Center for Drug Evaluation and Research (CDER)

# Arthritis Advisory Committee (AAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503) 10903 New Hampshire Avenue, Silver Spring, Maryland July 12, 2016

#### DRAFT MEETING ROSTER

#### **ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)**

#### Moon Hee V. Choi, PharmD

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

# **ARTHRITIS ADVISORY COMMITTEE MEMBERS (Voting)**

#### Mara L. Becker, MD, MSCE

Associate Professor of Pediatrics University of Missouri-Kansas City Director, Division of Pediatric Rheumatology Children's Mercy Kansas City Kansas City, Missouri

#### Beth L. Jonas, MD

Director, Rheumatology Fellowship Training Program University of North Carolina School of Medicine Chapel Hill, North Carolina

# Andreas M. Reimold, MD

Chief of Rheumatology
Dallas VA Medical Center
Rheumatology Section, Medical Service
Dallas, Texas

#### Jennifer Horonjeff, PhD

(Consumer Representative)
Research Fellow & Patient Advocate
Center for Immune Disease with Onset in Childhood
Division of Rheumatology
Department of Medicine Columbia University Medical
Center
New York, New York

# Donald R. Miller, PharmD, FASHP

Professor of Pharmacy Practice School of Pharmacy North Dakota State University College of Health Professions Fargo, North Dakota

# Therese M. Wolpaw, MD, MHPE

Vice Dean for Educational Affairs The Pennsylvania State University College of Medicine Hershey, Pennsylvania

# TEMPORARY MEMBERS (Voting)

#### Jeremy Adler, MD, MSc

Director, Pediatric Inflammatory Bowel Disease Program Assistant Professor, Pediatric Gastroenterology and Health Services Research Child Health Evaluation and Research (CHEAR) Unit C.S. Mott Children's Hospital University of Michigan Ann Arbor, Michigan

#### Diane Aronson, BS in Ed.

(Patient Representative)
Naples, Florida

Center for Drug Evaluation and Research (CDER)

# Arthritis Advisory Committee (AAC) Meeting July 12, 2016

# **DRAFT MEETING ROSTER (cont.)**

# TEMPORARY MEMBERS (Voting) (cont.)

# Wilma F. Bergfeld, MD, FAAD

Professor of Dermatology and Pathology Senior Dermatologist & Emeritus Director Dermatopathology Director, Dermatopathology Fellowship Departments of Dermatology and Pathology Cleveland Clinic Cleveland, Ohio

#### Erica Brittain, PhD

Deputy Branch Chief and Mathematical Statistician Biostatistics Research Branch National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Bethesda, Maryland

# Nancy L. Geller, PhD

Director, Office of Biostatistics Research National Heart, Lung, and Blood Institute National Institutes of Health Bethesda, Maryland

# Robert J. Hohman, PhD

Chief, Research Technologies Branch Chief, Protein Chemistry Section NIAID, NIH Bethesda, Maryland

# David J. Margolis, MD, PhD

Professor of Dermatology Professor of Epidemiology University of Pennsylvania School of Medicine Philadelphia, Pennsylvania

# Warren B. Bilker, PhD

Professor of Biostatistics
Department of Biostatistics and Epidemiology
Perelman School of Medicine
University of Pennsylvania
Philadelphia, Pennsylvania

# Linda A. Feagins, MD

Associate Professor, Division of Digestive and Liver Diseases University of Texas Southwestern Medical Center Director, Inflammatory Bowel Diseases Clinic VA North Texas Health Care System Dallas, Texas

# William Hancock, PhD, DSc

Professor
Department of Chemistry and Chemical Biology and
Barnett Institute
Bradstreet Chair of Bioanalytical Chemistry
Northeastern University
Boston, Massachusetts

# Donald E. Mager, PharmD, PhD

Professor of Pharmaceutical Sciences University at Buffalo, SUNY Buffalo, New York

# Jeffrey W. Nathanson, MD

Senior Clinical Educator University of Chicago Pritzker School of Medicine Medical Director Highland Park Medical Group GI Lab NorthShore University Health System Highland Park, Illinois

Center for Drug Evaluation and Research (CDER)

# Arthritis Advisory Committee (AAC) Meeting July 12, 2016

# **DRAFT MEETING ROSTER (cont.)**

# TEMPORARY MEMBERS (Voting) (cont.)

# Alyce M. Oliver, PhD, MD

Professor of Medicine

Director, Rheumatology Fellowship Training Program Ambulatory Medical Director of Medicine

Medical College of Georgia

Augusta, Georgia

#### Jose U. Scher, MD

Assistant Professor of Medicine

New York University School of Medicine

Director, NYU Psoriatic Arthritis Center

Director, NYU-Langone Hospital for Joint Diseases

Arthritis Clinic

Director, Microbiome Center for Rheumatology and

Autoimmunity

New York, New York

# Steven F. Solga, MD

Gastroenterology

Solo, Independent Practice

Bethlehem, Pennsylvania

# June K. Robinson, MD

Research Professor of Dermatology

Northwestern University Feinburg School of Medicine

Chicago, Illinois

# Richard Siegel, MD, PhD

Senior Investigator and Chief, Autoimmunity Branch

Clinical Director

National Institute of Arthritis and Musculoskeletal and

Skin Diseases, NIH

Bethesda, Maryland

# David Solomon, MD, MPH

(Acting Chairperson)

Professor of Medicine

Harvard Medical School

Chief, Section of Clinical Sciences

Division of Rheumatology

Division of Pharmacoepidemiology

Brigham and Women's Hospital

Boston, Massachusetts

#### Sarah E. Streett, MD

Clinical Director of Inflammatory Bowel Diseases

Clinical Associate Professor

Department of Gastroenterology

Stanford University

Stanford, California

# Scott A. Waldman, MD, PhD, FCP, FAHA

Director, Gastrointestinal Cancer Program of the

Sidney Kimmel Cancer Center

Samuel M.V. Hamilton Professor of Medicine and

Chair, Department of Pharmacology and Experimental

Therapeutics

Sidney Kimmel Medical College

Thomas Jefferson University

Philadelphia, Pennsylvania

Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC) Meeting July 12, 2016

# **DRAFT MEETING ROSTER (cont.)**

# ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

# Sean P. Curtis, MD

Head, Global Scientific Affairs Merck Research Laboratories Merck and Co, Inc.

# FDA PARTICIPANTS (Non-Voting)

# Leah Christl, PhD

Associate Director Therapeutic Biologics Therapeutic Biologics and Biosimilars Staff Office of New Drugs (OND) CDER, FDA

#### Nikolay P. Nikolov, MD

Clinical Team Leader
DPARP, ODE-II, OND, CDER, FDA

# Joel Welch, PhD

Product Quality Team Leader Division of Biotechnology Research and Review II OBP, OPQ, CDER, FDA

# Badrul Chowdhury, MD, PhD

Director
Division of Pulmonary, Allergy, and Rheumatology
Products (DPARP)
Office of Drug Evaluation II (ODE-II)
OND, CDER, FDA

# Steven Kozlowski, MD

Director Office of Biotechnology Products (OBP) Office of Pharmaceutical Quality (OPQ) CDER, FDA