

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

AGENDA

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.

Day 1: February 14, 2018

1:30 p.m.	Call to Order and Introduction of Committee	Mary Ellen McCann, MD, MPH Acting Chairperson, AADPAC
1:40 p.m.	Conflict of Interest Statement	Moon Hee V. Choi, PharmD Designated Federal Officer, AADPAC
1:45 p.m.	FDA Introductory Remarks	Sharon Hertz, MD 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.	APPLICANT PRESENTATIONS	Pacira Pharmaceuticals, Inc.
	Introduction	Michael Rozycki, PhD Vice President, Regulatory Affairs Pacira Pharmaceuticals, Inc.
	Unmet Need	Anoushka Afonso, MD Director, Enhanced Recovery after Surgery Department of Anesthesiology & Critical Care Memorial Sloan Kettering Cancer Center
	Efficacy	Roy S. Winston, MD Sr Vice President Anesthesia, Surgery, and Medical Affairs Pacira Pharmaceuticals, Inc.
	Safety	Richard Scranton, MD, MPH Sr Vice President and Chief Scientific Officer Pacira Pharmaceuticals, Inc.

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AGENDA (cont.)

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 Review 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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AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

Pharmacokinetics (PK) 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**