

**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, the Great Room (Rm. 1503)  
White Oak Conference Center, Silver Spring, Maryland  
November 24-25, 2014

**DRAFT AGENDA**

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*The committee will discuss the risk of serious neurologic adverse reactions associated with epidural steroid injections (ESI) administered to reduce inflammation for pain management. The committee will also consider the efficacy of ESI and the overall risk benefit balance of injecting steroids in the epidural space to treat pain. These considerations will assist the Agency in our discussions of possible regulatory options, including but not limited to changes to the product labeling.*

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**Day 1: Monday, November 24, 2014**

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| 8:00 a.m.  | Call to Order and Introduction of Committee     | <b>Randall P. Flick, MD, MPH</b><br>Chairperson, AADPAC   |
| 8:05 a.m.  | Conflict of Interest Statement                  | <b>Stephanie L. Begansky, PharmD</b><br>Designated Federal Officer, AADPAC  |
| 8:15 a.m.  | FDA Introductory Remarks                        | <b>Sally Seymour, MD</b><br>Deputy Director for Safety<br>Division of Pulmonary, Allergy, and<br>Rheumatology Products (DPARP)<br>Office of Drug Evaluation II (ODE II)<br>Office of New Drugs (OND), CDER, FDA |
| 8:35 a.m.  | <b>GUEST SPEAKERS' PRESENTATIONS</b>            |   |
|            | Epidural Injections: Are They Effective?        | <b>Steven P. Cohen, MD</b><br>Professor of Anesthesiology and Critical Care<br>Medicine<br>Johns Hopkins School of Medicine   |
|            | Safety of Epidural Steroid Injection<br>Therapy | <b>Charles E. Argoff, MD</b><br>Professor of Neurology<br>Albany Medical College  |
| 9:55 a.m.  | Clarifying Questions                            |   |
| 10:25 a.m. | <b>BREAK</b>                                    |   |

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**DRAFT AGENDA (cont.)**

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10:40 a.m.    **FDA PRESENTATIONS**

Epidural Steroid Injections:  
Postmarketing Serious Neurological  
Adverse Events Reported to the FDA  
Adverse Event Reporting System  
(FAERS) and Medical Literature

**CDR Laurelle Cascio, PharmD**  
Safety Evaluator  
Division of Pharmacovigilance II (DPV II)  
Office of Surveillance and Epidemiology (OSE)  
CDER, FDA

**Jane L. Gilbert, MD, PhD**  
Medical Officer, DPV I, OSE, CDER, FDA

11:10 a.m.    Drug Utilization Patterns for Epidural  
Steroid Injections: Years 2009-2013

**Rajdeep Gill, PharmD**  
Drug Utilization Analysis Team Leader (Acting)  
Division of Epidemiology II, OSE, CDER, FDA

11:30 a.m.    Clarifying Questions

12:00 p.m.    **LUNCH**

1:00 p.m.    **FDA PRESENTATIONS (CONT.)**

Safe Use Initiative

**John Whyte, MD, MPH**  
Director  
Professional Affairs and Stakeholder  
Engagement (PASE)  
Office of the Center Director, CDER, FDA

1:05 p.m.    **GUEST SPEAKER PRESENTATION**

Safeguards to Prevent Neurologic  
Complications During Epidural Steroid  
Injection

**James P. Rathmell, MD**  
Henry Knowles Beecher Professor of Anesthesia  
Harvard Medical School

1:30 p.m.    Clarifying Questions

2:00 p.m.    Open Public Hearing

3:30 p.m.    **BREAK**

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**DRAFT AGENDA (cont.)**

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- 3:45 p.m. Charge to the Committee **Judith A. Racoosin, MD, MPH**  
Deputy Director for Safety  
Division of Anesthesia, Analgesia, and  
Addiction Products (DAAAP)  
ODE II, OND, CDER, FDA
- 4:00 p.m. Questions to the Committee/Committee Discussion
- 5:00 p.m. **ADJOURNMENT**

**Day 2: Tuesday, November 25, 2014**

- 8:00 a.m. Call to Order and Introduction of Committee **Randall P. Flick, MD, MPH**  
Chairperson, AADPAC
- 8:05 a.m. Conflict of Interest Statement **Stephanie L. Begansky, PharmD**  
Designated Federal Officer, AADPAC
- 8:15 a.m. Questions to the Committee/Committee Discussion (cont.)
- 10:15 a.m. **BREAK**
- 10:30 a.m. Questions to the Committee/Committee Discussion (cont.)
- 12:00 p.m. **ADJOURNMENT**