FDA Updates Relevant to PRGLAC Recommendation 13: Optimize Registries for Pregnancy and Lactation

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Disclaimer

- I do not have any financial disclosures to report
- The presentation reflects the views of the speaker and should not be construed to represent FDA's views or policies

Objectives

- Background
- Overview of FDA regulatory authorities regarding pregnancy registries
- FDA efforts supporting PRGLAC recommendation 13

Background

- There are approximately 5.5 million pregnancies in the U.S./year
- Pregnant individuals may need treatment for chronic or acute conditions
- Pregnant individuals have historically been left out of drug development trials
- Most drugs are approved with only nonclinical reproductive toxicology data
- Human data are needed to inform labeling and clinical care
  - These data are generally collected postapproval
  - At the time of new drug approval, FDA can issue postmarketing requirements to conduct pregnancy safety studies

Pregnancy Postmarketing Requirements

- Pregnancy safety studies can be required under section 505(o)(3) of the FD&C Act
- Historically, pregnancy registries have been issued as postmarketing requirements/commitments (PMRs/PMCs)
- More recently, 2 types of pregnancy PMRs (a pregnancy registry and a complementary database study) have been issued in FDA's Center for Drug Evaluation and Research (CDER)

FDA Efforts Supporting PRGLAC Recommendation 13

Recommendation 13A: Create a user-friendly pregnancy registry for registry listing

a. Identify the elements needed for a registry listing
b. Develop a public-private partnership to host a pregnancy/lactation registry listing webpage

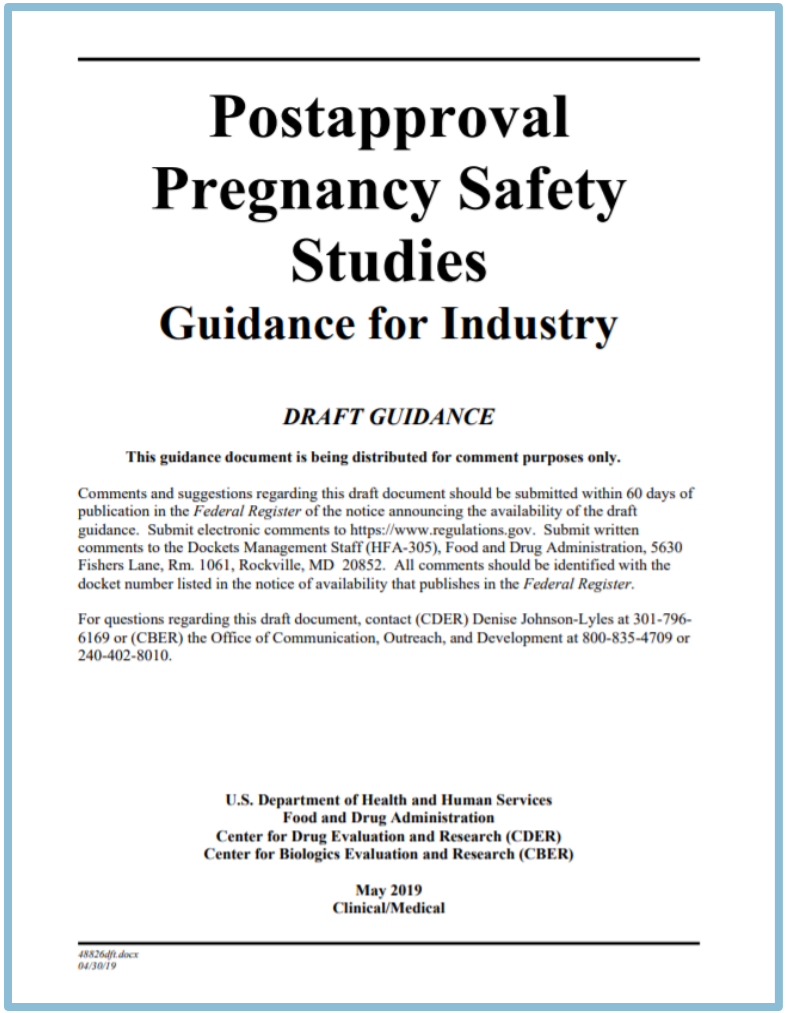
Status Update

- *FDA maintains a Pregnancy Registry Webpage for FDA approved medical products*
  - *Standard elements and processes are in place for listing a registry*
  - *Are there other needs that can be addressed by a public-private partnership for registry listings?*

Recommendation 13B: Develop registry standards and common data elements (CDEs) that facilitate input of pertinent data with easy, transparent access to obtain information in real time

Status Update

- *FDA has published a Guidance for Industry on Postapproval Pregnancy Safety Studies for FDA approved medical products*
  - *Registry standards and CDEs are described*
  - *The guidance is currently being updated based on public comments*
  - *Data from pregnant individuals is being collected in real time through the use of apps*
  - *Are there other registries outside of FDA's purview that need to address CDEs?*



Postapproval Pregnancy Safety Studies

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Denise Johnson-Lyles at 301-796-6169 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
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- Published in 2019
- Under revision

Recommendation 13C: Facilitate access to data and transparency of information in registries; use the Antiretroviral Pregnancy Registry as a model

Status Update

- *FDA supports this recommendation*
- *Where does the authority lie to operationalize this recommendation?*

Recommendation 13D: Develop disease/ condition-focused registries

- Move toward a single registry for all therapeutic products with input from stakeholders
  a. Build a collaboration between the public-private partnership and other industry representatives to work toward a single registry for therapeutic products used by pregnant women and lactating women
  b. Expand the use of disease/condition postmarketing studies

Status Update

- *FDA is supportive of these recommendations*
- *What is the best way to operationalize these recommendations?*

Thank you