsylvania

Mori Krantz, M.D., F.A.C.C.

Associate Professor, Cardiology University of Colorado Denver Health Medical Center Denver, Colorado

TEMPORARY MEMBERS (Voting) – Afternoon Session

Charles Emala, M.D.

Associate Professor of Anesthesiology Department of Anesthesiology Columbia University Medical Center New York, New York

Daniel L. Gillen, Ph.D.

Associate Professor Department of Statistics University of California Irvine, California

Mori Krantz, M.D., F.A.C.C.

Associate Professor, Cardiology University of Colorado Denver Health Medical Center Denver, Colorado <u>Raymond McGlamery</u> (*Patient Representative*) Austin, Texas

Joseph Tobin, M.D.

Professor of Anesthesiology and Pediatrics Department of Anesthesiology Medical Center Boulevard Winston-Salem, North Carolina

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DRAFT MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Norman Stockbridge, M.D., Ph.D.

Director Division of Cardiovascular and Renal Drug Products Office of Drug Evaluation I (ODE I) Office of New Drugs (OND), CDER, FDA

Robert Temple, M.D.

Deputy Director for Clinical Science CDER, FDA

Ellis Unger, M.D. Acting Director, ODE I OND, CDER, FDA