

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, Maryland

March 8-9, 2016

DRAFT MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Cindy Hong, PharmD

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

PHARMACY COMPOUNDING ADVISORY COMMITTEE MEMBERS (Voting)

Michael A. Carome, MD, FASHP

(Consumer Representative)

Director of Health Research Group
Public Citizen
Washington, District of Columbia

Gigi S. Davidson, BSpH, DICVP

*U.S. Pharmacopeial Convention
(USP) Representative*

Director of Clinical Pharmacy Services
North Carolina State University
College of Veterinary Medicine
Raleigh, North Carolina

John J. DiGiovanna, MD

Staff Clinician, DNA Repair Section
Dermatology Branch, Center for Cancer Research
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Padma Gulur, MD

Professor, Department of Anesthesiology and
Perioperative Care
University of California, Irvine
Orange, California

Stephen W. Hoag, PhD

Professor
Department of Pharmaceutical Science
University of Maryland, Baltimore
Baltimore, Maryland

William A. Humphrey, BSpHarm, MBA, MS

Director of Pharmacy Operations
St. Jude's Children's Research Hospital
Memphis, Tennessee

Elizabeth Jungman, JD

Director, Public Health Programs
The Pew Charitable Trusts
Washington, District of Columbia

Katherine Pham, PharmD

Neonatal Intensive Care Unit Pharmacy Specialist
Children's National Medical Center
Washington, District of Columbia

Allen J. Vaida, BSc, PharmD, FASHP

Executive Vice President
Institute for Safe Medication Practices
Horsham, Pennsylvania

Jürgen Venitz, MD, PhD

(Chairperson)
Associate Professor
Department of Pharmaceutics
School of Pharmacy
Virginia Commonwealth University
Richmond, Virginia

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DRAFT MEETING ROSTER (cont.)

Donna Wall, PharmD

National Association of Boards of Pharmacy

(NABP) Representative

Clinical Pharmacist

Indiana University Hospital

Indianapolis, Indiana

PHARMACY COMPOUNDING ADVISORY COMMITTEE INDUSTRY REPRESENTATIVE MEMBERS (Non-Voting)

Ned S. Braunstein, MD

(Participation in March 8th PM session and March 9th session)

Senior Vice President and Head of Regulatory Affairs

Regeneron Pharmaceuticals, Inc.

Tarrytown, New York

William Mixon, RPh, MS, FIACP

Owner-Manager

The Compounding Pharmacy

Hickory, North Carolina

TEMPORARY MEMBERS (Voting)

Lenore Buckley, MD, MPH

(Participation in quinacrine, boswellia, D-ribose, and chondroitin discussions)

Professor of Internal Medicine and Pediatrics

Yale University School of Medicine

New Haven, Connecticut

Jeffrey A. Cohen, MD, FACP

(Participation in acetyl-L-carnitine discussion via telephone)

Professor and Chair, Neurology

Geisel School of Medicine at Dartmouth

Dartmouth Hitchcock Medical Center

Lebanon, New Hampshire

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Christopher Smalley, MS, MBA

(Participation in March 8th AM session)

Director, Engineering Biosterile Validation

Merck & Co

West Point, Pennsylvania