

HUMANITARIAN USE DEVICE DESIGNATION

WELCOME REMARKS

8:30-8:35 AM Introductions and Opening Remarks
Gayatri Rao, MD., JD, Office of Orphan Products Development

PLENARY SESSION

8:35-9:05 AM FDA HUD Designation 101
Eric Chen, MS, Office of Orphan Products Development

9:05-9:35AM FDA HDE Applications 101
Sheila Brown, RN, Center for Devices and Radiological Health

9:35-9:55 AM OOPD Grant Program/PDC Overview
Linda Ulrich, MD, Office of Orphan Products Development

9:55-10:25 AM Panel Discussion

10:25-10:30 AM Closing Remarks
Debra Lewis, OD, MBA, Office of Orphan Products Development

10:30 – 11:00 am Break & Transition to FDA Staff Consultations

FDA STAFF CONSULTATIONS (with intermittent Grant Meetings)

11:00-11:40 PM OOPD Staff Consultation Meeting- Mtg. 1

11:40-12:20 PM OOPD Staff Consultation Meeting- Mtg. 1

12:20-1:00 PM OOPD Staff Consultation Meeting- Mtg. 1

1:00-1:20 BREAK

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

2:00-2:40 PM OOPD Staff Consultation Meeting- Mtg. 1

2:40-3:20 PM OOPD Staff Consultation Meeting- Mtg. 1

3:20-4:00 PM OOPD Staff Consultation Meeting – Mtg 1