

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Nonprescription Drugs Advisory Committee (NDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
September 4-5, 2014

MEETING ROSTER

ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)

Cindy Hong, PharmD

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

NONPRESCRIPTION DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Ralph B. D'Agostino, Sr., PhD

Professor of Mathematics and Statistics
Biostatistics and Epidemiology
Executive Director MA/PhD Program in Biostatistics
Director, Statistics and Consulting Unit
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and Urology
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Durham, North Carolina

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Internal Medicine and Pediatrics
Institute for Medicine and Public Health
Vanderbilt University
Staff Physician, Veterans Affairs (VA) Tennessee
Valley Healthcare System
Nashville, Tennessee

NONPRESCRIPTION DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

Lorna C. Totman, PhD, DABT

(Industry Representative)
Lorna Totman Consulting, LLC
Annandale, Virginia

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

Sergio Coelho, PhD

Biologist, Laboratory of Cell Biology
Center for Cancer Research
National Cancer Institute
National Institutes of Health (NIH)
Bethesda, Maryland

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Lecturer, Harvard Medical School
Department of Dermatology
Wellman Center for Photomedicine
Massachusetts General Hospital
Boston, Massachusetts

Mary E. Maloney, MD

Professor of Medicine/Dermatology
Chief, Division of Dermatology
University of Massachusetts Medical School
Worcester, Massachusetts

David J. Margolis, MD, PhD

Chair, Committee on Appointments and Promotions
Professor of Dermatology
Professor of Epidemiology
Perelman School of Medicine
University of Pennsylvania
Philadelphia, Pennsylvania

Richard Neill, MD

(Acting Chairperson)
Associate Professor of Clinical Family Medicine and
Community Health
Chief, Department of Family Medicine and
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(Acting Consumer Representative)
Director of Policy
Harm Reduction Coalition
New York, New York

Michael D. Reed, PharmD, FCCP, FCP

Director, Rebecca D. Considine Research Institute
Director, Clinical Pharmacology and Toxicology
Associate Chair, Department of Pediatrics
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June K. Robinson, MD

Research Professor of Dermatology
Northwestern University Feinberg School of
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Geoffrey L. Rosenthal, MD, PhD

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Linda S. Tyler, PharmD

Administrative Director of Pharmacy Services
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Professor (Clinical) and Associate Dean, Pharmacy
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Meg Watson, MPH

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MEETING ROSTER (cont.)

SPEAKER (Non-Voting)

Elma D. Baron, MD

Professor, Dermatology
Director of Photomedicine
University Hospitals Case Medical Center
Case Western Reserve University
Chief of Dermatology
Louis Stokes Cleveland VA Medical Center
Cleveland, Ohio

GUEST SPEAKER (Non-Voting)

Markus Müller, MD

Professor and Head of Department of
Clinical Pharmacology
Vienna General Hospital
Medical University of Vienna
Vienna, Austria

FDA PARTICIPANTS (Non-Voting)

Sandra L. Kweder, MD, FACP

RADM (Ret.), U.S. Public Health Service
Acting Director, Office of Drug Evaluation IV
(ODE IV)
Deputy Director, Office of New Drugs (OND)
CDER, FDA

Theresa Michele, MD

Director, Division of Nonprescription Clinical
Evaluation (DNCE)
ODE IV, OND, CDER, FDA

Paul Brown, PhD

Office of Drug Evaluation (ODE) Associate Director
for Pharmacology/Toxicology
Office of New Drugs (OND), Immediate Office
CDER, FDA

CAPT E. Dennis Bashaw, PharmD

Director, Division of Clinical Pharmacology III
Office of Clinical Pharmacology
Office of Translational Sciences, CDER, FDA