Food and Drug Administration
Center for Drug Evaluation and Research

Drug Safety and Risk Management Advisory Committee (DSaRM)
in joint session with the
Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC)
Hilton, 620 Perry Parkway, Gaithersburg, Maryland

QUESTIONS

Isotretinoin Pregnancy-Prevention Risk Management Program

1. Based on reports and patient surveys received by sponsors and FDA, there does not appear to be a meaningful decrease in the number of pregnancies reported in women taking a course of isotretinoin since implementation of the current risk management program. Please discuss measurement and implementation factors that may have contributed to these findings.

2. Based on prescription audits and patient surveys, use of the qualification sticker is high. Patient surveys suggest an inconsistent link between monthly pregnancy testing and use of stickers. Reported pregnancies and patient surveys indicate incomplete or inadequate birth control measures among females. Please comment on measurement and implementation aspects of the program that may contribute to these findings.

3. FDA's goals for the Isotretinoin Pregnancy Prevention Risk Management Program are that:

   - no woman who is already pregnant will be prescribed/dispensed isotretinoin

   - no pregnancies should occur while on isotretinoin therapy (effective pregnancy prevention will occur throughout the course of treatment).

   In recommending changes to the risk management program, it is important to consider potential tools and strategies in light of:

   a) Likelihood of effectiveness in further reducing fetal exposure
   b) The practical impact on health care providers who prescribe and dispense the product
   c) The impact on patients who must navigate the program.

   Given these factors, which option(s) do you recommend be pursued?
   (a) *Continue the current risk management program without additional tools*
   - If so, what approaches do you recommend to improve adherence with the program by patients, physicians, pharmacists and health educators?

   (b) *Modify the current program with additional risk management tools to reduce fetal exposure, such as*
   - Programs to enhance education and interaction with patients to identify and minimize high risk behaviors
   - Tighter linkage of prescriptions dispensed by pharmacists with required check of pregnancy test results
   - Registration of patients, pharmacists, physicians and health educators
   - Limited access/distribution of drug
   - Other tools – please describe

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QUESTIONS (cont.)

4. In order to adequately monitor the Isotretinoin Pregnancy Prevention Risk Management Program:

   (a) Given the limitations of the data presented, would it improve monitoring of risk management program performance to register patients, pharmacists, physicians, or other relevant participants (such as health educators)?

   (b) If participants in the isotretinoin risk management program are to be registered, how can this be done in a multi-source environment so that individuals are not registered multiple times and double-counted?

5. Please identify the critical benchmarks for determining the success or failure of the pregnancy risk management program (e.g., reducing to zero the number of women who are pregnant at the initiation of isotretinoin treatment, others?).