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

Nonprescription Drugs Advisory Committee (NDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
September 18, 2019

AGENDA

The committee will discuss data submitted by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, to support new drug application (NDA) 208425, for over-the-counter (OTC) marketing of nicotine oral spray (1 milligram (mg) per spray). The proposed OTC use is to reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking. The applicant proposes to label the product for adults 18 years and older. The committee will be asked to consider whether data support an acceptable risk/benefit profile for the nonprescription use of nicotine oral spray (1 mg per spray) by OTC consumers.

8:00 a.m.	Call to Order and Introduction of Committee	**Richard Neill, MD** Chairperson, NDAC
8:05 a.m.	Conflict of Interest Statement	**Cindy Chee, PharmD** Acting Designated Federal Officer, NDAC
8:10 a.m.	FDA Introductory Remarks	**Jenny Kelty, MD** Lead Medical Officer Division of Nonprescription Drug Products (DNDP) Office of Drug Evaluation IV (ODE IV) Office of New Drugs (OND), CDER, FDA
8:25 a.m.	**APPLICANT PRESENTATIONS**	**GlaxoSmithKline (GSK) Consumer Healthcare Holdings (US) LLC**
	Introduction	**Sue James** Vice President & Head of Global Regulatory Affairs GSK Consumer Healthcare
	Efficacy Review	**Mitchell Nides, PhD** President Los Angeles Clinical Trials
	Real-World Nicotine Replacement Therapy (NRT) Effectiveness	**John Hughes, MD** Professor, Board Certified Psychiatrist University of Vermont College of Medicine
	Safety Review	**Rajesh Mishra, MD, PhD** Vice President Global Medical & Clinical Sciences Johnson & Johnson Consumer Inc.

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Consumer Studies Review	**Julie Aker, MT (ASCP)** President & CEO Concentrics Research
	Benefit-Risk Summary and Conclusion	**Sue James**
9:55 a.m.	Clarifying Questions	
10:10 a.m.	**BREAK**	
10:25 a.m.	**FDA PRESENTATIONS**	
	Efficacy and Safety Data in Clinical Trials	**Sarah Arnold, MD, MPH** Medical Officer Division of Anesthesia, Analgesia, and Addiction Products Office of Drug Evaluation II (ODE II) OND, CDER, FDA **Katherine Meaker, MS** Statistical Reviewer Division of Biometrics II, Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Postmarketing Safety Data	**Martha Lenhart, MD, PhD** Medical Officer DNDP, ODE IV, OND, CDER, FDA
	Label Comprehension Study	**Barbara Cohen, MPA** Social Science Analyst DNDP, ODE IV, OND, CDER, FDA
11:45 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	FDA Charge to the Committee	**Theresa Michele, MD** Division Director DNDP, ODE IV, OND, CDER, FDA

AGENDA (cont.)

2:10 p.m.	Questions to the Committee/Committee Discussion
3:00 p.m.	**BREAK**
3:15 p.m.	Questions to the Committee/Committee Discussion
5:00 p.m.	**ADJOURNMENT**