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

DRAFT QUESTIONS

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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?