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 17, 2018

AGENDA

The committee will discuss supplemental new drug application (sNDA) 021200, supplement 015, for ZELNORM (tegaserod maleate) tablets for oral administration, submitted by Sloan Pharma S.a.r.l, Bertrange, Cham Branch, proposed for the treatment of women with irritable bowel syndrome with constipation who do not have a history of cardiovascular ischemic disease, such as myocardial infarction, stroke, transient ischemic attack, or angina, and who do not have more than one risk factor for cardiovascular disease.

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.	Introductory Remarks	**Preeti Venkataraman, 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
8:25 a.m.	**APPLICANT PRESENTATIONS**	**Sloan Pharma S.a.r.l, Bertrange, Cham Branch**
	Zelnorm™ History and Program Introduction	**Kristen Gullo** VP, Development & Regulatory Affairs US WorldMeds
	Cardiovascular Safety Evaluation	**Philip Sager, MD, FACC, FAHA** Adjunct Professor of Medicine Stanford University School of Medicine
	General Safety and Efficacy Overview	**Rachael Gerlach, PhD** Regulatory Science Manager US WorldMeds
	Medical Landscape and Benefit-Risk	**Colin Howden, MD** Chief, Division of Gastroenterology University of Tennessee Health Science Center
	Sponsor Commitments	**Kristen Gullo**
9:40 a.m.	Clarifying Questions to the Presenters	
10:05 a.m.	**BREAK**	

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AGENDA (cont.)

10:20 a.m.	**FDA PRESENTATIONS**	
	Clinical Efficacy in Severely Symptomatic IBS-C Female Patients	**Irena Lavine, MD** Medical Officer DGIEP, ODE III, OND, CDER, FDA
	Nonclinical Safety Findings of Tegaserod	**Ke Zhang, PhD** Pharmacology Reviewer DGIEP, ODE III, OND, CDER, FDA
	Clinical Pharmacology Findings of Tegaserod	**Jie Cheng, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology III Office of Clinical Pharmacology Office of Translational Sciences (OTS), CDER, FDA
	Clinical Safety Evaluation	**Sandhya Apparaju, PhD** Safety Reviewer DGIEP, ODE III, OND, CDER, FDA
	Cardiovascular Outcomes Meta-Analysis of Clinical Trials	**Thanh Tran, PhD** Safety Statistical Reviewer Division of Biometrics VII Office of Biostatistics, OTS, CDER, FDA
	An Assessment of A Cohort Study of Tegaserod and Cardiovascular Events	**Joel Weissfeld, MD** Medical Officer Division of Epidemiology I Office of Pharmacovigilence and Epidemiology Office of Surveillance and Epidemiology, CDER, FDA
11:30 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**	