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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
July 15, 2020

DRAFT AGENDA

The committee will discuss new drug application (NDA) 22231, terlipressin, lyophilized powder for solution for injection, submitted by Mallinckrodt Pharmaceuticals, for the proposed indication of treatment of hepatorenal syndrome Type 1.

9:00 a.m.	Call to Order and Introduction of Committee	**Julia B. Lewis, MD** Chairperson, CRDAC
9:05 a.m.	Conflict of Interest Statement	**Joyce Yu, PharmD** Designated Federal Officer, CRDAC
9:10 a.m.	FDA Opening Remarks	**Aliza Thompson, MD, MS** Deputy Director Division of Cardiology and Nephrology (DCN) Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) Office of New Drugs (OND), CDER, FDA
9:15 a.m.	**APPLICANT PRESENTATIONS**	**Mallinckrodt Pharmaceuticals**
	Introduction	**Khurram Jamil, MD** Vice President, Clinical Research in Hepatology Critical Care Division, Mallinckrodt
	Pathophysiology of HRS-1 and Rationale for Terlipressin	**Michael P. Curry, MD** Section Chief of Hepatology Beth Israel Deaconess Medical Center Harvard Medical School
	Efficacy	**Khurram Jamil, MD**
	Safety	**Chris Pappas, MD, JD, FAASLD** Clinical Hepatologist Consultant, Mallinckrodt
	Risk Management	**Khurram Jamil, MD**
	Benefit/Risk and Clinical Considerations	**Arun Sanyal, MD** Professor, Department of Internal Medicine Division of Gastroenterology, Hepatology and Nutrition Virginia Commonwealth University School of Medicine

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10:45 a.m.	Clarifying Questions
11:15 a.m.	**BREAK**
11:25 a.m.	**FDA PRESENTATIONS**

	Efficacy, Safety, and Benefit/Risk	**Rekha Kambhampati, MD, MHS** Medical Officer DCN, OCHEN, OND, CDER, FDA
		Tzu-Yun McDowell, PhD Clinical Analyst DCN, OCHEN, OND, CDER, FDA

12:10 p.m.	Clarifying Questions
12:30 p.m.	**LUNCH**
1:30 p.m.	**OPEN PUBLIC HEARING**
2:30 p.m.	Questions to the Committee/Committee Discussion
3:15 p.m.	**BREAK**
3:25 p.m.	Questions to the Committee/Committee Discussion (cont.)
5:00 p.m.	**ADJOURNMENT**