Promoting Effective Drug Development Programs: Opportunities and Priorities for FDA's Office of New Drugs

November 7, 2019
9:00 AM – 5:00 PM

U.S Food and Drug Administration
White Oak Campus
Building 31, Room 1503 - Great Room
10903 New Hampshire Avenue
Silver Spring, MD 20993

ABSTRACT

The purpose of this public meeting is to solicit from external stakeholders specific, actionable policy suggestions that could be implemented in the near-term by the review staff of the Office of New Drugs (OND) in the Center for Drug Evaluation and Research (CDER) to promote effective drug development programs without compromising our regulatory standards for assessment of safety and effectiveness.

Please note that times may vary based on participation and other logistics and are subject to change.

AGENDA

8:15 AM – 9:00 AM	**Registration** Great Room Lobby
9:00 AM – 9:30 AM	**Introductions and Opening Remarks** Patrizia Cavazzoni, Deputy Director for Operations, Office of the Center Director (OCD), CDER, FDA Keith Flanagan, Director, OND Policy, OND, CDER, FDA
9:30 AM – 10:45 AM	**Session 1 Public Presentations** Peter Pitts, President, Center for Medicine in the Public Interest Jennifer Hamilton, Sr. Director and Head, Precision Medicine, and Maya Bermingham, VP, Public Policy & Governmental Affairs, Regeneron Pharmaceuticals Judith Prescott, Executive Director, Merck & Co., Inc. Paul Melmeyer, Director of Regulatory Affairs, Muscular Dystrophy Association Arthur Krieg, Founder and CSO, Checkmate Pharmaceuticals Tim Yu, Attending Physician, Boston Children's Hospital, and Julia Vitarello, CEO, Mila's Miracle Foundation Janice Soreth, Managing Director, Janice M Soreth MD, LLC
10:45 AM – 11:00 AM	**Break**

11:00 AM – 12:15 PM	**Session 2 Public Presentations** Elliott Levy, SVP Global Development, Amgen Katrin Rupalla, SVP Regulatory Affairs, MedDoc & R&D Quality, Lundbeck Mark Stewart, VP, Science Policy, Friends of Cancer Research Russell Reeve, Sr. Biostatistics Director, IQVIA, Inc. Peter Schiemann, Managing Partner, Widler & Schiemann AG Jitendra Ganju, Principal, Ganju Clinical Trials, LLC Meg Jardine, Deputy Director of the Renal & Metabolic Division, The George Institute for Global Health
12:15 PM – 1:15 PM	**Lunch Break**
1:15 PM – 2:30 PM	**Session 3 Public Presentations** Ting-Chao Chou, President, PD Science, LLC Charles Fisher, Founder and CEO, Unlearn. AI, Inc. Andrew Emmett, FDA Liaison, Global Regulatory Policy & Intelligence, Pfizer Inc. Kelly Close, Founder and CEO, Emily Fitts, Senior Manager, Advocacy & Policy, and Cherise Shockley, Community Manager, The diaTribe Foundation James Love, Director, Knowledge Ecology International Andrew Robertson, Head, Regulatory Science and Policy, Sanofi Andrew Gustafson, Sr. Director, US Regulatory Policy and Advocacy, GlaxoSmithKline
2:30 PM – 2:45 PM	**Break**
2:45 PM – 4:00 PM	**Session 4 Public Presentations** Frank Sasinowski, Vice Chair, EveryLife Foundation for Rare Diseases Frederick Derosier, Executive Medical Director, Rare Disease & Pediatrics Team, Covance Inc. Lucy Vereshchagina, VP Science and Regulatory Advocacy, PhRMA Martin Roessner, Corporate Vice President, Biostatistics, Parexel James Valentine, Associate, Hyman, Phelps & McNamara. P.C. Cartier Esham, Executive VP, Emerging Companies Section, SVP, Science and Regulatory Affairs, Biotechnology Innovation Organization Liza O'Dowd, VP Global Regulatory Affairs, Immunology, Regulatory Policy and Intelligence, and North American Liaison, Janssen R&D
4:00 PM – 4:15 PM	**Conclusions and Closing Remarks** Keith Flanagan, Director, OND Policy, OND, CDER, FDA