

Food and Drug Administration
Center for Drug Evaluation and Research
Versailles Ballroom, Holiday Inn, Bethesda, MD
Anesthetic & Life Support Drugs Advisory Committee
Meeting Agenda
September 9-10, 2003

Please note the agenda times listed are subject to
change as the meeting progresses

September 9, 2003

8:00 a.m.	Call to Order and Opening Remarks
	Introduction of Committee
	Conflict of Interest (COI) Statement
8:15 a.m.	Opening Remarks
	Risk Management of Opiate Analgesics
8:30 a.m.	FDA's Role in the Risk Management of Opiate Analgesics
8:45 a.m.	The Controlled Substances Act and Sponsor Presentation Risk Management
9:00 a.m.	The Drug Enforcement Agency's Role in Risk Management of Opiate Analgesics
9:15 a.m.	Review of Current Medical Practice, Clinical Use and Benefit of Opiate Analgesic Treatment
9:45 a.m.	<i>Break</i>
10:00 a.m.	Opiate Use Data
10:15 a.m.	Misuse and Abuse of Opiate Analgesics in the Medical Setting
10:45 a.m.	Opiate Abuse Data
11:45 a.m.	Prescription Opiate Diversion
12:15 p.m.	<i>Lunch</i>
1:15 p.m.	Open Public Hearing
	Existing Risk Management Plans
2:15 p.m.	Goals of Risk Management Plans/ Non-Opiate Risk Management Plans
2:45 p.m.	<i>Break</i>
3:00 p.m.	Current Opioid Risk Management Plans
3:30 p.m.	Committee Discussion
5:00 p.m.	Adjournment

**Food and Drug Administration
Center for Drug Evaluation and Research**

Versailles Room, Holiday Inn, Bethesda, MD

**Anesthetic & Life Support Drugs Advisory Committee
Meeting Agenda**

September 9-10, 2003

Please note the agenda times listed are subject to
change as the meeting progresses

September 10, 2003

8:00 a.m.	Call to Order and Opening Remarks
	Conflict of Interest Statement
8:45 a.m.	Sponsor Presentation (Purdue Pharma, L.P.)
	Introductory Comments
	Palladone Risk Management Plans
	Concluding Remarks
9:45 a.m.	Questions from the Committee
10:00 a.m.	Abuse Liability
10:30 a.m.	<i>Break</i>
10:45 a.m.	Long Acting Opiates: Challenges and Risks
11:15 a.m.	FDA Presentation
12:15 p.m.	Open Public Hearing
12:45 p.m.	<i>Lunch</i>
1:45 p.m.	Committee Discussion
3:00 p.m.	<i>Break</i>
5:00 p.m.	Adjournment