

### Characteristics of Old vs. New FDA Pregnancy/Lactation Labeling

	Old FDA Labeling	New FDA Labeling
Organization of Sections	<ol style="list-style-type: none"> <li>1. Pregnancy</li> <li>2. Labor &amp; delivery</li> <li>3. Nursing mothers</li> </ol>	<ol style="list-style-type: none"> <li>1. Pregnancy (includes labor &amp; delivery)</li> <li>2. Lactation (new term for “nursing mothers”)</li> <li>3. Females and males of reproductive potential</li> </ol>
How Pregnancy Risk Information Is Imparted	<ol style="list-style-type: none"> <li>1. Categories A, B, C, D, X</li> <li>2. Narrative with subsections: <ul style="list-style-type: none"> <li>• Teratogenic effects</li> <li>• Non-teratogenic effects</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. No categories</li> <li>2. Narrative with subsections: <ul style="list-style-type: none"> <li>• Pregnancy exposure registry</li> <li>• Risk summary</li> <li>• Clinical considerations</li> <li>• Data</li> </ul> </li> </ol>
How Lactation Risk Information Is Imparted	Narrative providing animal or human data	Narrative with subsections: <ul style="list-style-type: none"> <li>• Risk summary</li> <li>• Clinical considerations</li> </ul>
How Reproductive Information Is Imparted	Was not addressed	If applicable, narrative describing if pregnancy testing or contraception required and effects on fertility

From the full article:  
**“What’s New with the FDA Labeling for Pregnancy and Lactation?”**  
 by Talia Puzantian, PharmD, BCPP  
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