FOOD AND DRUG ADMINISTRATION (FDA)

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 25, 2019

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Yinghua Wang, PharmD, MPH, RAC

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 Division of Rheumatology Duke Children's Hospital and Health Center Duke Clinical Research Institute Durham, North Carolina

Jennifer Horonjeff, PhD

(Consumer Representative) Founder and Patient Advocate Savvy Cooperative Patient Outcome and Quality Consultant Division of Rheumatology Department of Medicine Columbia University Medical Center Sunnyside, New York

Alyce M. Oliver, MD, PhD

Joseph P. Bailey MD Chair in Rheumatology Professor of Medicine Medical College of Georgia at Augusta University Augusta, Georgia

Daniel H. Solomon, MD, MPH

(Chairperson) Professor of Medicine Matthew H. Liang Distinguished Chair Harvard Medical School Chief. Section of Clinical Sciences Division of Rheumatology Division of Pharmacoepidemiology Brigham and Women's Hospital Boston, Massachusetts

Jeffrey Curtis, MD, MS, MPH

Marguerite Jones Harbert - Gene Ball Endowed Professor of Medicine Division of Clinical Immunology & Rheumatology University of Alabama at Birmingham Birmingham, Alabama

Martha C. Nason, PhD

Mathematical Statistician Division of Clinical Research National Institute of Allergy and Infectious Diseases National Institutes of Health Rockville, Maryland

J. Steuart Richards, MD

Chief Division of Rheumatology Veterans Affairs Pittsburgh Healthcare System Clinical Associate Professor of Medicine University of Pittsburgh Pittsburgh, Pennsylvania

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

William Calhoun, MD, FACP, FCCP, FAAAAI, FACAAI

Nelda C and HJ Stark Distinguished Chair in Internal Medicine Professor and Vice Chair for Research Department of Internal Medicine University of Texas Medical Branch Galveston, Texas

Nancy Geller, PhD

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

James Katz, MD

Senior Research Physician

Director, Rheumatology Fellowship and Training Branch National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH Bethesda, Maryland

Susanne May, PhD

Professor of Biostatistics Director, University of Washington Clinical Trials Center University of Washington Seattle, Washington

James Stoller, MD

Professor and Chairman, Education Institute Staff, Respiratory Institute Jean Wall Bennett Professor of Medicine and Samson Global Leadership Endowed Chair Cleveland Clinic Cleveland, Ohio

Brian Garibaldi, MD, MEHP

Director, Johns Hopkins Biocontainment Unit Associate Professor of Medicine and Physiology Johns Hopkins University School of Medicine Baltimore, Maryland

Todd Gilligan, MA

(Patient Representative)
Dubuque, Iowa

Gail Kerr, MD, FRCP(Edin)

Chief, Rheumatology Washington DC Veterans Affairs Medical Center and Howard University Hospital Professor of Medicine Georgetown ad Howard University Hospitals Washington, District of Columbia

Carrie Redlich, MD, MPH

Professor of Medicine, Pulmonary Section & Occupational and Environmental Medicine Director, Yale Occupational and Environmental Medicine Program Yale University School of Medicine Professor of Epidemiology, Department of Environmental Health Sciences Yale University School of Public Health New Haven, Connecticut

Michael Weisman, MD

Distinguished Professor of Medicine Emeritus
David Geffen School of Medicine
University of California Los Angeles
Professor of Medicine Emeritus
Cedars-Sinai Medical Center
Los Angeles, California

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MEETING ROSTER (cont.)

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Sean Curtis, MD

(Acting Industry Representative)
Vice President, Clinical Research
Vice President, Clinical Therapeutic Area Head
Respiratory and Immunology
Merck Research Laboratories
Rahway, New Jersey

FDA PARTICIPANTS (Non-Voting)

Sally Seymour, MD

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

Rachel Glaser, MD

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

Yu Wang, PhD

Statistical Reviewer Division of Biometrics II Office of Biostatistics Office of Translational Sciences CDER, FDA

Nikolay Nikolov, MD

Associate Director for Rheumatology DPARP, ODE-II, OND, CDER, FDA

Nadia Habel, MD

Medical Officer DPARP, ODE-II, OND, CDER, FDA