

Table 1: NDAs, BLAs, Efficacy Supplements (ESs) Required to Have Labeling Meet PLLR Format and Content Requirements (Effective Date of PLLR Final Rule: 6/30/2015)^{1,2}

	NDAs, BLA, ESs	Required Submission Date for PLLR Format/Content ³
New NDAs, BLAs, and ESs	Originally submitted ⁴ on or after 6/30/2015	At time of submission of new NDA, BLA, or ES
NDAs, BLAs, or ESs approved 6/30/2001 through 6/29/2015 or <i>pending</i> ⁴ on 6/30/2015	Approved 6/30/2001 through 6/29/2002 Approved 6/30/2005 through 6/29/2007	6/30/2018
	Approved 6/30/2007 through 6/29/2015 <i>Pending</i> ⁴ on 6/30/2015	6/30/2019
	Approved 6/30/2002 through 6/29/2005	6/30/2020
NDAs or BLAs approved prior to 6/30/2001 (with no ES approved on or after 6/30/2001)	Voluntary PLR conversion originally submitted on or after 6/30/2015	At time of submission of voluntary PLR conversion labeling supplement

¹ See PLLR final rule for all the PLLR format and content requirements:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Labeling/ucm093307.htm>

² Includes 505(b)(1) and 505(b)(2) NDAs and 351(a) and 351(k) BLAs

³ If more than one required submission date for PLLR format/content applies to an NDA, BLA, or ES, choose the earliest required submission date. For example, if an NDA was approved in 2003 (PLLR required submission date is 6/30/2020), an ES was approved in 2004 (PLLR required submission date is 6/30/2020), and another ES was approved in 2006 (PLLR required submission date is 6/30/2018); the required PLLR submission date is 6/30/2018.

⁴ For the purposes of PLLR implementation, “*pending*” applications are those that are either under review, have received a complete response (CR), or have received a tentative approval. For example, if an NDA was originally submitted in July 2014, received a CR in May 2015, and was resubmitted on or after the PLLR effective date (i.e., 6/30/2015), the NDA is considered *pending* on 6/30/2015 and the required submission date for PLLR format is 6/30/2019 (the labeling is not required to be in PLLR format upon initial approval of the NDA).

Table 2: PLLR Requirement and Recommendations for Other NDAs and BLAs¹

	NDAs and BLAs	Requirement	Recommendations
NDAs or BLAs approved prior to 6/30/2001 (with no ES approved on or after 6/30/2001)	Voluntary PLR conversion originally submitted prior to 6/30/2015 ²	Must remove pregnancy category by 6/29/2018 ³	Not required (but encouraged) to convert to PLLR format
	Labeling is in non-PLR (old) format <u>and</u> no voluntary PLR conversion was ever submitted		Not required (but encouraged) to convert to PLR and PLLR format

¹ Includes 505(b)(1) NDAs, 505(b)(2) NDAs, and 351(a) BLAs; ² PLLR effective date; ³ Although the pregnancy categories must be removed from the labeling, the standard statements required by § 201.80(f)(6) must remain in the labeling