

USPTO-FDA Public Listening Session

January 19, 2023

Agenda:

10:00 – 10:10	Welcome and Introductions
10:10 – 10:20	Opening Remarks Dr. Robert M. Califf , Commissioner of Food and Drugs
10:20 – 10:30	Opening Remarks Katherine K. Vidal , Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office
10:30 – 10:40	Announcements
10:40 – 11:00	Session 1: Patient perspectives Ms. Leslie Ritter , <i>National Multiple Sclerosis Society</i> Ms. Sneha Dave (<i>virtual</i>), <i>Generation Patient</i>
11:00 – 11:15	Session 2: Examiner training on publicly available FDA resources Mr. Kevin Wren (<i>virtual</i>), <i>T1International</i>
11:15 – 11:30	<i>Break</i>
11:30 – 12:30	Session 3: Applicant statements made to USPTO and FDA Prof. Robin Feldman , <i>University of California Hastings College of the Law</i> Mr. Tahir Amin , <i>Initiative for Medicines Access & Knowledge (I-MAK)</i> Mr. Hans Sauer , <i>Biotechnology Innovation Organization (BIO)</i> Ms. Shaina Kasper , <i>T1International</i> Prof. Adam Mossoff , <i>George Mason University, Antonin Scalia Law School</i> Ms. Carol Nielsen , <i>Nielsen IP Law, on behalf of American Intellectual Property Law Association (AIPLA)</i>
12:30 – 2:00	<i>Lunch break</i>
2:00 – 3:10	Session 4: Patenting practices in the pharmaceutical sector Ms. Juliana Reed , <i>Biosimilars Forum</i> Mr. David Korn , <i>PhRMA</i> Prof. Liza Vertinsky , <i>University of Maryland Francis King Carey School of Law</i> Dr. S. Sean Tu (<i>virtual</i>), <i>West Virginia University College of Law</i> Mrs. Sarah Bourland , <i>Patients for Affordable Drugs</i> Mr. Corey Salsberg , <i>Novartis</i> Mrs. Azeen James , <i>Fresenius Kabi</i>
3:10 – 3:30	<i>Break</i>

3:30 – 4:10	Session 5: Patent term extension and patent use codes Mr. Victor Van de Wiele , <i>Harvard Medical School</i> Miss Emmabella Rudd , <i>T1International</i> Ms. Patricia Kelmar , <i>U.S. Public Interest Research Group (U.S. PIRG)</i> Prof. John R. Thomas , <i>Georgetown University Law Center</i>
4:10– 4:20	Closing Remarks Derrick Brent , Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office