The expectation is that a simplified and transparent process such as a stepwise decision tree will aid drug companies, consultants, advocacy groups, federal drug agencies, and regulators in having a common understanding and consistency of the necessary evaluations in the assessment of abuse potential.

This presentation is the initial FDA draft of the decision tree to assess the abuse potential of a drug. The assessment of abuse potential occurs throughout the nonclinical and clinical evaluation of a drug's safety and efficacy during the drug development process.

The sequence of studies depicted in the decision tree may not reflect the optimal plan for every Sponsor. FDA recognizes that abuse-related studies are conducted throughout all phases of drug development. However, if the drug exposure in the nonclinical and clinical abuse-related studies is not comparable to that produced by the final human therapeutic dose, the abuse-related studies may not be valid.

The decision tree is designed for and limited to the evaluation of drugs that may have abuse potential. It is not intended to determine whether a drug has abuse potential and whether it should be recommended for scheduling under the Controlled Substances Act (CSA). These decisions cannot be made until data submitted in an NDA have been fully reviewed by FDA.

The Controlled Substance Staff welcomes feedback on this draft decision tree and the draft guidance. Comments may be sent to: Corinne P. Moody Center for Drug Evaluation and Research Food and Drug Administration 10903 New Hampshire Avenue Bldg. 51, Rm. 5144 Silver Spring, MD 20993-0002 301-796-5402

DISCLAIMER
The opinions and information in this presentation are those of the authors and do not necessarily reflect the views and policies of the FDA.

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REFERENCE