

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Nonprescription Drugs Advisory Committee (NDAC) and the
Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)***

February 15, 2023

DRAFT QUESTIONS

1. **DISCUSSION:** Discuss the safety profile for use of Narcan Nasal Spray (NNS) in the nonprescription setting.
2. **DISCUSSION:** Discuss if the results of the Human Factors validation study (HFVS) support that consumers are able to correctly administer nonprescription NNS in an emergency situation.
 - a. Discuss the HFVS study design and the interpretability of the study.
 - b. Discuss the use errors observed in the HFVS where participants started with Step 3 (Call 911) during the simulation and bypassed Steps 1 and 2.
 - i. Could the intend-to-market nonprescription carton be further improved to mitigate risk of delayed administration?
 - c. Discuss the incorrect finger placement on the nasal spray observed during the HFVS.
 - i. Could the pictogram be further improved to optimize correct administration?
 - d. Discuss if the HFVS data submitted using the “mock” nonprescription user interface support the safe and effective use of:
 - i. the proposed nonprescription NNS and
 - ii. the modified intend-to-market user interface.

If not, what additional data are needed?
3. **DISCUSSION:** Discuss whether there is any additional labeling information that might mitigate risk of use errors.
4. **VOTE:** Is the benefit-risk profile of NNS supportive of its use as a nonprescription opioid overdose reversal agent?
 - a. If you voted ‘No’, what further data should be obtained?