U.S. FOOD & DRUG ADMINISTRATION

TOPICS FOR DISCUSSION
DAY 2

Topics for Discussion – Day 2

1. What technical and quantitative issues should FDA consider as it develops guidance to recommend standardization of in vitro testing to evaluate the abuse deterrence of opioid drug product formulations for various routes of abuse, including ingestion, insufflation, injection, and smoking? For example, what should FDA consider with respect to mechanical manipulations (e.g., equipment, amount of effort, and time), chemical manipulations (e.g., solvent choice and availability), particle size distribution, and volume of solvent used for extraction?

2. How can FDA standardize in vitro testing to help substantiate appropriate and consistent product manufacture that assures abuse deterrence at release and through a drug product's shelf life?

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3. How can performance attributes measured by in vitro testing be quantified and linked to their impact on abuse deterrence? For example, discuss what amount of time delay in defeating an abuse-deterrent property should be considered significant and the basis for the recommendation.

4. How can FDA build flexibility into standardized testing so that it may be suitable for application to emerging technologies? Are there any specific emerging technologies that might require new types of testing?