

**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

**DRAFT AGENDA**

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*The committees will discuss new drug application (NDA) 209257, proposed tradename, HYDEXOR, a fixed-dose combination oral tablet, submitted by Ōlas 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.*

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9:00 a.m.	Call to Order and Introduction of Committee	<b>Brian T. Bateman, MD</b> Acting Chairperson, AADPAC
9:05 a.m.	Conflict of Interest Statement	<b>Moon Hee V. Choi, PharmD</b> Designated Federal Officer, AADPAC
9:10 a.m.	FDA Opening Remarks	<b>Rigoberto Roca, MD</b> Division Director Division of Anesthesiology, Addiction Medicine and Pain Medicine (DAAP) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
9:15 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Ōlas Pharma, Inc.</b>
	Introduction: Today's Purpose	<b>George A. Scott, Jr., JD, MBA</b> Executive VP of Corporate Affairs & Chief Legal Officer Ōlas Pharma, Inc. Jupiter, Florida
	Summary of Efficacy and Safety	<b>Bernard P. Schachtel, MD</b> Chief Scientific Officer Ōlas Pharma, Inc. Jupiter, Florida
	Alignment to Mitigate Safety Concerns	<b>George A. Scott, Jr., JD, MBA</b>
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**