

**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

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
	Clinical Perspectives	Ann Marie Navar, MD, PhD Assistant Professor of Cardiology Duke University School of Medicine Duke Clinical Research Institute

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	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 Medical Officer DMEP, ODE-II, OND, CDER, FDA
	Statistical Review of Efficacy	Roberto Crackel, PhD Statistical Reviewer 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
	Additional Statistical Analysis and Conclusions	Roberto Crackel, PhD
	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	