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 14, 2019

DRAFT AGENDA

The committee will discuss supplemental new drug application 202057/S-035, for VASCEPA (icosapent ethyl) capsules for oral administration, sponsored by Amarin Pharma Inc., for the following proposed indication: to reduce the risk of cardiovascular events, as an adjunct to statin therapy in adult patients with elevated triglycerides levels (135 mg/dL or greater) and other risk factors for cardiovascular disease, based on the results of a clinical study entitled "A Study of AMR101 to Evaluate Its Ability to Reduce Cardiovascular Events in High Risk Patients With Hypertriglyceridemia and on Statin. The Primary Objective is to Evaluate the Effect of 4 g/Day AMR101 for Preventing the Occurrence of a First Major Cardiovascular Event. (REDUCE-IT)" (available at: https://clinicaltrials.gov/ct2/show/NCT01492361).

8:00 a.m.	Call to Order and Introduction of Committee	**Kenneth D. Burman, MD** Chairperson, EMDAC
8:05 a.m.	Conflict of Interest Statement	**Jay Fajiculay, PharmD** Designated Federal Officer (Acting), EMDAC
8:10 a.m.	FDA Introductory Remarks	**John Sharretts, MD** Deputy 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**	**Amarin Pharma Inc.**
	Introduction	**Rebecca Juliano, PhD** Senior Vice President Clinical Research and Development Amarin Pharma Inc.
	Medical Need	**Michael Miller, MD** Professor of Cardiovascular Medicine, Epidemiology & Public Health Director, Center for Preventative Cardiology University of Maryland School of Medicine
	REDUCE-IT Clinical Efficacy and Safety Data	**Deepak L. Bhatt, MD, MPH** Executive Director of Interventional Cardiovascular Programs, Professor Brigham and Women's Hospital Harvard Medical School

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DRAFT AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Clinical Perspectives	**Ann Marie Navar, MD, PhD** Assistant Professor of Cardiology Duke University School of Medicine Duke Clinical Research Institute
	Closing Remarks	**Rebecca Juliano, PhD**
9:50 a.m.	Clarifying Questions to Applicant	
10:05 a.m.	**BREAK**	
10:20 a.m.	**FDA PRESENTATIONS**	
	Introduction and Clinical Review	**Iffat Nasrin Chowdhury, MD** Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA
	Statistical Review of Efficacy	**Roberto Crackel, PhD** Mathematical Statistician Division of Biometrics II Office of Biostatistics Office of Translational Sciences (OTS), CDER FDA
	Clinical Pharmacology Review	**Yunzhao Ren, MD, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology II Office of Clinical Pharmacology, OTS, CDER, FDA
	Clinical Review of Safety	**Iffat Nasrin Chowdhury, MD**
11:50 a.m.	Clarifying Questions to FDA	
12:05 p.m.	**LUNCH**	
1:05 p.m.	**OPEN PUBLIC HEARING**	
2:15 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**	