FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting Tommy Douglas Conference Center 10000 New Hampshire Avenue, Silver Spring, Maryland April 25, 2019

DRAFT MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Lauren Tesh Hotaki, PharmD, BCPS

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

ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Lindsey R. Baden, MD

(Chairperson) Director of Clinical Research Division of Infectious Diseases Brigham and Women's Hospital Director, Infectious Disease Service Dana-Farber Cancer Institute Associate Professor, Harvard Medical School Boston, Massachusetts

Nina M. Clark, MD

Professor Stritch School of Medicine Clinical Division Director, Infectious Diseases Director, Transplant Infectious Disease Program Loyola Medical Center Maywood, Illinois

Michael Green, MD, MPH

Professor of Pediatrics, Surgery and Clinical & Translational Science University of Pittsburgh School of Medicine Division of Infectious Diseases Director, Antimicrobial Stewardship & Infection Prevention Co-Director, Transplant Infectious Diseases Children's Hospital of Pittsburgh Pittsburgh, Pennsylvania

Ighovwerha Ofotokun, MD, MSc

Professor of Medicine Division of Infectious Diseases Department of Medicine Emory University School of Medicine Atlanta, Georgia

CAPT Timothy H. Burgess, MD, MPH, FACP

Director Infectious Disease Clinical Research Program Preventative Medicine & Biostatistics Uniformed Services University of the Health Sciences Bethesda, Maryland

Dean A. Follmann, PhD

Assistant Director of Biostatistics Chief Biostatistics Research Branch National Institute of Allergy and Infectious Diseases National Institutes of Health Bethesda, Maryland

Barbara M. Gripshover, MD

Associate Professor of Medicine University Hospitals Cleveland Medical Center Case Western Reserve University Division of Infectious Diseases and HIV Medicine Cleveland, Ohio

George K. Siberry, MD, MPH

Medical Officer Adult Clinical Branch, Office of HIV/AIDS S/GAC Senior Technical Advisor for Pediatrics U.S. Agency for International Development Arlington, Virginia

Page 1 of 3

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DRAFT MEETING ROSTER (cont.)

ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting) (cont.)

Sankar Swaminathan, MD

Professor and Chief, Division of Infectious Diseases Department of Internal Medicine University of Utah School of Medicine Salt Lake City, Utah

Peter Joseph Weina, PhD, MD

Colonel, Medical Corps, US Army Branch Chief, Research Regulatory Oversight Office Office of the Under Secretary of Defense (Personnel and Readiness) Defense Health Headquarters Falls Church, Virginia

ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEMBERS (Non-Voting)

Nicholas A. Kartsonis, MD

(Industry Representative) Sr. Vice President Infectious Diseases & Vaccines, Clinical Research Merck Research Laboratories North Wales, Pennsylvania

TEMPORARY MEMBERS (Voting)

Judith Baker, DrPH, MHSA

(Consumer Representative) Public Health Director Western States Regional Hemophilia Network Pacific Sickle Cell Regional Collaborative Center for Inherited Blood Disorders Adjunct Assistant Professor UCLA-Division of Pediatric Hematology/Oncology Los Angeles, California

James A. Ellison, PhD (speaker and temporary

<u>member</u>) Microbiologist Poxvirus and Rabies Branch Division of High-Consequence Pathogens and Pathology National Center for Emerging and Zoonotic Infectious Diseases Centers for Disease Control and Prevention Atlanta, Georgia

Catherine M. Brown, DVM, MSc, MPH

State Epidemiologist and State Public Health Veterinarian Bureau of Infectious Disease and Laboratory Sciences Massachusetts Department of Public Health National Association of State Public Health Veterinarian's Compendium of animal Rabies Control and Prevention, Co-chair Boston, Massachusetts

Alexia Harrist, MD, PhD

State Health Officer and State Epidemiologist Chief, Public Health Sciences Section Public Health Division Wyoming Department of Health Cheyenne, Wyoming

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DRAFT MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Susan M. Moore, PhD, MS, HCLD(ABB),

MT(ASCP)SBB Clinical Assistant Professor/Rabies Laboratory Director Kansas State Veterinary Diagnostic Laboratory College of Veterinary Medicine Kansas State University Manhattan, Kansas

FDA PARTICIPANTS (Non-Voting)

John Farley, MD, MPH

Deputy Director Office of Antimicrobial Products (OAP) Office of New Drugs (OND) CDER, FDA

Jeffrey Murray, MD, MPH Deputy Director DAVP, OAP, OND, CDER, FDA

Tanvir Bell, MD, FACP, FIDSA Medical Officer DAVP, OAP, OND, CDER, FDA

Laura D. Porter, MD

(*Patient Representative*) Cheverly, Maryland

Debra Birnkrant, MD Director Division of Antiviral Products (DAVP) OAP, OND, CDER, FDA

<u>Stephanie Troy, MD</u> Medical Officer DAVP, OAP, OND, CDER, FDA

Damon Deming, PhD Clinical Virology Reviewer DAVP, OAP, OND, CDER, FDA