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)

<table>
<thead>
<tr>
<th>New Applications (prospective cohort)</th>
<th>NDAs, BLA, ES&lt;sup&gt;†&lt;/sup&gt;</th>
<th>Required Submission Date of PLLR Format</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Submitted on or after 6/30/2015</td>
<td>At time of submission</td>
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<tr>
<th>Older Approved Applications (retrospective cohort)</th>
<th>NDAs, BLA, ES&lt;sup&gt;†&lt;/sup&gt;</th>
<th>Required Submission Date of PLLR Format</th>
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<tbody>
<tr>
<td>Approved 6/30/2001 to 6/29/2002</td>
<td>6/30/2018</td>
<td></td>
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<tr>
<td>Approved 6/30/2007 to 6/29/2015 or pending on 6/30/2015</td>
<td>6/30/2019</td>
<td></td>
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<tr>
<td>For applications approved prior to 6/30/2001 in old format labeling</td>
<td>Not required to be in PLLR format. However, must remove Pregnancy Category by 6/29/2018</td>
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</tbody>
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- 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.

<sup>†</sup>NDA = New Drug Application, BLA = New Biologic Application, ES = efficacy supplement
PLLRR 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