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

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC)
March 28-29, 2023

QUESTIONS

---

1. **VOTE:** The REMS currently requires a 19-day lockout period for patients who can become pregnant and do not pick up their first prescription of isotretinoin within the 7-day prescription window.

   Should the iPLEDGE REMS retain the 19-day lockout period requirement before patients can take an additional pregnancy test to be eligible to receive isotretinoin?

   a. Yes
   b. No

   If you voted "No", please provide your rationale and recommendations on when the additional pregnancy test should occur before starting treatment.

2. **DISCUSSION:** Discuss whether the REMS should require pregnancy tests be completed in a medical setting (e.g., office, laboratory) rather than at home.

3. **VOTE**: For patients who cannot become pregnant, when should the REMS require the prescriber document counseling the patient in the iPLEDGE system?

   a. Only with the first prescription as part of patient enrollment
   b. Monthly (current requirement)
   c. Every 120 days
   d. Some other frequency (and provide the frequency and rationale)

4. **DISCUSSION**: The iPLEDGE Pregnancy Registry collects information on fetal exposure, pregnancy outcome, fetal outcome, and root cause analysis. Discuss recommendations on the pregnancy registry requirement and ways in which it could be streamlined to encourage more participation to yield high quality data.

5. **DISCUSSION**: Discuss any additional recommendations to minimize burden in the iPLEDGE REMS.