

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting***  
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)  
10903 New Hampshire Avenue, Silver Spring, Maryland  
February 14-15, 2018

**DRAFT AGENDA**

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*The committee will discuss supplemental new drug application (sNDA) 022496/S-009, for EXPAREL (bupivacaine liposomal injectable suspension), submitted by Pacira Pharmaceuticals, Inc., to produce local analgesia and as a nerve block to produce regional analgesia.*

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**Day 1: February 14, 2018**

1:30 p.m.	Call to Order and Introduction of Committee	<b>Mary Ellen McCann, MD, MPH</b> Acting Chairperson, AADPAC
1:40 p.m.	Conflict of Interest Statement	<b>Moon Hee V. Choi, PharmD</b> Designated Federal Officer, AADPAC
1:45 p.m.	FDA Introductory Remarks	<b>Sharon Hertz, MD</b> Director Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
2:00 p.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Pacira Pharmaceuticals, Inc.</b>
	Introduction	<b>Michael Rozycki, PhD</b> Vice President, Regulatory Affairs Pacira Pharmaceuticals, Inc.
	Unmet Need	<b>Anoushka Afonso, MD</b> Director, Enhanced Recovery after Surgery Department of Anesthesiology & Critical Care Memorial Sloan Kettering Cancer Center
	Efficacy	<b>Roy S. Winston, MD</b> Sr Vice President Anesthesia, Surgery, and Medical Affairs Pacira Pharmaceuticals, Inc.
	Safety	<b>Richard Scranton, MD, MPH</b> Sr Vice President and Chief Scientific Officer Pacira Pharmaceuticals, Inc.

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**DRAFT AGENDA (cont.)**

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**APPLICANT PRESENTATIONS (CONT.)**

Clinical Perspective

**Jeff Gadsden, MD, FRCPC, FANZCA**  
Associate Professor  
Duke University School of Medicine  
Chief, Division of Orthopaedic, Plastic and  
Regional Anesthesiology  
Regional Anesthesiology and Acute Pain Medicine  
Fellowship Director  
Duke University Medical Center

Conclusions

**Richard Scranton, MD, MPH**

3:30 p.m. **BREAK**

3:45 p.m. Clarifying Questions

5:00 p.m. **ADJOURNMENT**

**Day 2: February 15, 2018**

8:00 a.m. Call to Order

**Mary Ellen McCann, MD, MPH**  
Acting Chairperson, AADPAC

8:15 a.m. Conflict of Interest Statement

**Moon Hee V. Choi, PharmD**  
Designated Federal Officer, AADPAC

8:20 a.m. FDA Introductory Remarks

**Sharon Hertz, MD**  
Director  
DAAAP, ODE-II, OND, CDER, FDA

8:30 a.m. **FDA PRESENTATIONS**

Assessment of Efficacy Data of Studies  
Submitted in Support of sNDA

**Alla Bazini, MD**  
Medical Officer  
DAAAP, ODE-II, OND, CDER, FDA

Statistical Analysis of EXPAREL Efficacy  
from Nerve-block Studies

**Katherine Meaker, MS**  
Statistics Reviewer  
Division of Biometrics II  
Office of Biostatistics  
Office of Translational Sciences (OTS)  
CDER, FDA

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**DRAFT AGENDA (cont.)**

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**FDA PRESENTATIONS (CONT.)**

Pharmacokinetics of EXPAREL from  
Infiltration and Nerve-block Studies

**Suresh Naraharisetti, DVM, PhD**  
Clinical Pharmacology Reviewer  
Division of Clinical Pharmacology II  
Office of Clinical Pharmacology (OCP)  
OTS, CDER, FDA

Assessment of Safety Data of Studies  
Submitted in Support of sNDA

**Alla Bazini, MD**

10:30 a.m. **BREAK**

10:45 a.m. Clarifying Questions

11:45 a.m. **LUNCH**

12:45 p.m. Open Public Hearing

1:45 p.m. Charge to the Committee

**Sharon Hertz, MD**

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

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee  
Discussion

5:00 p.m. **ADJOURNMENT**