



## FDA Alerts and Label Changes – What Neonatologists Need to Know

### ***Internet Enduring***

***Release Date:*** 05/18/2020

***Expiration Date for Credit:*** 05/17/2023

***Content was originally presented at NEO: The Conference for Neonatology on February 20, 2020.***

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The ACCME recognizes this educational activity as an Internet Enduring Material. The estimated time for completion of this Internet Enduring Material is 50 minutes. This presentation was released on May 18, 2020. The expiration date of this Internet Enduring Material is May 17, 2023.

The ANCC recognizes this educational activity as an Internet Enduring Material. The estimated time for completion of this Internet Enduring Material is 50 minutes. This presentation was released on May 18, 2020. The expiration date of this Internet Enduring Material is May 17, 2023.

### ***Target Audience:***

This presentation is intended for physicians, advanced practice providers, and other clinicians who treat and care for premature infants.

### ***Disclosure of Financial Relationships:***

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*The planners, moderators or speakers of this activity have the following financial relationship(s) with commercial interests to disclose:*

**Rachel G. Greenberg, MD, MB, MHS** - Assistant Professor of Pediatrics, Division of Neonatology, Duke University School of Medicine, Durham, NC.

*Disclosure(s) - I/we have no financial relationships to report. FDA: Off-Label - caffeine citrate; acyclovir; meropenem; Unapproved - fluconazole.*

**Nicole Brenson, MSED** Disclosure(s) - I/we have no financial relationships to report.

**Hilja Dodd Sousa Conceicao, CHCP, CPHQ** Disclosure(s) - I/we have no financial relationships to report.

**Kassandra S Greci, DNP, APRN, WHNP-BC** Disclosure(s) - I/we have no financial relationships to report.

**Commercial Support:**

There is no commercial support for this educational activity.

*Please note that the content of this educational activity was originally presented at a live conference (NEO: The Conference for Neonatology) on February 20, 2020, which was supported in part, through restricted medical education grants from Mead Johnson Nutrition, Mallinckrodt Pharmaceuticals, and Abbott Nutrition.*

**Gap or Purpose:**

The purpose of this educational activity is to enhance clinician knowledge in the ever-changing area of complications associated with Neonatology as well as promising new techniques and interventions for improving outcomes in this arena. This presentation will address the new evidence-based FDA guidance and label updates for drugs and devices used in the Neonatal Intensive Care Unit, as it is critical for clinicians to stay current regarding new drug and device development and drug label updates that pertain to therapeutics used in premature infants.

**Objectives: At the conclusion of this activity, the participant will be able to:**

ACCME Objectives

1. Describe the new FDA guidance on clinical pharmacology considerations for neonatal studies for drugs and biological projects.
2. Identify new label changes for commonly used drugs and devices in the NICU.
3. Summarize the importance of obtaining label changes for drugs in infants.

CME – ACGME/ABMS Competencies

1. Patient Care and Procedural Skills
2. Systems-Based Practice

ANCC Learning Outcomes

1. Describe the new FDA guidance on clinical pharmacology considerations for neonatal studies for drugs and biological projects.
2. Identify new label changes for commonly used drugs and devices in the NICU.
3. Summarize the importance of obtaining label changes for drugs in infants.

ANCC – IOM Competencies

1. Employ evidence-based practice

**Participation and Credit:**

Participants are expected to review all content in the video, access reference materials as needed for additional self-directed learning, take and score 70% or greater correct on the post test, and complete the evaluation in order to earn *AMA PRA Category 1 Credit(s)<sup>™</sup>, nursing contact hour(s), and/or pharmacotherapeutics contact hour(s)*.

There are no fees for participating in or receiving credit for this online educational activity. For information on applicability and acceptance of credit for this activity, please consult your professional licensing board.

**Contact:**

Should you have any questions or concerns, please contact us at [continuing\\_education@mednax.com](mailto:continuing_education@mednax.com)