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

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
March 8, 2018

DRAFT AGENDA

The committee will discuss supplemental new drug application (sNDA) 203214 supplement 18, XELJANZ (tofacitinib) tablets, submitted by Pfizer Inc., proposed for the treatment of adult patients with moderately to severely active ulcerative colitis who have demonstrated an inadequate response, loss of response, or intolerance to corticosteroids, azathioprine, 6-mercaptopurine, or tumor necrosis factor inhibitor therapy.

8:00 a.m.	Call to Order and Introduction of Committee	**Jean-Pierre Raufman, MD** Chairperson, GIDAC
8:05 a.m.	Conflict of Interest Statement	**Jay Fajiculay, PharmD** Designated Federal Officer, GIDAC
8:10 a.m.	FDA Introductory Remarks	**Tara Altepeter, MD** Clinical Team Leader Division of Gastroenterology and Inborn Errors Products (DGIEP) Office of Drug Evaluation (ODE) III Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Pfizer, Inc.**
	Introduction	**Lou Ferrara** Director, Regulatory Affairs Pfizer, Inc.
	Ulcerative Colitis: A Clinician's Perspective / Unmet Medical Need	**William Sandborn, MD** Chief, Division of Gastroenterology Director, Inflammatory Bowel Disease Center University of California, San Diego
	Tofacitinib Ulcerative Colitis Development Program and Efficacy	**Eric Maller, MD** Executive Director, UC Development Program Inflammation and Immunology, Pfizer Inc
	Safety of Tofacitinib in Ulcerative Colitis Development Program	**Chinyu Su, MD** Senior Director, Global Clinical Lead UC Inflammation and Immunology, Pfizer Inc
	Risk Management	**Thomas Jones, MD** Senior Director, Safety Risk Management Pfizer Inc

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Benefit:Risk and Conclusion	**Michael Corbo, PhD** Senior VP, Chief Development Officer Inflammation and Immunology, Pfizer Inc
9:50 a.m.	Clarifying Questions	
10:05 a.m.	**FDA PRESENTATIONS**	
	Clinical Pharmacology Findings of Tofacitinib for Treatment of Moderately to Severely Active Ulcerative Colitis (UC)	**Dilara Jappar, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology III Office of Clinical Pharmacology Office of Translational Sciences (OTS), CDER, FDA
	Analyses of Efficacy Data for Proposed Dosing Regimens	**Sara Jimenez, PhD** Mathematical Statistician Division of Biostatistics III Office of Biostatistics, OTS, CDER, FDA
	Focused Tofacitinib UC Program Safety Evaluation	**Lesley Hanes, MD, MSc** Medical Officer DGIEP, ODE III, OND, CDER, FDA
	Remarks About Results from Truven Marketscan®	**Joel Weissfeld, MD, MPH** Medical Officer Division of Epidemiology I Office of Surveillance and Epidemiology, CDER, FDA
	Tofacitinib Development Program: Pediatric Ulcerative Colitis	**Melanie Bhatnagar, MD** Medical Officer Division of Pediatric and Maternal Health ODE IV, OND, CDER, FDA
11:50 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Questions to the Committee/Committee Discussion	
3:15 p.m.	**BREAK**	

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DRAFT AGENDA (cont.)

3:30 p.m. Questions to the Committee/Committee Discussion (cont.)

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