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

Arthritis Advisory Committee (AAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
August 3, 2017

AGENDA

The committee will discuss supplemental new drug applications (sNDAs) 203214 supplement 17, for XELJANZ (tofacitinib) tablets and 208246 supplement 3, for XELJANZ XR (tofacitinib) extended release tablets submitted by Pfizer Inc., for the treatment of adult patients with active psoriatic arthritis. The committee will discuss the efficacy and safety data and benefit-risk considerations.

8:00 a.m.	Call to Order and Introduction of Committee	**Daniel H. Solomon, MD, MPH** Chairperson, AAC
8:05 a.m.	Conflict of Interest Statement	**Philip A. Bautista, PharmD** Acting Designated Federal Officer, AAC
8:10 a.m.	FDA Introductory Remarks	**Janet Maynard, MD, MHS** 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**	**Pfizer, Inc.**
	Introduction	**Nancy McKay** Director, Regulatory Affairs Pfizer, Inc.
	Psoriatic Arthritis: A Physician's Perspective/Unmet Medical Need	**Philip Mease, MD, MACR** Director, Rheumatology Research Swedish-Providence-St. Joseph Health Systems Clinical Professor University of Washington, School of Medicine
	Tofacitinib PsA Development Program and Efficacy	**Keith Kanik, MD, FACR** Senior Director, Global Clinical Lead PsA Inflammation and Immunology Pfizer, Inc.
	Tofacitinib PsA Safety	**Daniela Graham, MD** Clinician, PsA Development Program Inflammation and Immunology Pfizer, Inc.
	Risk Management	**Thomas Jones, MD** Senior Director, Safety Risk Management Pfizer, Inc.

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

Arthritis Advisory Committee (AAC) Meeting
August 3, 2017

AGENDA (cont.)

	APPLICANT PRESENTATIONS (cont.)	
	Benefit: Risk and Conclusions	**Michael Corbo, PhD** Senior VP Chief Development Officer, Inflammation and Immunology Pfizer, Inc.
9:15 a.m.	Clarifying Questions	
9:30 a.m.	**FDA PRESENTATIONS**	
	Introduction and Clinical Overview	**Raj Nair, MD** Medical Officer DPARP, ODE II, OND, CDER, FDA
	Statistical Considerations on Efficacy	**Rebecca Rothwell, PhD** Mathematical Statistician Division of Biometrics II (DB II) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Summary of Safety and Risk/Benefit Considerations	**Raj Nair, MD**
10:15 a.m.	Clarifying Questions	
10:30 a.m.	**BREAK**	
10:45 a.m.	**OPEN PUBLIC HEARING**	
11:45 a.m.	Charge to the Committee	**Janet Maynard, MD, MHS**
12:00 p.m.	Questions to the Committee/Committee Discussion	
1:00 p.m.	**ADJOURNMENT**	