FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

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

DRAFT AGENDA

May 6, 2008

The committee will discuss supplemental new drug application (sNDA) 21-947/s-005, FENTORA (fentanyl buccal tablet), Cephalon, Inc., and its safety for the proposed indication of breakthrough pain in opioid tolerant non-cancer patients with chronic pain

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8:00 a.m.	Call to Order Introduction of Committee	**Sulpico de Guzman Soriano, III, M.D.** Acting Chair, ALSDAC
	Conflict of Interest Statement	**Teresa Watkins, Pharm.D., R.Ph.** Acting Designated Federal Officer, ALSDAC/DSaRM
8:10 a.m.	Opening Remarks	**Bob Rappaport, M.D.** Director, Division of Analgesia, Anesthesia, and Rheumatology Products (DAARP), CDER/FDA
8:15 a.m.	**Sponsor Presentation**	Cephalon
	Introduction and Closing	**Eric Floyd, M.S., M.B.A., Ph.D.** Vice President, Regulatory Affairs Cephalon, Inc.
	Medical Need/Overview of Breakthrough Pain(BTP)	**Perry G. Fine, M.D.** Professor of Anesthesiology The University of Utah School of Medicine
	Efficacy, Landscape, and Perceived Risks	**John Messina, PharmD** Senior Director, Clinical Research Cephalon, Inc.
	Safety and Risk Management	**Juergen Schmider, M.D., Ph.D.** Corporate Safety Officer and Vice President, Global Pharmacovigilance and Epidemiology Cephalon, Inc.
9:15 a.m.	Background on Transmucosal Fentanyl Products	**Ellen Fields, M.D., M.P.H.** Clinical Team Leader, DAARP, CDER/FDA
9:30 a.m.	Actiq and Fentora Drug Utilization Trends	**LCDR Kendra Worthy, Pharm.D.** U.S. Public Health Service Commissioned Corps Drug Utilization Analyst Division of Epidemiology Office of Surveillance and Epidemiology (OSE), CDER/FDA
9:45 a.m.	Break	

10:00 a.m.	Review of Fentora and Actiq Adverse Events from the Adverse Event Reporting System (AERS) Database	**Yoo Jung Chang, Pharm.D.** Safety Evaluator Division of Adverse Event Analysis II, OSE, CDER/FDA
10:20 a.m.	FENTORA Medication Errors	**Kristina C. Arnwine, Pharm.D.** Acting Team Leader Division of Medication Error Prevention OSE, CDER/FDA
10:30 a.m.	Fentora Abuse Potential in the Noncancer Population	**Lori A. Love, M.D., Ph.D**. Medical Officer Controlled Substance Staff (CSS), CDER/FDA
10:45 a.m.	Findings from the Drug Abuse Warning Network (DAWN)	**Judy K. Ball, Ph.D., M.P.A.** Acting Director, Division of Operations Office of Applied Studies Substance Abuse and Mental Health Services Administration, DHHS
11:05 a.m.	FDA Safety Analysis of Supplement 005	**Robert Shibuya, M.D.** Medical Officer, DAARP, CDER/FDA
11:20 a.m.	Fentora Risk Management: Postmarketing Experience and Recommendations	**Jeanine Best, M.S.N., R.N., P.N.P.** Senior Drug Risk Management Analyst Division of Risk Management OSE, CDER/FDA
11:35 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 (Vote)	
4:30 p.m.	Adjourn	