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).

<table>
<thead>
<tr>
<th>Time</th>
<th>Item</th>
<th>Presenter/Officer</th>
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<tbody>
<tr>
<td>8:00 a.m.</td>
<td>Call to Order and Introduction of Committee</td>
<td>Kenneth D. Burman, MD Chairperson, EMDAC</td>
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<td>8:05 a.m.</td>
<td>Conflict of Interest Statement</td>
<td>Jay Fajiculay, PharmD Designated Federal Officer (Acting), EMDAC</td>
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<td>8:10 a.m.</td>
<td>FDA Introductory Remarks</td>
<td>John Sharretts, MD Deputy Director (Acting)</td>
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<td>Division of Metabolism and Endocrinology Products (DMEP)</td>
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<td>Office of Drug Evaluation II (ODE-II)</td>
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<td>Office of New Drugs (OND), CDER, FDA</td>
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<tr>
<td>8:20 a.m.</td>
<td><strong>APPLICANT PRESENTATIONS</strong></td>
<td>Amarin Pharma Inc.</td>
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<tr>
<td></td>
<td>Introduction</td>
<td>Rebecca Juliano, PhD Senior Vice President</td>
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<td>Clinical Research and Development Amarin Pharma Inc.</td>
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<td>Medical Need</td>
<td>Michael Miller, MD Professor of Cardiovascular Medicine, Epidemiology &amp; Public Health</td>
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<td>Director, Center for Preventative Cardiology University of Maryland School of Medicine</td>
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<td>REDUCE-IT Clinical Efficacy and Safety Data</td>
<td>Deepak L. Bhatt, MD, MPH Executive Director of Interventional Cardiovascular Programs, Professor Brigham and Women’s Hospital Harvard Medical School</td>
</tr>
</tbody>
</table>
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