

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

***Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the  
Drug Safety and Risk Management (DSaRM) Advisory Committee***

October 8, 2020

**DRAFT AGENDA**

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*The committees will discuss new drug application (NDA) 211179, for amphetamine sulfate immediate-release oral capsules, submitted by Arbor Pharmaceuticals, LLC, for the proposed indication of Attention Deficit Hyperactivity Disorder. The product has been formulated with properties intended to deter non-oral abuse, and the applicant has submitted data to support these abuse-deterrent properties for this product. The committees will be asked to discuss the overall risk-benefit profile of the product, including the potential public health impact, and whether the applicant has demonstrated abuse-deterrent properties for their product that would support labeling.*

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10:00 a.m.	Call to Order	<b>Rajesh Narendran, MD</b> Chairperson, PDAC
10:15 a.m.	Introduction of Committee and Conflict of Interest Statement	<b>LaToya Bonner, PharmD</b> Acting Designated Federal Officer, PDAC
10:20 a.m.	FDA Opening Remarks	<b>Tiffany R. Farchione, MD</b> Director (Acting) Division of Psychiatry (DP) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
10:40 a.m.	<b>APPLICANT PRESENTATION</b>  Summary Presentation – AR19 (amphetamine sulfate) Manipulation-Resistant, Immediate- Release Capsules for the Treatment of ADHD	<b>Arbor Pharmaceuticals</b>  <b>Evan Scullin, MD</b> Vice President, Medical Affairs Arbor Pharmaceuticals  <b>Stephen Faraone, PhD</b> Vice Chair for Research, Department of Psychiatry Distinguished Professor of Psychiatry Distinguished Professor of Neuroscience & Physiology SUNY Upstate Medical University  <b>Beatrice Setnik, PhD</b> Chief Scientific Officer Altasciences  <b>Eric Kinzler, PhD</b> President and Founder Pellucid Advantage, LLC Study Director DRUGSCAN

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**DRAFT AGENDA (cont.)**

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**APPLICANT PRESENTATION (CONT.)**

**John Dillberger, DVM, PhD**

President

J. Dillberger, LLC

Fellow, International Academy of Toxicologic Pathology

**Anthony Rostain, MD, MA**

Chair of Psychiatry and Behavioral Health

Cooper University Healthcare

- 11:00 a.m. Clarifying Questions to Applicant
- 11:30 a.m. Clarifying Questions to FDA
- 12:00 p.m. **LUNCH**
- 1:00 p.m. **OPEN PUBLIC HEARING**
- 2:00 p.m. Questions to the Committee/Committee Discussion
- 3:30 p.m. **BREAK**
- 3:40 p.m. Questions to the Committee/Committee Discussion (cont.)
- 5:00 p.m. **ADJOURNMENT**