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

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
September 14, 2016

AGENDA

The committees will discuss a completed postmarketing-requirement randomized, placebo controlled trial of the neuropsychiatric effects of CHANTIX (varenicline), ZYBAN (bupropion), and nicotine replacement therapy, along with relevant published observational studies to determine whether the findings support changes to product labeling.

8:00 a.m.	Call to Order and Introduction of Committee	**Ruth Parker, MD** Acting Chairperson, PDAC
8:05 a.m.	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Designated Federal Officer, PDAC
8:10 a.m.	FDA Introductory Remarks / Regulatory History	**Judith A. Racoosin, MD, MPH** Deputy Director for Safety Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:25 a.m.	**APPLICANT PRESENTATIONS**	**Pfizer, Inc.**
	Introduction	**James Rusnak, MD, PhD** Chief Development Officer, Cardiovascular and Metabolic Diseases Pfizer
	Evidence from Observational Studies	**Judith Prochaska, PhD, MPH** Associate Professor, Department of Medicine Stanford University
	EAGLES Study Design, Investigator's Perspective on Study Conduct and on Treating Patients for Smoking Cessation	**Robert M. Anthenelli, MD** Professor and Executive Vice Chair, Department of Psychiatry University of California, San Diego, School of Medicine
	EAGLES Study Execution	**James Rusnak, MD, PhD** Chief Development Officer, Cardiovascular and Metabolic Diseases Pfizer

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	EAGLES Study Results I	**Cristina Russ, MD, PhD** Director, Medical Affairs Pfizer
	Clinical Perspective on EAGLES Study Results	**A. Eden Evins, MD, MPH** Director, Center for Addiction Medicine Massachusetts General Hospital and Cox Family Associate Professor of Psychiatry Harvard Medical School
	Conclusions and Labeling Proposal	**James Rusnak, MD, PhD** Chief Development Officer, Cardiovascular and Metabolic Diseases Pfizer
9:55 a.m.	Clarifying Questions to Applicant	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Clinical Review of the PMR Safety Outcome Trial	**Celia Winchell, MD** Clinical Team Leader, Addiction Products Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
	Statistical Review of the PMR Safety Outcome Trial	**Eugenio Andraca-Carrera, PhD** Reviewer, Division of Biometrics VII Office of Translational Sciences (OTS) CDER, FDA
	Review of Observational Studies of Neuropsychiatric Events Associated With Smoking Cessation Products	**Chih-Ying (Natasha) Pratt, PhD** Reviewer, Division of Epidemiology Office of Surveillance and Epidemiology (OSE) CDER, FDA
12:00 p.m.	Clarifying Questions to FDA	
12:20 p.m.	**LUNCH**	

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1:20 p.m.	**OPEN PUBLIC HEARING**	
2:20 p.m.	Charge to the Committee	**Judith A. Racoosin, MD, MPH**
2:30 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**	