

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

***Arthritis Advisory Committee (AAC) Meeting***  
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)  
White Oak Conference Center, Silver Spring, Maryland  
May 9, 2012

**DRAFT AGENDA**

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*The committee will discuss new drug application (NDA) 203214, tofacitinib tablets, Pfizer Inc., for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).*

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| 8:00 a.m.  | Call to Order and Introduction of Committee | <b>Lenore Buckley, M.D.</b><br>Chairperson, AAC  |
| 8:05 a.m.  | Conflict of Interest Statement              | <b>Philip Bautista, Pharm.D.</b><br>Designated Federal Officer, AAC  |
| 8:10 a.m.  | FDA Introductory Remarks                    | <b>Sarah Yim, M.D.</b><br>Associate Director<br>Division of Pulmonary, Allergy &<br>Rheumatology Products (DPARP)<br>Office of Drug Evaluation II (ODE II)<br>Office of New Drugs (OND), CDER, FDA |
| 8:20 a.m.  | <b>SPONSOR PRESENTATIONS</b>                | <b>Pfizer Inc.</b>   |
|            | Introduction                                |  |
|            | Rheumatoid Arthritis: Medical Need          |  |
|            | Tofacitinib: Efficacy Review                |  |
|            | Tofacitinib: Safety Review                  |  |
|            | Tofacitinib: Clinical Perspective           |  |
|            | Conclusion                                  |  |
| 9:50 a.m.  | Clarifying Questions to Sponsor             |  |
| 10:05 a.m. | <b>BREAK</b>                                |  |
| 10:20 a.m. | <b>FDA PRESENTATIONS</b>                    |  |
|            | Clinical Overview                           |  |

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May 8, 2012

**DRAFT AGENDA (cont.)**

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Efficacy Considerations

Safety and Risk Benefit Considerations

11:50 a.m. Clarifying Questions to the FDA

12:05 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Charge to the Committee

**Sarah Yim, M.D.**

2:05 p.m. Questions to the Committee and Committee  
Discussion

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

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

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