FDA-Industry IVD Roundtable Meeting

Hosted by CBER

FDA White Oak Campus
Building 2, Room 2046
10903 New Hampshire Avenue
Silver Spring, MD20993

AGENDA
Wednesday, January 13, 2010
9:00 AM - 4:00 PM

9:00 – 9:15 AM	**Welcome and Introductions** *Sayah Nedjar, FDA/CBER/OBBR*
9:15 – 10:00 AM	**CBER Update** *Sayah Nedjar, FDA/CBER/OBRR*
10:00 – 10:45 AM	**OIVD Update** *Alberto Gutierrez, FDA/CDRH/OIVD*
10:45 AM – 11:15 AM	**RUO** *Zivana Tezak, FDA/CDRH/OIVD*
11:15 AM – 12:00 PM	**Personalized Medicine Update** *Elizabeth Mansfield, FDA, CDRH, OIVD*
12:00 – 1:15 PM	**Lunch** (may be purchased in FDA Cafeteria)
1:15 – 1:45 PM	**Class I/II IVD Exemptions Project** *Robert DiTullio, Proteogenix*
1:45 – 2:15 PM	**Dec. 14-15 Arbovirus Workshop Update** *Maria Rios, FDA/CBER/OBRR* *Deborah Taylor, FDA/CBER/OBRR*
2:15 – 2:45 PM	**OTC HIV Tests** *Elliot Cowan, FDA/CBER/OBRR*
2:45 – 3:30 PM	**Migration Studies** *Sally Hojvat, FDA/CDRH/OIVD/DMD* *Marina Kondratovich, FDA, CDRH/OIVD* *Stephanie Axelrod, FDA/CDRH/OIVD/DMD*
3:30 – 4:00 PM	**New Business and Next Meeting**