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

Arthritis Advisory Committee Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
April 23, 2018

DRAFT AGENDA

The committee will discuss the new drug application (NDA) 207924, for baricitinib tablets, submitted by Eli Lilly and Company, for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. The discussion will include the following: efficacy, safety, including the risk of thromboembolic adverse events, dose selection, and overall risk benefit considerations.

8:00 a.m.	Call to Order and Introduction of Committee	**Jose Scher, MD** Acting Chairperson, AAC
8:05 a.m.	Conflict of Interest Statement	**Yinghua Wang, PharmD, MPH** Designated Federal Officer, AAC
8:10 a.m.	FDA Opening Remarks	**Nikolay Nikolov, MD** Clinical Team Leader, Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Eli Lilly & Company**
	Introduction	**Robin Wojcieszek, RPh** Senior Director, Global Regulatory Affairs Eli Lilly & Company, USA
	Unmet Need for Patients with Rheumatoid Arthritis	**Mark Genovese, MD** Director of the Rheumatology Clinic in the Division of Immunology & Rheumatology Stanford University Medical Center, USA
	Clinical Design and Efficacy of Baricitinib	**Terence Rooney, MD** Senior Medical Director, Immunology Eli Lilly & Company, USA
	Safety of Baricitinib	**Melissa Veenhuizen, DVM, MS** Senior Medical Director, Global Patient Safety Eli Lilly & Company, USA

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Clinical Perspective	**Josef Smolen, MD** Professor of Medicine & Chairman of the Department of Medicine III & Division of Rheumatology Medical University of Vienna, Austria
	Conclusion	**James McGill, MD** Global Development Leader, Immunology Eli Lilly & Company, USA
9:45 a.m.	Clarifying Questions	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	Efficacy of Baricitinib	**Robert Abugov, PhD** Acting Biostatistics Team Leader Division of Biometrics II Office of Biostatistics (OB) Office of Translational Sciences (OTS) CDER, FDA
	Safety of Baricitinib	**Raj Nair, MD** Clinical Reviewer DPARP, ODE-II, OND, CDER, FDA
	Potential Biological Mechanisms for Baricitinib-induced Increase in Platelets	**Matthew Whittaker, PhD** Nonclinical Reviewer DPARP, ODE-II, OND, CDER, FDA
	Epidemiology Safety Study Review	**Veronica Sansing-Foster, PhD, MS** Epidemiologist Division of Epidemiology II Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Benefit Risk Considerations	**Raj Nair, MD**

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DRAFT AGENDA (cont.)

11:45 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Charge to Committee	**Nikolay Nikolov, MD**
2:05 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	