ABUSE DETERRENT FORMULATION SCIENCE MEETING

- Discussion of the FDA Draft Guidance for Industry: Abuse Deterrent Opioids - Evaluation and Labeling

September 30 – October 1, 2013
Bethesda North Marriott Hotel & Conference Center, Salon F-H (lobby level)

Organized by the Cross-Company Abuse Liability Consortium, CCALC,
Facilitated with the aid of the College on Problems of Drug Dependence, CPDD.

September 30, 2013

7:30am – 5:00pm	**Registration (Foyer H)**
7:30am – 8:30am	**Breakfast (Foyer)**
8:30am – 8:45am	**I. Welcome and Opening Remarks** Co-chairs: Marta Sokolowska, Grünenthal (CCALC); Patrick Beardsley, Virginia Commonwealth University (CPDD)
8:45am – 9:15am	**II. Keynote** Speaker: Douglas C. Throckmorton (FDA/CDER)
9:30am – 9:45am	**III. Background** 1. Overview of the FDA guidance documents regarding drug abuse assessments Speaker: Michael Klein (FDA/CDER/CSS)
9:45am – 10:00am	2. Overview of the prescription drug abuse epidemic and public health risk associated with oral versus non-oral (IN and IV) routes of administration Speaker: Nathaniel Katz (Analgesic Solutions)
10:00am – 10:15am	**Coffee Break**
10:15am – 10:30am	**IV. Laboratory Manipulation and Extraction Studies (Category 1)** **Chair: Edward J. Cone (Pinney Associates)** 1. Introduction: Category 1 studies overview Speaker: James Tolliver (FDA/CDER/CSS)
10:30am – 10:45am	2. Design of in vitro studies and the standardization of core in vitro tests Speaker: Robert Bianchi (Prescription Drug Research Center)
10:45am – 11:00am	3. Implications of in vitro testing of ADFs for industry and real world abusers Speaker: Edward Cone

11:00am – 12:00pm	4. Panel discussion Panelists: Edward Cone (Moderator); Nagesh Bandi (Pfizer), Robert Bianchi, Cliff Herman (Mallinckrodt), Sharon Hertz (FDA/CDER/DAAAP), James Tolliver, Lawrence Yu (FDA)
12:00pm – 1:00pm	**Lunch (White Oak Dining Room, lower level)**
	V. Pharmacokinetic (Category 2) & Clinical Abuse Potential Studies (Category 3) **Chair: Edward M. Sellers (DL Global Partners)**
1:00pm – 1:15pm	1. Introduction: Category 2 and Category 3 studies overview Speaker: Silvia Calderon (FDA/CDER/CSS)
1:15pm – 1:30pm	2. The role and interpretation of pharmacokinetic parameters in the assessment of abuse potential Speaker: Sharon Walsh (University of Kentucky)
1:30pm – 1:45pm	3. Methodological challenges associated with the adaptation of human abuse potential studies for ADF assessment Speaker: Marta Sokolowska (Grünenthal USA)
1:45pm – 2:00pm	4. Recommendations for the pre-qualification assessment in human abuse potential studies Speaker: Beatrice Setnik (Pfizer)
2:00pm – 2:15pm	5. Interpretation of human abuse potential studies while addressing how to define clinically important responses to ADFs Speaker: Kerri Schoedel (Altreos Research Partners)
2:15pm – 2:30pm	6. Statistical analysis of clinical abuse potential studies Speaker: Nacer E. Abrouk (Nektar Therapeutics)
2:30pm – 3:00pm	**Coffee Break**
3:00pm – 5:00pm	7. Panel discussion Panelists: Edward Sellers (Moderator), Nacer Abrouk, Silvia Calderon, Ling Chen (FDA), Sharon Hertz, Srikanth Nallani (FDA), Kerri Schoedel, Beatrice Setnik, Marta Sokolowska, Sharon Walsh
5:00pm- 6:00pm	**Wine & Cheese Reception (Foyer H)**

October 1, 2013

7:30am – 1:30pm	**Registration (Foyer H)**
7:30am - 8:30am	**Breakfast (Foyer)**
8:30 am – 8:45 am	**Day 2: Opening Remarks**
	VI. Post Marketing Studies (Category 4) **Chair: Sidney Schnoll (Pinney Associates)**
8:45 am – 9:00 am	1. Introduction: Category 4 Studies Overview Speaker: Cynthia J Kornegay (FDA/OSE)
9:00 am – 9:15 am	2. Measures to Assess Abuse and Misuse (Addiction, Overdose, and Death) Speaker: Joe Gfroerer (SAMHSA)
9:15 am – 9:30 am	3. Challenges in Conducting Post Marketing Abuse Investigations Speaker: Paul Coplan (Purdue Pharma)
9:30am – 10:30am	4. Panel Discussion Panelists: Sidney Schnoll (Moderator); Simon Budman (Inflexxion), Paul Coplan, Rick Dart (RADARs), Joe Gfroerer, Cynthia Kornegay, Carl Roland (Pfizer)
10:30 am-10:45 am	**Coffee Break**
	VII. Drug Labeling **Chair: Jack Henningfield (Pinney Associates)**
10:45 am-11:00 am	1. Introduction: Drug Labeling Overview Speaker: Bob Rappaport (FDA/DAAAP)
11:00 am -11:15am	2. Structuring the submission of abuse deterrence data and formulating the ADF label Speaker: Naama Levy Cooperman (Altreos Research Partners)
11:15 am -12:15pm	3. Panel discussion Panelists: Jack Henningfield (Moderator); Todd Baumgartner (Purdue), Naama Levy Cooperman, Mark Mannebach (Mallinckrodt), Bob Rappaport, Beatriz Rocha (Covance)
12:15pm – 1:15pm	**Lunch (White Oak Dining Room, lower level)**

	VIII.	**Additional Research Needs: Data Requirements for Generic Drug Approvals & Implications for Drug Labeling** **Chair: Lynn McPherson (University of Maryland)**
1:15 pm – 1:30 pm		1. FDA perspective Speaker: Andre Raw (OGD/FDA)
1:30 pm - 1:45 pm		2. Proposed approaches for generic drug approval and drug labeling issues Speaker: Penny Levin (Teva)
1:45 pm – 2:00 pm		3. PK/PD Modeling: Evaluation of the Quantitative Link Between Pharmacokinetic and Human Abuse Potential Study Pharmacodynamic Results Speaker: Megan Shram (Altreos Research Partners)
2:00 pm – 2:15 pm		4. Assessment of the predictive value of in vitro and human abuse potential testing in relation to the post marketing impact of ADF: A review of the OxyContin case study Speaker: Edward Sellers
2:15 pm – 3:15 pm		5. Panel Discussion Panelists: Lynn McPherson (Moderator), Penny Levin, Andre Raw, Megan Shram, Edward Sellers, Diane Servello (Mallinckrodt), Sharon Walsh
3:15 pm – 3:30 pm		**Coffee Break**
	IX.	**Summary and Conclusion** **Speakers: Chairs of each section**
3:30 pm – 3:45 pm		1. Laboratory Manipulation and Extraction Studies (Category 1)
3:45 pm – 4:00 pm		2. Pharmacokinetic Studies (Category 2) & Human Abuse Potential Studies (Category 3)
4:00 pm – 4:15 pm		3. Post-marketing Studies (Category 4)
4:15 pm – 4:30 pm		4. Drug Labeling
4:30 pm – 4:45 pm		5. Additional Research Needs (Generics)
4:45 pm – 5:00 pm	X.	**Closing remarks**