

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)***

November 2, 2020

AGENDA

The committees will discuss new drug application (NDA) 209257, proposed tradename, HYDEXOR, a fixed-dose combination oral tablet, submitted by Õlas Pharma, Inc., that contains hydrocodone, acetaminophen, and promethazine, for the short-term (not to exceed 3 days) management of acute post-operative pain severe enough to require an opioid analgesic and the prevention of opioid-induced nausea and vomiting in patients who are at risk for or have a history of nausea and vomiting.

9:00 a.m.	Call to Order and Introduction of Committee	Brian T. Bateman, MD Acting Chairperson, AADPAC
9:05 a.m.	Conflict of Interest Statement	Moon Hee V. Choi, PharmD Designated Federal Officer, AADPAC
9:10 a.m.	FDA Opening Remarks	Rigoberto Roca, MD Division Director Division of Anesthesiology, Addiction Medicine and Pain Medicine Office of Neuroscience Office of New Drugs, CDER, FDA
9:15 a.m.	APPLICANT PRESENTATIONS	Õlas Pharma, Inc.
	Introduction: Today's Purpose	George A. Scott, Jr., JD, MBA Executive Vice President of Corporate Affairs & Chief Legal Officer Õlas Pharma, Inc. Jupiter, Florida
	Clinical Efficacy and Safety	Bernard P. Schachtel, MD Chief Scientific Officer Õlas Pharma, Inc. Jupiter, Florida
	Aligned Proposal to Mitigate Safety Concerns	George A. Scott, Jr., JD, MBA
10:00 a.m.	Clarifying Questions	

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10:10 a.m. **FDA PRESENTATIONS**

FDA Perspective

Rigoberto Roca, MD

Carolyn Tieu, PharmD, MPH

Acting Team Leader

Division of Risk Management

Office of Medication Error Prevention and Risk
Management

Office of Surveillance and Epidemiology

CDER, FDA

10:40 a.m. Clarifying Questions

10:50 a.m. **BREAK**

11:00 a.m. **OPEN PUBLIC HEARING**

12:00 p.m. Charge to the Committee

Rigoberto Roca, MD

12:05 p.m. Questions to the Committee/Committee Discussion

1:00 p.m. **ADJOURNMENT**