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Two Years of PLLR Implementation

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Disclaimer

- The views expressed in this presentation are those of the speaker, and do not necessarily represent an official FDA position.

Division of Pediatric and Maternal Health (DPMH)

- Located within Office of New Drugs/CDER/FDA
- Comprised of Maternal Health Team, Pediatrics Team, and Pediatrics Regulatory Team
- To develop clinically relevant, evidence-based labeling and other communications that facilitate informed use of medicines in children and females of reproductive potential.

DPMH's Role with PLLR

- To provide consultation to CDER/CBER review divisions in issues related to maternal health, including pregnancy and lactation.
- To collaborate within the Agency for consistency of process (including revision of the draft PLLR guidance)
- To track the drug product labeling compliance with PLLR
- To raise awareness amongst external and internal stakeholders

PLLR Implementation (1)

	NDAs, BLA, ESs†	Required Submission Date of PLLR Format
New Applications (prospective cohort)	Submitted on or after 6/30/2015	At time of submission
Older Approved Applications (retrospective cohort)	Approved 6/30/2001 to 6/29/2002 Approved 6/30/2005 to 6/29/2007	6/30/2018
	Approved 6/30/2007 to 6/29/2015 or pending on 6/30/2015	6/30/2019
	Approved 6/30/2002 to 6/29/2005	6/30/2020
	For applications approved prior to 6/30/2001 in old format labeling	Not required to be in PLLR format. However, must remove Pregnancy Category by 6/29/2018

- Includes 505(b)(1) and 505(b)(2) NDAs and 351(a) and 351(k) BLAs
- If more than one required submission date for PLLR format/content applies to an NDA, BLA, or efficacy supplement, choose the earliest required submission date.

†NDA = New Drug Application, BLA = New Biologic Application, ES = efficacy supplement

PLLR Implementation (2)

- Applications approved prior to 6/30/2001, with no ES approved after 6/30/2001 and have *not voluntarily converted* to Physician Labeling Rule (PLR):
  - Pregnancy category removed from the labeling by 6/30/2018
  - Required standard statements under § 201.80(f)(6) must remain.
- For all applications, review if existing data or recommendations are accurate and up-to-date.

Tracking PLLR Converted Labeling*

- Since June 30, 2015, > 500 labelings converted under the PLLR
- Future PLLR submissions anticipated via Prior Approval Supplement (PAS):
  - 2018 cohort ~ 400
  - 2019 cohort ~ 800
  - 2020 cohort ~ 300

*Applications (including NDA, BLA and Efficacy Supplements) approved on or after June 30, 2001 required to comply with full PLLR format