

**Advisory Committee for Pharmaceutical Science  
and Clinical Pharmacology**

**July 22-23, 2008**

**Food and Drug Administration, Center for Drug Evaluation and Research  
Advisory Committee Conference Room, Rm 1066, 5630 Fishers Lane, Rockville Maryland**

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**Meeting Roster**

**ADVISORY COMMITTEE for PHARMACEUTICAL SCIENCE AND CLINICAL  
PHARMACOLOGY MEMBERS (Voting)**

Kenneth R. Morris, Ph.D. (Chair)

Professor of Pharmaceutics  
College of Pharmacy  
University of Hawaii at Hilo  
Hilo, HI

Jessie L-S. Au, Pharm.D., Ph.D.\*

Distinguished University Professor  
The Ohio State University  
Columbus, OH

Carol A. Gloff, Ph.D.\*\*

Carol Gloff & Associates  
Natick, MA

Merrill Goozner (Consumer Representative)

Director of Integrity and Science Project  
Washington, DC

\*Dr. Jessie L-S. Au is recused from the presentation from the Office of Pharmaceutical Science (OPS) and the discussion of the current thinking on issues pertaining to the use of nanotechnology in drug manufacturing, drug delivery, or drug products.

\*\*Dr. Carol A. Gloff is recused from the discussion of the presentations from the Office of Generic Drugs (OGD) on the use of inhaled corticosteroids dose-response as a means to establish bioequivalence of inhalation drug products.

**TEMPORARY MEMBERS (Voting)**

Jerry M. Collins, Ph.D.

Associate Director for Developmental Therapeutics  
Division of Cancer Treatment and Diagnosis  
NCI, NIH  
Rockville, MD

Arthur H. Kibbe, Ph.D.

Chair, Pharmaceutical Sciences  
Nesbitt School of Pharmacy, Wilkes University  
Wilkes-Barre, PA

Marilyn E. Morris, Ph.D.

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

Anne S. Robinson, Ph.D.

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

Elizabeth M. Topp, Ph.D.

Professor, Department of Pharmaceutical Chemistry  
The University of Kansas  
Lawrence, KS

Melvin V. Koch, Ph.D.

CPAC Executive Director  
University of Washington  
Seattle, WA

Marvin C. Meyer, Ph.D.

Professor Emeritus  
Department of Pharmaceutical Sciences  
The University of Tennessee College of Pharmacy  
Memphis, TN

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**Meeting Roster**

**TEMPORARY MEMBERS (Voting) -Continued-**

Harriet B. Nembhard, Ph.D.  
Associate Professor  
Pennsylvania State University  
University Park, PA

**ADVISORY COMMITTEE for PHARMACEUTICAL SCIENCE AND CLINICAL  
PHARMACOLOGY MEMBERS (Non-Voting)**

Richard J. Stec, Jr., Ph.D. (Industry Representative)  
Vice President, Regulatory Affairs, Americas  
Hospira, Inc.  
Lake Forest, IL

Patricia C. Tway, Ph.D. (Industry Representative)  
Vice President, Regulatory & Analytical Sciences  
Merck Manufacturing Division  
West Point, PA

**GUEST SPEAKERS for July 22, 2008 (Non-Voting)**

Darrell R. Abernethy, MD, Ph.D.  
Chief Science Officer  
United States Pharmacopeia  
Rockville, MD

Stephen B. Ruddy, Ph.D.  
Senior Director, Pharmaceutical Development  
Elan NanoSystems  
King of Prussia, PA

Lawrence Tamarkin, Ph.D.  
President & CEO  
CytImmune Sciences, Inc.  
Rockville, MD

Darin Y. Furgeson, Ph.D.  
Assistant Professor of Pharmaceutical Sciences and  
Biomedical Engineering,  
Biomedical Engineering Center for Translational Research  
University of Wisconsin-Madison  
Madison, WI

**GUEST SPEAKER for July 23, 2008 (Non-Voting)**

James Polli, Ph.D.  
University of Maryland School of Pharmacy  
Department of Pharmaceutical Sciences  
Baltimore, MD

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**FDA PARTICIPANTS for July 22, 2008 (Non-Voting)**

Helen Winkle  
Director, OPS, CDER, FDA

Keith Webber, Ph.D.  
Deputy Director, OPS, CDER, FDA

Norman Schmuff (Topic 2 Only)  
Branch Chief, Division of Pre-Marketing  
Assessment II, ONDQA, OPS, CDER, FDA

**FDA PARTICIPANTS for July 23, 2008 (Non-Voting)**

Helen Winkle  
Director, OPS, CDER, FDA

Lawrence Yu, Ph.D. (Topic 1 and 3 Only)  
Director for Science, OGD, OPS, CDER, FDA

Keith Webber, Ph.D.  
Deputy Director, OPS, CDER, FDA

Frank Holcombe, Jr., Ph.D. (Topic 2 Only)  
Associate Director for Chemistry, OGD, OPS, CDER,  
FDA

Gary Buehler, R.Ph. (Topic 1 and 3 Only)  
Director, OGD, OPS, CDER, FDA