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 Sclicher, 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

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AGENDA (cont.)

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	**Sharon Hertz, MD**
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**	