Food and Drug Administration

Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products

Public Meeting

Agenda

October 31, 2016 – Day 1: Evaluating the Abuse Deterrence of Generic Opioid Drug Products

8:30 a.m. – 8:45 a.m.	**Welcome and Logistics**
8:45 a.m. – 9:15 a.m.	**Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products – Framing the Meeting** Douglas C. Throckmorton, MD, Deputy Director, Regulatory Programs, CDER
9:15 a.m. – 9:45 a.m.	**Introduction to FDA's Draft Guidance on the General Principles for Evaluation of Abuse Deterrence of Generic Solid Oral Opioid Drug Products (Hereinafter, Generics ADF Guidance)** Robert Lionberger, Ph.D., Director, Office of Research and Standards, Office of Generic Drugs, CDER
9:45 a.m. – 10:00 a.m.	**Break**
10:00 a.m. – 10:40 a.m.	**Foundations of In Vitro Comparisons of Generic Opioids to Reference Listed Drugs (RLDs) with Labeling Describing Abuse-Deterrent Properties**
	10:00 a.m. – 10:20 a.m. Xiaoming Xu, Ph.D., Senior Staff Fellow, Division of Product Quality Research, Office of Testing and Research, Office of Pharmaceutical Quality, CDER
	10:20 a.m. – 10:40 a.m. Stephen W. Hoag, Ph.D., Professor, Department of Pharmaceutical Sciences, University of Maryland School of Pharmacy
10:40 a.m. – 11:00 a.m.	**Foundations of Pharmacokinetic Comparisons of Generic Opioids to RLDs with Labeling Describing Abuse-Deterrent Properties** Liang Zhao, Ph.D., Director, Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, CDER

11:00 a.m. – 11:30 a.m.	**Generic Industry Perspective on the Generics ADF Guidance** Penny Levin, MS, Director, Global Regulatory Intelligence & Policy, Teva Pharmaceuticals
11:30 a.m. – 12:00 p.m.	**Brand Industry Perspective on the Generics ADF Guidance** Jeffrey M. Dayno, MD, Chief Medical Officer, Egalet Corporation
12:00 p.m. – 1:00 p.m.	**Lunch**
1:00 p.m. – 2:00 p.m.	**Payer Perspective – Prescription of and Payment for ADF Opioids**
	1:00 p.m. – 1:20 p.m. John Coster, Ph.D., R.Ph., Director, Division of Pharmacy, Center for Medicare and Medicaid Services Jeffrey Kelman, MD, Chief Medical Officer, Center for Medicare and Medicaid Services
	1:20 p.m. – 1:40 p.m. Chester (Bernie) Good, MD, MPH, Chair, Medical Advisory Panel for Pharmacy Benefits Management, Department of Veteran Affairs; Professor of Medicine and Pharmacy, University of Pittsburgh
	1:40 p.m. – 2:00 p.m. Anshu Choudhri, MHS, Managing Director, Value-Based Policy, Office of Policy and Representation, Blue Cross and Blue Shield Association
2:00 p.m. – 2:15 p.m.	**Break**
2:15 p.m. – 3:30 p.m.	**Public Comment Period** **Evaluating the Abuse Deterrence of Generic Opioid Drug Products**
3:30 p.m. – 4:30 p.m.	**Panel Discussion** **Generics ADF Guidance and Potential Future Improvements in the Evaluation of the Equivalence of Proposed Generic Opioids to RLDs with Labeling Describing Abuse-Deterrent Properties** **Generic Industry:** Gregg DeRosa, VP, Global Clinical Research & Development, Teva Pharmaceuticals

	Innovator Industry: Daniel Cohen, MALS, Executive Vice President, Government & Public Relations, Kem Pharm, Inc. **CDER, FDA:** Ellen Fields, Deputy Director, Division of Anesthesia, Analgesia, and Addiction Products, Office of New Drugs, CDER Patrick Raulerson, Regulatory Counsel, Office of Regulatory Policy, CDER James Tolliver, Ph.D., Pharmacologist, Controlled Substance Staff, CDER **<u>Panelists/Speakers</u>** Lucinda Buhse, Ph.D. Anshu Choudhri, MHS John Coster, PhD, R.Ph. Chester (Bernie) Good MD, MPH Stephen W. Hoag, Ph.D. Jeffrey Kelman, MD Robert Lionberger, Ph.D. Richard (Rik) Lostritto, Ph.D. Douglas C. Throckmorton, MD Xiaoming Xu, Ph.D. Liang Zhao, Ph.D.

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November 1, 2016 – Day 2: Development of Standardized In Vitro Testing to Evaluate Abuse Deterrence

8:30 a.m. – 8:35 a.m.	**Welcome and Logistics**
8:35 a.m. – 9:15 a.m.	**Vision for Standardizing In Vitro Testing to Evaluate Abuse Deterrence of New Oral Opioid Drug Products** Richard (Rik) Lostritto, Ph.D., Acting Associate Director for Science, Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality, CDER
9:15 a.m. – 9:45 a.m.	**Office of Pharmaceutical Quality Science and Research: Abuse-Deterrent Formulations** Lucinda Buhse, Ph.D., Director, Office of Testing and Research, Office of Pharmaceutical Quality, CDER
9:45 a.m. – 10:00 a.m.	**Break**
10:00 a.m. – 10:30 a.m.	**Generic Industry Perspective on Standardizing Testing** Elisabeth Kovacs, CSO Chemistry and Analytical Science, Apotex Inc.
10:30 a.m. – 11:00 a.m.	**Brand Industry Perspective on Standardizing Testing** Alison B. Fleming, PhD, Vice President, Product Development, Collegium Pharmaceutical, Inc.
11:00 a.m. – 12:00 p.m.	**Public Comment Period** **New Technologies/Formulations for Abuse Deterrence**
12:00 p.m. – 1:00 p.m.	**Lunch**
1:00 p.m. – 2:15 p.m.	**Public Comment Period** **Standardization of Testing of Abuse Deterrence of Opioids**

2:15 p.m. – 3:30 p.m.	**Panel Discussion** **Future Directions That Will Enable the Efficient Development and Evaluation of Abuse Deterrence of Opioids** **Generic Industry:** Venkatarama Yarasani, Ph.D., Executive Director, Product Development, Teva Pharmaceuticals **Innovator industry:** Karsten Lindhardt Ph.D., Msc, DBE, Senior Vice President, Head of Research & Development, Egalet Corporation **CDER, FDA** Sharon Hertz, MD, Director, Division of Anesthesia, Analgesia, and Addiction Products, Office of New Drugs, CDER Patrick Raulerson, Regulatory Counsel, Office of Regulatory Policy, CDER James Tolliver, Ph.D., Pharmacologist, Controlled Substance Staff, CDER **Panelists/Speakers** Lucinda Buhse, Ph.D. Robert Lionberger, Ph.D. Richard (Rik) Lostritto, Ph.D. Douglas C. Throckmorton, MD Liang Zhao, Ph.D.
3:30 p.m. – 4:00 p.m.	**Closeout and Summary of Meeting**