

**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

**QUESTIONS**

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1. **DISCUSSION:** Discuss the safety profile for use of Narcan Nasal Spray (NNS) in the nonprescription setting.
2. **DISCUSSION:** Discuss whether 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 in the HFVS.
    - i. Could the pictogram be further improved to optimize correct administration?
  - d. Discuss whether 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 vote ‘No’, what further data should be obtained?