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

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting
Bethesda Marriott, Grand Ballroom
5151 Pooks Hill Road, Bethesda, Maryland
October 18, 2018

AGENDA

The committee will discuss new drug application (NDA) 210166, for prucalopride tablets for oral administration, submitted by Shire Development, LLC, proposed for the treatment of chronic idiopathic constipation.

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	**Juli Tomaino, 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
8:20 a.m.	**APPLICANT PRESENTATIONS**	**Shire Development, LLC**
	Introduction	**Sunil Kadam, PhD** Senior Director, Global Regulatory Affairs Shire
	Unmet Need in Chronic Idiopathic Constipation	**Michael Camilleri, MD** Gastroenterologist and Professor of Medicine, Pharmacology, and Physiology Mayo Clinic
	Prucalopride Efficacy Results	**Heinrich Achenbach, MD** Global Clinical Development Team Lead Shire
	Prucalopride Safety	**John Caminis, MD** Therapeutic Area Head, Global Drug Safety Shire
	Clinical Perspective on Prucalopride	**Jan Tack, MD, PhD** Professor of Medicine Head of Clinic, Department of Gastroenterology University Hospital KU Leuven
	Concluding Remarks	**Debra Silberg, MD, PhD** Therapeutic Area Head, VP of Clinical Development Shire

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AGENDA (cont.)

9:30 a.m.	Clarifying Questions to the Presenters	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	Nonclinical Safety Findings of Prucalopride	**Babatunde Emmanuel Akinshola, PhD** Pharmacologist DGIEP, ODE III, OND, CDER, FDA
	Clinical Pharmacology Findings of Prucalopride for Treatment of Chronic Idiopathic Constipation (CIC)	**Shen (Steven) Li, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology III Office of Clinical Pharmacology Office of Translational Sciences (OTS), CDER, FDA
	Analysis of Prucalopride Efficacy Data for the CIC Program	**Ling Lan, PhD** Statistical Reviewer Division of Biometrics III Office of Biostatistics, OTS, CDER, FDA
	Safety Evaluation of the Clinical Trial Data for the CIC Program	**Charles Line, MD** Medical Officer DGIEP, ODE III, OND, CDER, FDA
	Assessment of Study 802, A Cohort Study of the Relative Incidence of Major Cardiovascular Events Among Patients Initiating Prucalopride Versus a Matched Comparator Cohort	**Joel Weissfeld, MD, MPH** Medical Officer Division of Epidemiology I Office of Pharmacovigiliance and Epidemiology Office of Surveillance and Epidemiology, CDER, FDA
11:25 a.m.	Clarifying Questions to the Presenters	
11:55 a.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Questions to the Committee/ Committee Discussion	
3:15 p.m.	**BREAK**	
3:30 pm.	Questions to the Committee/ Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	