

(Tentative agenda) - **ORPHAN DRUG DESIGNATION**

WELCOME REMARKS

8:30-8:45 AM Introductions and Opening Remarks
Gayatri R. Rao, MD, JD, Office of Orphan Products Development

PLENARY SESSION

8:45-9:15 AM FDA Orphan Designation 101
Gayatri R. Rao, MD, JD, Office of Orphan Products Development

9:15-9:45 AM EMA Orphan Designation 101
Jordi Llinares, MD, MSc, European Medicines Agency/Orphan Medicines

9:45-10:00 AM BREAK

10:00-10:20 AM Transition Talk- FDA Resources and Meetings
Larry Bauer, RN, Office of New Drugs/Rare Disease Program

10:20-10:50 AM OOPD Grant Program Overview
Kathy Needleman, PhD, Office of Orphan Products Development

10:50-11:05 AM EU/EC Publicly Funded Research Programs
Jordi Llinares, MD, MSc, European Medicines Agency/Orphan Medicines

11:05-11:35 AM Panel Discussion

11:35-11:45 AM Plenary Session Closing Remarks
Gayatri R. Rao, MD, JD, Office of Orphan Products Development

LUNCH- OPEN from 11:30 AM - 2:00 PM

FDA/EMA STAFF CONSULTATIONS (with intermittent Grant Meetings)

(PLEASE NOTE: Afternoon Attendance Requires 2nd Registration Process and Approval)

12:00-12:40 PM OOPD/EMA Staff Consultation Meeting- Mtg. 1

12:40-1:20 PM OOPD/EMA Staff Consultation Meeting- Mtg. 1

1:20-2:00 PM OOPD/EMA Staff Consultation Meeting- Mtg. 1

2:00-2:20 BREAK

2:20-3:00 PM OOPD/EMA Staff Consultation Meeting- Mtg. 1

3:00-3:40 PM OOPD/EMA Staff Consultation Meeting- Mtg. 1

3:40-4:00 PM OOPD/EMA Staff Consultation Meeting- Mtg. 2

4:00-4:10 BREAK

4:10 -4:30 PM OOPD/EMA Staff Consultation Meeting- Mtg. 2

4:30-4:50 PM OOPD/EMA Staff Consultation Meeting- Mtg. 2

4:50-5:10 PM OOPD/ EMA Staff Consultation Meeting- Mtg. 2

5:10-5:30 PM OOPD/EMA Staff Consultation Meeting- Mtg. 2