



U.S. Food and Drug Administration

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FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC)
and Drug Safety & Risk Management Advisory Committee (DSaRM)

Holiday Inn/Gaithersburg, Maryland, The Ballrooms
Two Montgomery Village Avenue,
Gaithersburg, Maryland

AGENDA
September 23, 2009

The committee will discuss new drug application (NDA) 21-217, EXALGO (hydromorphone HCl), Neuromed Pharmaceuticals, Inc., and its safety for the proposed indication of treatment of moderate-to-severe pain in opioid tolerant patients

8:00 a.m.	Call to Order Introduction of Committee	Jeffrey Kirsch, MD Chair, ALSDAC
	Conflict of Interest Statement	Kalyani Bhatt Designated Federal Officer, ALSDAC
8:10 a.m.	Opening Remarks	Ellen Fields, MD, MPH Clinical Team Leader, Division of Analgesia, Anesthesia, and Rheumatology Products (DAARP), CDER/FDA
8:15 a.m.	Sponsor Presentations	
	Introduction / Clinical Pharmacology/ Closing Remarks	C. Eugene Wright, PharmD, PhD Vice President, Project Leadership Neuromed Pharmaceuticals, Inc.
	Regulatory Overview	James Ottinger, RPh Vice President, Regulatory Affairs Premier Research Group
	Clinical Overview	Christopher Gallen, MD, PhD Chief Executive Officer Neuromed Pharmaceuticals, Inc.
	Extended Release Hydromorphone for Patients with Chronic Pain	Lynn R. Webster, MD, FACPM, FASAM Medical Director Lifetree Clinical Research and Pain Clinic
	Exalgo Alliance: Risk Evaluation & Mitigation Strategy (REMS)	Annette Stemhagen, DrPH, FISPE Senior Vice President Epidemiology, Registries and Risk Management United BioSource Corporation
	Exalgo Alliance: Implementation, Assessment and Commitment	Herbert Neuman, MD Vice President and Chief Medical Officer Covidien

9:45 a.m. Questions for Presenters

10:05 a.m. Break

10:20 a.m. **FDA Presentations**

10:20 a.m. Clinical Review of EXALGO

Elizabeth Kilgore, MD
Medical Officer
DAARP, CDER/FDA

10:40 a.m. Drug Utilization Trends

Patty Greene, PharmD
Drug Utilization Analyst
Division of Epidemiology I (DEPI)
Office of Safety and Epidemiology (OSE)
CDER/FDA

10:50 a.m. Findings from the Drug Abuse Warning
Network (DAWN)

Catherine Dormitzer, PhD
Epidemiologist
Division of Epidemiology I (DEPI),
OSE, CDER/FDA

11:10 a.m. EXALGO Abuse Liability

Jianping Gong, MD, PhD
Medical Officer
Controlled Substance Staff (CSS), CDER/FDA

11:25 a.m. EXALGO Risk Management: Postmarketing
Experience and Recommendations

Jeanne Perla, PhD
Risk Management Analyst
Division of Risk Management
OSE, CDER/FDA

11:40 a.m. Questions for Presenters

12:00 p.m. Lunch Break

1:00 p.m. Open Public Hearing

2:00 p.m. Discussion/Questions to the Committee

4:30 p.m. Adjourn