

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**- Discussion of the FDA Draft Guidance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

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

Meeting Objectives:

- To provide an open forum enabling discussion and recommendations on the FDA Draft Guidance for Industry: Abuse Deterrent Opioids – Evaluation and Labeling
- To provide an opportunity for presentations by experts addressing the Draft Guidance

We gratefully acknowledge sponsorship
from the following companies:

- AbbVie
- CRI LifeTree
- Eli Lilly and Company
- INC Research
- Inspirion Delivery Technologies, LLC
- Janssen Scientific Affairs, LLC
- Grünenthal USA
- GW Pharmaceuticals & Otsuka Pharmaceutical
Development and Commercialization
- Purdue Pharma L.P.
- Vince & Associates Clinical Research

CCALC - Introduction

- Founded in June 2006 as “Grass roots” Industry organization
- Approximately 80 people representing >25 pharmaceutical companies
- Mission Statement:
 - The purpose of CCALC is to provide an informal forum for colleagues from different pharmaceutical companies with diverse perspectives and expertise to share knowledge and to work together on issues related to the abuse potential of pharmaceutical products. Our mission is to advance the science of abuse potential assessment across the product life cycle (preclinical through post-marketing) and work with regulators, academic researchers, and public policy advocates in order to promulgate best practices in the assessment and management of pharmaceutical abuse liability.

CCALC - Key activities to date

- 2 meetings with the FDA
 - Dialogue Session I (Feb 2008), to facilitate open discussion between Industry and FDA on abuse liability assessment for pharmaceuticals
 - Dialogue Session II (Nov 2010), to discuss and provide recommendations on the FDA Draft Guidance for Industry: Assessment of Abuse Potential of Drugs
- RAPS Publication:
 - Companies Unite to Advance Regulatory Landscape of Abuse Potential Assessment
 - <http://www.raps.org/publications-amp-resources/regulatory-focus.aspx>

CCALC - organization

- CCALC includes 4 working groups
 - clinical
 - preclinical
 - regulatory
 - risk management/post-marketing
- For more information or to join please contact:
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