FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
November 14, 2018

AGENDA

The committees will discuss new drug application (NDA) 209774, for an immediate-release oral tablet formulation of oxycodone, which is intended to resist common methods of physical or chemical manipulation and to deter intravenous and intranasal abuse, submitted by SpecGx LLC, for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. The committees will also be asked to determine whether the Applicant adequately demonstrated that the abuse-deterrent properties of the proposed product are sufficient to include this information in the product label, and whether the product should be approved.

8:00 a.m. Call to Order and Introduction of Committee
Brian Bateman, MD
Acting Chairperson, AADPAC

8:05 a.m. Conflict of Interest Statement
Moon Hee V. Choi, PharmD
Designated Federal Officer, AADPAC

8:10 a.m. FDA Opening Remarks
Sharon Hertz, MD
Director, Division of Anesthesia, Analgesia, and Addiction Products (DAAAP)
Office of Drug Evaluation II (ODE-II)
Office of New Drugs (OND), CDER, FDA

8:30 a.m. APPLICANT PRESENTATIONS
SpecGx LLC

Introductions
Martha Selicher, PhD
Vice President, R&D
Mallinckrodt Pharmaceuticals

Public Health Need for Abuse-Deterrent IR Opioid Analgesics
Richard Dart, MD, PhD
Director Rocky Mountain Poison & Drug Center
Professor of Emergency Medicine
University of Colorado School of Medicine
Executive Director, RADARS® System

Category 1 In Vitro Studies
Edward Cone, PhD
Principal Scientist
Drug Delivery and Abuse Deterrent Drug Products
Pinney Associates
APPLICANT PRESENTATIONS (CONT.)

Nonclinical Excipient Safety Studies  Mike Orr, PhD, DABT
President/CEO
Orr Nonclinical Consulting, LLC

Intranasal Human Abuse Potential Study  Sandra Comer, PhD
Professor of Neurobiology (in Psychiatry)
Division on Substance Use Disorders
Columbia University

Clinical Perspective  Jeff Gudin, MD
Director
Pain Management and Palliative Care
Englewood Hospital and Medical Center

9:45 a.m.  Clarifying Questions
10:00 a.m.  BREAK
10:15 a.m.  FDA PRESENTATIONS

MNK-812 Introduction and Overview  Jennifer L. Nadel, MD
Medical Officer
DAAAP, ODE-II, OND, CDER, FDA

In Vitro Category I Abuse-Deterrent Studies of MNK-812  Valerie Amspacher, PharmD
Chemistry, Manufacturing and Controls Reviewer
Division of New Drug Products II
Office of New Drug Products (ONDP)
Office of Pharmaceutical Quality, CDER, FDA

Nonclinical Safety Assessment of MNK-812 Excipients  R. Daniel Mellon, PhD
Pharmacology Toxicology Supervisor
DAAAP, ODE-II, OND, CDER, FDA
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AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

Examination of Intranasal Human Abuse Potential Study
MNK48121013

James M. Tolliver, PhD
Pharmacologist
Controlled Substance Staff
Office of the Center Director
CDER, FDA

Review of Recent Epidemiologic Data on Use, Misuse and Abuse of Oxycodone

Tamra Meyer, PhD, MPH
Team Lead, Prescription Drug Abuse Team
Division of Epidemiology II
Office of Pharmacovigilance and Epidemiology
Office of Surveillance and Epidemiology
CDER, FDA

MNK-812 Clinical Summary of Abuse Deterrence

Jennifer L. Nadel, MD

11:30 a.m. Clarifying Questions

11:45 a.m. LUNCH

12:45 p.m. OPEN PUBLIC HEARING

1:45 p.m. Charge to the Committee

1:50 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. BREAK

3:15 p.m. Questions to the Committee/Committee Discussion (cont.)

5:00 p.m. ADJOURNMENT