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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
November 13, 2019

DRAFT AGENDA

The committee will discuss supplemental new drug application (sNDA) 204629/S-020 for empagliflozin oral tablet, sponsored by Boehringer Ingelheim Pharmaceuticals, Inc., for the following proposed indication: as an adjunct to insulin therapy to improve glycemic control in adults with type 1 diabetes mellitus.

8:00 a.m.	Call to Order and Introduction of Committee	**Kenneth Burman, MD** Chairperson, EMDAC
8:05 a.m.	Conflict of Interest Statement	**LaToya Bonner, PharmD** Designated Federal Officer, EMDAC
8:10 a.m.	FDA Introductory Remarks	**Lisa B. Yanoff, MD** Director (Acting) Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	**APPLICANT PRESENTATIONS**	**Boehringer Ingelheim Pharmaceuticals, Inc.**
	Introduction	**Jyothis George, MBBS. PhD, FRCP** Head of Medicine – Empagliflozin Boehringer Ingelheim Pharmaceuticals, Inc.
	Unmet Need	**Jennifer Green, MD** Professor of Medicine Duke University Medical Center Division of Endocrinology, Metabolism and Nutrition Faculty, Duke Clinical Research Institute Durham, North Carolina
	Efficacy	**Jan Marquard, MD** Clinical Development Lead – Empaglifozin Boehringer Ingelheim Pharmaceuticals, Inc.
	Safety	**Ona Kinduryte Schorling, MD, MSc** Head of Drug Safety – Metabolism Boehringer Ingelheim Pharmaceuticals, Inc.
	Clinical Implications	**Bruce Perkins, MD** Professor of Medicine and Clinician-Scientist University of Toronto, The Sam and Judy Pencer Family Chair in Diabetes and Director of the Diabetes Clinical Research Unit Leadership Sinai Centre for Diabetes, Sinai Health System Toronto, Canada

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DRAFT AGENDA (cont.)

9:50 a.m.	Clarifying Questions to Applicant	
10:05 a.m.	**BREAK**	
10:20 a.m.	**FDA PRESENTATIONS**	
	Overview of Development Program for Empagliflozin in Type 1 Diabetes Mellitus	**Mahtab Niyyati, MD** Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA
	Clinical Pharmacology and M-EASE-2	**Justin Penzenstadler, PharmD, MSc** Clinical Pharmacology Reviewer Division of Clinical Pharmacology II (DCP-II) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS), CDER, FDA
	Statistical Efficacy Assessment	**Roberto Crackel, PhD** Mathematical Statistician Division of Biometrics II (DB-II) Office of Biostatistics (OB), OTS, CDER, FDA
	Statistical Safety Assessment	**Shanti Gomatam, PhD** Mathematical Statistician Division of Biometrics VII (DB-VII) OB, OTS, CDER, FDA
	Clinical Safety Assessment and Summary	**Mahtab Niyyati, MD**
11:50 a.m.	Clarifying Questions to FDA	
12:05 p.m.	**LUNCH**	
1:05 p.m.	**OPEN PUBLIC HEARING**	
2:05 p.m.	Questions to the Committee/Committee Discussion	
3:45 p.m.	**BREAK**	
4:00 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	