FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503) 10903 New Hampshire Avenue, Silver Spring, Maryland March 8, 2018

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Jay Fajiculay, PharmD

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

GASTROINTESTINAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

David N. Assis, MD (via phone)

Assistant Professor of Medicine Section of Digestive Diseases Yale University School of Medicine New Haven, Connecticut

Sandeep Khurana, MBBS

Medical Director, Liver Transplantation Geisinger Medical Center Danville, Pennsylvania

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Vice Chair Division of Gastroenterology and Hepatology Mayo School of Graduate Medical Education Rochester, Minnesota

Lisa L. Strate, MD, MPH

Associate Professor of Medicine University of Washington School of Medicine Section Chief Gastroenterology Harborview Medical Center Seattle, Washington

Lin Chang, MD

Professor of Medicine Vice-Chief, Vatche and Tamar Manoukian Division of Digestive Diseases David Geffen School of Medicine at UCLA Los Angeles, California

Benjamin Lebwohl, MD, MS

Assistant Professor of Medicine and Epidemiology Director of Clinical Research, The Celiac Disease Center at Columbia University Director of Quality Improvement Division of Digestive and Liver Diseases Columbia University Medical Center New York, New York

Jean-Pierre Raufman, MD

(Chairperson)
Moses and Helen Golden Paulson Professor of
Medicine
Head, Division of Gastroenterology & Hepatology
University of Maryland School of Medicine
Baltimore, Maryland

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MEETING ROSTER (cont.)

GASTROINTESTINAL DRUGS ADVISORY COMMITTEE MEMBERS (Non-Voting)

Douglas S. Levine, MD

(Industry Representative)
Manager and Sole Member
DSL Consulting, LLC
Seekonk, Massachusetts

TEMPORARY MEMBERS (Voting)

Ivan J. Fuss, MD

Staff Clinician Immunology/Pediatric Gastroenterology National Institute of Allergy and Infectious Diseases National Institutes of Health (NIH)

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(Acting Consumer Representative)
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Tracy Matson

(Patient Representative) Little Rock, Arkansas

Mitchell H. Grayson, MD

Professor and Chief Division of Allergy and Immunology Department of Pediatrics Nationwide Children's Hospital The Ohio State University School of Medicine Columbus, Ohio

Beth L. Jonas, MD

Reeves Distinguished Professor of Medicine Interim Chief, Division of Rheumatology, Allergy, and Immunology Director, Rheumatology Fellowship Program University of North Carolina Chapel Hill Chapel Hill, North Carolina

Jenifer R. Lightdale, MD, MPH

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Donna Griebel, MD

Director
Division of Gastroenterology and Inborn Errors
Products (DGIEP)
Office of Drug Evaluation (ODE) III
Office of New Drugs (OND), CDER, FDA

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Sara Jimenez, PhD

Mathematical Statistician Division of Biostatistics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA