FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting June 9, 2021

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Takyiah Stevenson, PharmD

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

PHARMACY COMPOUNDING ADVISORY COMMITTEE MEMBERS (Voting)

Robin H. Bogner, PhD

Professor University of Connecticut School of Pharmacy Department of Pharmaceutical Sciences

Storrs, Connecticut

Seemal R. Desai, MD, FAAD

Founder & Medical Director Innovative Dermatology Clinical Assistant Professor Department of Dermatology

University of Texas Southwestern Medical Center

Dallas, Texas

Timothy D. Fensky, RPh, DPh, FACA

(National Association of Boards of Pharmacy Representative) Chief Pharmacy Operations Officer Sullivan's Pharmacy and Medical Supply, Inc.

Sullivan's Health Care, Inc.
Boston, Massachusetts

Sandra J. Fusco-Walker

(Consumer Representative) Allergy & Asthma Network

Vienna, Virginia

Padma Gulur, MD, FASA

(Chairperson)

Professor of Anesthesiology

Executive Vice Chair for Performance and

Operations

Department of Anesthesiology

Director of Pain Management Strategy and Opioid

Surveillance

Medical Director Acute Pain Consult Service

Duke University Health System

Durham, North Carolina

Anita Gupta, DO, MPP, PharmD

Head, Comprehensive Pain Center Head, Interventional Pain Management

Departments of Medicine and Orthopedic Surgery

Scripps Clinic MD Anderson Cancer Center

Associate Professor

Johns Hopkins School of Medicine

Baltimore, Maryland

<u>Kathleen M. Gura PharmD, BCNSP, FASHP, FASPEN</u>

Assistant Professor of Pediatrics Harvard Medical School

Manager, Pharmacy Clinical Research Program

Boston Children's Hospital Boston, Massachusetts

<u>Linda F. McElhiney PharmD, RPh, MSP, FAPC, FACA, FASHP, DPLA</u>

Team Lead Compounding Pharmacist Indiana University Health Indianapolis, Indiana

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting June 9, 2021

MEETING ROSTER (cont.)

PHARMACY COMPOUNDING ADVISORY COMMITTEE MEMBERS (Voting) (cont.)

Kuldip R. Patel, PharmD, FASHP

Senior Associate Chief Pharmacy Officer Duke University Hospital Durham, North Carolina

Jeanne H. Sun, PharmD, JD

(United States Pharmacopeia Representative)
Counsel
United States Pharmacopeial Convention
Rockville, Maryland

Elizabeth Rebello, RPh, MD, FASA, CPPS

Professor

Department of Anesthesiology and Perioperative Medicine

University of Texas MD Anderson Cancer Center Houston, Texas

Allen J. Vaida, BSc, PharmD, FASHP

Former Executive Vice President Institute for Safe Medication Practices Hatfield, Pennsylvania

PHARMACY COMPOUNDING ADVISORY COMMITTEE MEMBERS (Non-Voting)

Gus Bassani, PharmD

(Industry Representative, Neomycin Topic Only) Chief Scientific Officer Professional Compounding Centers of America Houston, Texas

Michael D. Bui, DDS, MPH, JD

(Industry Representative)
Senior Vice-President, Regulatory Affairs
Kadmon Pharmaceuticals
Cambridge, Massachusetts

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Richard L. Green, BS Pharm, RPh, BCNP, FAPhA

(Melatonin, Methylcobalamin, Choline Chloride and Oxitriptan Topics Only) Director of Radiopharmacy Practice Cardinal Health Nuclear & Precision Health Butler, Tennessee

TEMPORARY MEMBERS (Voting)

Jonathan Emens, MD, FAASM, DFAPA

(Melatonin Topic Only)
Associate Professor of Psychiatry
Assistant Professor of Internal Medicine
Oregon Health and Science University
Oregon Institute of Occupational Health Sciences
Deputy Director of Mental Health
Veterans Affairs Portland Health Care System
Portland, Oregon

Joanna Katzman, MD, MSPH

(Methylcobalamin Topic Only)
Director of Public Health Initiatives, Project ECHO
Executive Director of University of New Mexico
(UNM) Pain Center
Professor of Neurology
Department of Neurosurgery, UNM Pain Center
UNM School of Medicine
Albuquerque, New Mexico

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting June 9, 2021

MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Jennifer C. Lai, MD, MBA

(Choline Chloride Topic Only)
Associate Professor of Medicine In Residence
Hepatology, Liver Transplantation
Director, Advancing Research in Clinical
Hepatology
University of California San Francisco
San Francisco, California

Friedhelm Sandbrink, MD

(Methylcobalamin Topic Only)
National Program Director for Pain Management,
Opioid Safety and Prescription Drug Monitoring
Program, Specialty Care Program Office
Veterans Health Administration
Director for Pain Management Program
Department of Neurology
Washington Veterans Affairs Medical Center
Washington, District of Columbia

Suthat Liangpunsakul, MD, MPH

(Choline Chloride Topic Only)
Professor of Medicine, Biochemistry and Molecular Biology
Division of Gastroenterology and Hepatology
Department of Medicine
Indiana University School of Medicine
Indianapolis, Indiana

FDA PARTICIPANTS (Non-Voting)

Frances Gail Bormel, RPh, JD

Director
Office of Compounding Quality and Compliance
(OCQC)
Office of Compliance (OC), CDER, FDA

Rosilend Lawson, VMD, JD

Branch Chief (Acting)
DCPO, OCQC, OC, CDER, FDA

Susan Johnson, PharmD, PhD

Clinical Reviewer Pharmacy Compounding Review Team OSM, OND, CDER, FDA

Madeline Wolfert, MD

(Oxitriptan Topic Only)
Physician
Pharmacy Compounding Review Team
OSM, OND, CDER, FDA

Gabrielle Cosel

Director (Acting)
Division of Compounding Policy and Outreach (DCPO)
OCQC, OC, CDER, FDA

Charles Ganley, MD

Director Office of Specialty Medicine (OSM) Office of New Drugs (OND), CDER, FDA

Suhail Kasim, MD, MPH

Lead Physician Pharmacy Compounding Review Team OSM, OND, CDER, FDA

Jae Ho Hong, MD

(Neomycin Topic Only)
Medical Officer
Division of Anti-Infectives
Office of Infectious Diseases
OND, CDER, FDA

Page 3 of 3