Center for Drug Evaluation and Research (CDER) Food and Drug Administration Department of Health and Human Services

Generic Drug User Fee Amendments of 2017 Regulatory Science Initiatives: Request for Public Input for FY 2021 Generic Drug Research Public Work shop

Panel Members

Industry Leaders' Roundtable

Robert Lionberger, PhD (Moderator)

Director, Office of Research and Standards Office of Generic Drugs, CDER

Xiaodi Guo, PhD Chief Scientific Officer Prinston Pharmaceutical Inc.

Ajaz Hussain, PhD President National Institute for Pharmaceutical Technology and Education

Srinivas Kone, PhD Senior Vice President/Head of Scientific Affairs, R&D Global Generics Amneal Pharmaceuticals

Rosario LoBrutto, PhD Head of Scientific Affairs Sandoz, Inc.

Michelle Ryder, BS Principal Consultant Lachman Consultant Services, Inc.

Samrat Sisodia, PhD, MBA Vice President Regulatory Affairs - North America Glenmark Pharmaceuticals Inc.

Breakout 1: Post-market Surveillance of Generic Drugs Howard Chazin, M.D., MBA (Co-Moderator) Director, Clinical Safety Surveillance Staff Office of Generic Drugs, CDER

Jason Rodriguez, Ph.D. (Co-Moderator) Laboratory Chief, Division of Complex Drug Analysis Office of Testing and Research Office of Pharmaceutical Quality, CDER Raphael Brykman, PhD Consumer Safety Officer Office of Quality Surveillance Office of Pharmaceutical Quality, CDER

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Samrat Sisodia, PhD, MBA Vice President Regulatory Affairs - North America Glenmark Pharmaceuticals Inc.

<u>Breakout 2: Combination Products</u> Markham Luke, M.D., Ph.D. (Moderator) Director, Division of Therapeutic Performance Office of Research and Standards Office of Generic Drugs, CDER

Elizabeth Bielski, PhD Chemist, Division of Therapeutic Performance Office of Research and Standards Office of Generic Drugs, CDER

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Molly Story, PhD Senior Director, Global Advisor, Medical Device Development Unit Sanofi

Róisín Wallace, BSc. Vice President, Head of Global Device Development Mylan

Kimberly Witzmann, MD Acting Deputy Director, Office of Bioequivalence Office of Generic Drugs, CDER

Breakout 3: In Vitro Bioequivalence Methods Yan Wang, Ph.D. (Moderator) Acting Team Leader, Division of Therapeutic Performance Office of Research and Standards Office of Generic Drugs, CDER

Denise Conti, PhD Staff Fellow, Division of Therapeutic Performance Office of Research and Standards Office of Generic Drugs, CDER

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Shawn Zhang, PhD Founder and CEO

DigiM Solution LLC

Breakout 4: Data Analysis and Model-Based Bioequivalence Liang Zhao, Ph.D., M.B.A. (Moderator) Director, Division of Quantitative Methods and Modeling Office of Research and Standards Office of Generic Drugs, CDER

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