

(Tentative agenda) – **HUMANITARIAN USE DEVICE DESIGNATION**

WELCOME REMARKS

8:30-8:45 AM Introductions and Opening Remarks
Debra Lewis, OD, MBA, Office of Orphan Products Development

PLENARY SESSION

8:45-9:15 AM FDA HUD Designation 101
Eric Chen, MS, Office of Orphan Products Development

9:15-9:45 AM FDA HDE Applications 101
Elizabeth Hillebrenner, MSE, Center for Devices and Radiological Health

9:45-10:00 AM BREAK

10:00-10:20 AM Transition Talk- FDA Resources and Meetings
William Sutton, Center for Devices and Radiological Health

10:20-10:50 AM OOPD Grant Program/PDC Overview
Linda Ulrich, MD, Office of Orphan Products Development

10:50-11:20 AM Panel Discussion

11:20-11:30 AM Closing Remarks
Debra Lewis, OD, MBA, Office of Orphan Products Development

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

FDA STAFF CONSULTATIONS (with intermittent Grant Meetings)

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

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

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

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

2:00-2:20 BREAK

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

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

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

4:00-4:10 BREAK

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

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

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

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