

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 Advisory Committee (DSaRM)*

October 8, 2020

QUESTIONS

1. **DISCUSSION:** Considering the patterns of prescription stimulant nonmedical use in the United States, please discuss the potential public health impact of prescription stimulants formulated to be abuse-deterrent.

2. **VOTE:** Based on the information provided, including the intranasal study comparing this product to amphetamine sulfate, has the Applicant provided adequate evidence that the immediate-release oral formulation of amphetamine sulfate (AR19) would deter intranasal use?

3. **VOTE:** Based on the information provided, including the syringeability study, has the Applicant provided adequate evidence that AR19 would deter intravenous use?

4. **VOTE:** Based on the information provided, has the Applicant adequately characterized the safety of AR19?

5. **VOTE:** Do the benefits of AR19 outweigh the risks for the proposed indication?

6. **DISCUSSION:** What, if any, additional data are needed to address outstanding issues of AR19?