

PinneyAssociates ALERRT® Methodology for Category 1 *In Vitro* Assessment of Abuse-Deterrent Pharmaceutical Drug Products

The **PinneyAssociates** ALERRT® proprietary methodology enables pharmaceutical developers to assess “the degree of effort required to bypass or defeat” an opioid formulation’s abuse-deterrent properties as part of the Category 1 *in vitro* testing described in the Food and Drug Administration (FDA)’s 2015 final Guidance to Sponsors for Abuse-Deterrent Opioids. It measures the amount of “work” (defined as the combination of time, individual effort, and resources) involved in performing physical manipulations (e.g., crushing/grinding) on abuse-deterrent pharmaceutical drug products.

The ALERRT system is comprised of a set of visual analog scales (VASs) designed specifically to objectively measure “work” across a continuum from very easily accomplished to extremely difficult using specific common household tools.

FDA has long recognized the validity of VASs, recommending use of such instruments as a means of assessing drug abuse potential. By extension, use of ALERRT techniques will serve as a valid means of measuring the “work” involved in performing physical manipulations on pharmaceutical drug products.

ALERRT-related services include but are not limited to the following:

- Providing comparative analysis of pharmaceuticals, namely, preparation of reports, statistical analysis, studies and ratings comparing abuse-deterrent features of abuse-deterrent formulations and or new chemical entities with abuse-deterrent features with comparator products and similar prototype abuse-deterrent formulations
- Consulting services in the field of pharmaceuticals, namely, quantitative assessment of drug tamperability and manipulation as it relates to abuse by various routes of drug administration
- Regulatory compliance consulting services in the field of abuse-deterrent formulations and or new chemical entities with abuse-deterrent features to ensure compliance with government standards concerning labeling, advertising and marketing, risk management and strategic communications, namely, translation of information to regulatory agencies