



Public Meeting: Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD Pathway)

July 12, 2019
9:00 AM – 12:00 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

This meeting is to hear public comments on the [Limited Population Pathway for Antibacterial and Antifungal Drugs](#) (LPAD pathway) draft guidance. This guidance provides information on the implementation of section 506(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ([21 U.S.C. 356](#)(h)), added by section 3042 of the 21st Century Cures Act.

Each public presentation is allotted 10 minutes. Five minutes are allotted following each presentation to offer an opportunity for the panel to ask clarifying questions. *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
9:00 AM – 9:20 AM	Introductions and Opening Remarks Ed Cox, MD, MPH, Director, OAP, OND, CDER, FDA
9:20 AM – 9:30 AM	Public Presentation: John Rex, M.D. Chief Medical Officer, F2G Ltd.
9:30 AM – 9:35 AM	Questions
9:35 AM – 9:45 AM	Public Presentation: Thomas Walsh, M.D., Ph.D., Professor of Medicine, Pediatrics, Microbiology & Immunology, Cornell University
9:45 AM – 9:50 AM	Questions
9:50 AM – 10:00 AM	Public Presentation: Phoebe Mounts, Ph.D., General Counsel, Cormedix
10:00 AM – 10:05 AM	Questions
10:05 AM – 10:15 AM	Public Presentation: Colin McGoodwin, Infectious Diseases Society of America
10:15 AM – 10:20 AM	Questions
10:20 AM – 10:30 AM	Public Presentation: Jack Mitchell, Director of Health Policy, National Center for Health Research
10:30 AM – 10:35 AM	Questions



10:35 AM – 10:45 AM	Public Presentation: Elizabeth Lovinger, Government Relations & Policy Officer, Treatment Action Group
10:45 AM – 10:50 AM	Questions
10:50 AM – 11:00 AM	Public Presentation: Glen Park, Executive Director, Regulatory Affairs and Quality Assurance Scynexis, Inc., on behalf of Biotechnology Innovation Organization
11:00 AM – 11:05 AM	Questions
11:05 AM – 11:15 AM	Public Presentation: Lisa Wittmer, Ph.D., Chief Development Officer, VenatoRx Pharmaceuticals, Inc., on behalf of Biotechnology Innovation Organization
11:15 AM – 11:20 AM	Questions
11:20 AM – 11:30 AM	Public Presentation: Rienk Pypstra, Vice President, Anti-Infectives, Pfizer, on behalf of the Biotechnology Innovation Organization
11:30 AM – 11:35 AM	Questions
11:35 AM – 11:50 AM	Open Public Comments
11:50 AM – 11:55 AM	Closing Remarks

FDA Panel

Edward Cox, MD, MPH, Director, OAP, OND, CDER, FDA

Sumathi Nambiar, MD, MPH, Director, DAIP, OAP, OND, CDER, FDA

Abimbola Adebowale, PhD, Associate Director for Labeling, DAIP, OAP, OND, CDER, FDA

Sarah Walinsky, JD, Policy Advisor, OND, CDER, FDA

Julia Tierney, JD, Senior Policy Advisor for Strategic Planning and Legislation, CBER, FDA

Katherine Schumann, MS, Policy Advisor, OND, CDER, FDA