

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

*Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
and the Drug Safety and Risk Management Advisory Committee (DSaRM)*
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
February 14, 2018

QUESTIONS

1. **DISCUSSION:** Does the Applicant's clinical program support the safe and effective use of Hydexor as an analgesic and for prevention of opioid-induced nausea and vomiting (OINV) that is limited to use in individuals likely to experience OINV?
2. **DISCUSSION:** There are currently no immediate-release, hydrocodone-acetaminophen combination products with abuse-deterrent properties that are approved and on the market. Do you have concerns that Hydexor does not have abuse-deterrent properties?
3. **DISCUSSION:** Epidemiological data suggest that misuse and abuse of promethazine, either alone or in combination with opioids or other drugs, have resulted in emergency department visits, contact with poison control centers, and deaths. Please discuss whether you think Hydexor poses greater risks than currently-marketed hydrocodone-acetaminophen products.
4. **VOTE:** Should Hydexor be approved?