Activity Outline
Pregnancy and Lactation Medication Information for the Healthcare Provider
May 11, 2022
FDA Building, White Oak, MD (if COVID-19 guidelines permit in-person) and/or Zoom virtual webinar

Activity Coordinators:
Erin South (Erin.South@fda.hhs.gov),

Description

FDA implemented a revised pregnancy and lactation labeling system. The updated labeling system replaces the pregnancy letter categories – A, B, C, D and X – used to classify prescription drugs used during pregnancy with a description of risks within the real-world context of caring for pregnant women who may need medication. This presentation will provide an overview of the current pregnancy and lactation labeling system, also known as the Pregnancy and Lactation Labeling Rule (PLLR), lessons learned, and feedback received from healthcare providers. Further, it will help learners examine how prescription drug labeling can be used to inform prescribing in pregnant and lactating individuals.

References

- Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products-Content and Format: Draft Guidance for Industry. http://www.fda.gov/media/90160/download
- Dinatale M, Roca C, Sahin L, Johnson T, Mulugeta LY, Fletcher EP, Yao L. The Importance of Clinical Research in Pregnant Women to Inform Prescription Drug Labeling. J Clin Pharmacol. 2020 Dec;60 Suppl 2:S18-S25. doi: 10.1002/jcph.1761. PMID: 33274508.
- Namazy J, Chambers C, Sahin L, Johnson T, Dinatale M, Lappin B, Schatz M. Clinicians' Perspective of the New Pregnancy and Lactation Labeling Rule (PLLR): Results from an AAAAI/FDA Survey. J Allergy Clin Immunol Pract. 2020 Jun;8(6):1947-1952. doi: 10.1016/j.jaip.2020.01.056. Epub 2020 Feb 19. PMID: 32084595.
- Byrne JJ, Saucedo AM, Spong CY. Evaluation of Drug Labels Following the 2015 Pregnancy and Lactation Labeling Rule. JAMA Netw Open. 2020 Aug 3;3(8):e2015094. doi: 10.1001/jamanetworkopen.2020.15094. PMID: 32865574; PMCID: PMC7489861.

Learning Objectives

- Discuss the history of pregnancy and lactation labeling.
- Explain the current prescription drug labeling for pregnancy, lactation, and females and males of reproductive potential.
- Describe the FDA review process for incorporating information in prescription labeling on drug use in pregnancy and lactation.
- Identify the limitations of prescription drug labeling recommendations (i.e., lack of data, quality of limited data).
- Examine how prescription drug labeling can be used to inform prescribing in pregnant and lactating individuals.

Target Audience
This activity is intended for physicians, pharmacists, nurses, and members of the scientific or clinical care community interested in drug labeling to inform prescribing in pregnant lactating individuals.

Agenda
Day 1 May 11, 2022

Time	Topic	Speaker
12:00 - 1:00 PM EDT	Pregnancy and Lactation Medication Information for the Healthcare Provider	Tamara Johnson Erin South, PharmD

Continuing Education Accreditation

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In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-22-042-L04-P for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Johnson, Tamara, Lead Medical Officer, CDER/OND - *nothing to disclose*
- South, Erin, PharmD, Pharmacist, FDA - *nothing to disclose*

Planning Committee

- Bersoff-Matcha, Susan, MD, Deputy Director, OC - *nothing to disclose*
- Dinatale, Miriam, Team Leader, Food and Drug Administration - *nothing to disclose*
- Johnson, Tamara, Lead Medical Officer, CDER/OND - *nothing to disclose*
- Sahin, Leyla, MD, Deputy Director for Safety (Acting), Division of Pediatrics and Maternal Health - *nothing to disclose*
- Shahidzadeh, Rokhsareh, RN, MSN, Senior Regulatory Health Education Specialist, FDA - *nothing to disclose*
- South, Erin, PharmD, Pharmacist, FDA - *nothing to disclose*

CE Consultation and Accreditation Team

- Bueide, Rachel E., MPhil, Training Specialist, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

All of the relevant financial relationships listed for these individuals have been mitigated.

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 100% of the activity.