FDA issues new drug label rules to better inform pregnant women

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Agency official says labeling changes should help patients 'make critical decisions' about medicines.

(HealthDay)—A new labeling system should give women and their doctors clearer information on the risks and benefits of prescription medicines when taken during pregnancy and breast-feeding, the U.S. Food and Drug Administration said Wednesday.

The agency "wants pregnant and breast-feeding women and their health care providers to benefit from the most useful and latest information about their prescription medicines," Dr. Sandra Kweder, deputy director of the FDA's Office of New Drugs, explained in an agency news release.

"The new labeling rule provides for explanations, based on available information, about the potential benefits and risks for the mother, the fetus and the breast-feeding child," she added.

The new regulations are aimed at labels on prescription drugs and biological products, and will take effect for newly approved drugs beginning on June 30 of next year. Older drugs will have their labels changed more gradually, the FDA said.

Right now, drugs are labeled by a series of lettered categories—A, B, C, D and X—that used to classify the risk of using medicines during pregnancy and breast-feeding.

According to Kweder, that system "was overly simplistic and was misinterpreted as a grading system, which gave an over-simplified view of the product risk."

So, beginning next June, the lettered system will be replaced with three detailed subsections—"Pregnancy," "Lactation" and "Females and Males of Reproductive Potential," the FDA said.

The new labeling should mean that "doctors will have up-to-date and well-organized information on pregnancy and lactation. They will be in a better position to help their patients make critical decisions," Kweder said.

She added that providing this information in a clear manner is important, because the typical woman in the United States takes an average of three to five prescription drugs during a pregnancy.

Many pregnant women have chronic medical conditions, such as asthma or high blood pressure, and need to continue taking prescription drugs to treat those conditions during pregnancy and breast-feeding. Other pregnant women may need to take medicines for new conditions that develop during pregnancy or for health problems that worsen during pregnancy, the FDA said.

Also, changes that occur to a woman's body during pregnancy may affect the medication dose she requires, Kweder said.

The "Lactation" subsection on the new labels will provide more information on whether or not a medicine gets into breast milk and how that may or may not affect a breast-feeding infant. The "Females and Males of Reproductive Potential" subsection will also offer information about pregnancy testing, birth control and how a medicine affects fertility, the FDA said.

"For medications that may cause infertility or present risks in pregnancy, the revised labeling will include information to be considered when deciding such issues as birth control or planning a pregnancy," Kweder said.

It could take drug makers several years to make all the required label changes on older medications, according to the FDA.

"The greatest benefit to patients is that these changes will result in better-informed prescribing based on the latest scientific information for thousands of medical products," Kweder said.

Dr. Jacques Moritz, director of gynecology at Mount Sinai St. Luke's and Mount Sinai Roosevelt in New York City, welcomed the FDA's move.

"The alphabet grading system that was used previously was both antiquated and confusing," he said. "This is a great day for both pregnant women and physicians. Now patients are empowered to make a decision based on the risks and benefits of the drug in pregnancy and lactation. It is a much needed change from the previous system."

More information: The U.S. Office on Women's Health has more about pregnancy and medicines.