U.S. FOOD & DRUG ADMINISTRATION

# TOPICS FOR DISCUSSION
# DAY 1

# Topics for Discussion – Day 1

1. Based on any testing you have attempted to perform or performed in accordance with the March 2016 draft guidance, are there any aspects of the guidance that need clarification or improvement?

2. Are there any characteristics of the currently approved abuse-deterrent RLDs for which issuance of product specific guidance, beyond what is described in FDA's March 2016 draft guidance, would facilitate development of abuse-deterrent generic opioid drug products?

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3. Are there approaches or technologies for evaluating the abuse deterrence of generic opioid drug products that were not included in the March 2016 draft guidance that should be?

4. What additional actions could FDA take to encourage the submission of ANDAs that reference an opioid drug product whose labeling describes abuse-deterrent properties?

5. Are there potential consequences of the development and introduction of abuse-deterrent opioid drug products that warrant further consideration?