

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Advisory Committee for Pharmaceutical Science and Clinical Pharmacology
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
July 27, 2011

MEETING ROSTER

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE AND CLINICAL PHARMACOLOGY MEMBERS (Voting)

Merrill Goozner
(Consumer Representative)
Silver Spring, MD

Fernando J. Muzzio, Ph.D.
Professor of Chemical Engineering
Department of Chemical and Biochemistry
Rutgers University
Piscataway, New Jersey

Harriet B. Nembhard, Ph.D. *(Topic 1 Only)*
Professor of Industrial Engineering
Pennsylvania State University
University Park, Pennsylvania

James E. Polli, Ph.D.
Professor and Vice-Chair
Department of Pharmaceutical Sciences
University of Maryland School of Pharmacy
Baltimore, Maryland

Fadia T. Shaya, Ph.D., M.P.H.
Professor
University of Maryland School of Pharmacy
Department of Pharmaceutical Health Services
Research
Baltimore, Maryland

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE AND CLINICAL PHARMACOLOGY MEMBER (Non-Voting)

Patricia C. Tway, Ph.D.
(Industry Representative)
President
CMC Technical Navigator
Phoenixville, Pennsylvania

TEMPORARY MEMBERS (Voting)

Arthur Kibbe, Ph.D.
Professor of Pharmaceutical Sciences
Wilkes University
Wilkes-Barre, Pennsylvania

Melvin Koch, Ph.D.
Executive Director, the Center for Process
Analytical Chemistry (CPAC)
University of Washington
Seattle, Washington

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

Joseph S. Kosler, Ph.D.

Statistician
U.S. Department of Agriculture
National Agricultural Statistics Service
Research and Development Division
Fairfax, Virginia

Kenneth R. Morris, Ph.D.

(participating by telephone)
Professor of Pharmaceutics
College of Pharmacy
University of Hawaii at Hilo
Hilo, Hawaii

Marilyn E. Morris, Ph.D.

Professor, Department of Pharmaceutical Sciences
University at Buffalo, State University of New York,
School of Pharmacy
Amherst, New York

Anne S. Robinson, Ph.D.

Professor, Department of Chemical Engineering
University of Delaware
Newark, Delaware

Elizabeth M. Topp, Ph.D.

(Acting Chair)
Head, Department of Industrial and Physical
Pharmacy, College of Pharmacy, Nursing, and Health
Sciences
Purdue University
West Lafayette, Indiana

GUEST SPEAKERS (Non-Voting)

Yatindra Joshi, Ph.D. *(Topic 1 Only)*

Vice President, Generics Research and Development
Teva Pharmaceuticals
North Wales, Pennsylvania

Evdokia Korakianiti, Ph.D. *(Topic 1 Only)*

European Medicines Agency
London, United Kingdom

Gerry Migliaccio, M.S. *(Topic 1 Only)*

Senior Vice President of Network Performance
Pfizer Global Supply
Pfizer, Inc.
New York, New York

Rachael Roehrig, Ph.D. *(Topic 2 Only)*

Director, Technical and Scientific Affairs
Consumer Healthcare Products Association
Washington, District of Columbia

Karen Russo, Ph.D. *(Topic 2 Only)*

Vice President, Small Molecules
United States Pharmacopeia (USP)
Rockville, Maryland

Catherine Sheehan, M.S. *(Topic 2 Only)*

Director, Excipients Group
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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Helen N. Winkle

Director, Office of Pharmaceutical Science (OPS)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Keith Webber, Ph.D.

Deputy Director, OPS and
Acting Director, Office of Generic Drugs (OGD)
OPS, CDER, FDA

Moheb Nasr, Ph.D. *(Topic 1 Only)*

Director
Office of New Drug Quality Assessment (ONDQA)
OPS, CDER, FDA

Steven Kozlowski, M.D. *(Topic 1 Only)*

Director, Office of Biotechnology Products
OPS, CDER, FDA

Larry Ouderkirk *(Topic 2 Only)*

Consumer Safety Officer
Office of Manufacturing & Product Quality (OMPQ)
Office of Compliance (OC), CDER, FDA