



FDA News

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FDA Proposes New Rule to Provide Updated Information on the Use of Prescription Drugs and Biological Products during Pregnancy and Breast-feeding

The U.S. Food and Drug Administration today proposed major revisions to the physician labeling for prescription drugs (including biological products) to provide better information about the effects of medicines used during pregnancy and breast-feeding.

The proposed changes to prescription drug labeling would give health care professionals more comprehensive information for making prescribing decisions and for counseling women who are pregnant, breast-feeding, or of child-bearing age about using prescription medications.

Although physician labeling is directed to health care professionals, it is sometimes adapted for use in consumer-directed labeling such as patient package inserts or medication guides when such labeling is approved for a prescription drug.

"With this proposal, FDA's goal is to help women, their physicians and their pharmacists have better information about the effects of prescription medicines so that pregnant women, nursing mothers, and breast-feeding infants will benefit," said Rear Admiral Sandra Kweder, M.D., Center for Drug Evaluation and Research, FDA. "This proposal would help make drug labeling a better communication tool, and would potentially have a huge impact on public health and well being for women."

There are about six million pregnancies in the United States every year, and pregnant women take an average of three to five prescription drugs during pregnancy. Additionally, women with pre-existing medical conditions, such as asthma or high blood pressure, may need to continue to use prescription drugs to treat those conditions during pregnancy.

The proposed rule outlines what important information about the use of medicines during pregnancy and breast-feeding would be required to be added to product labeling for newly approved drugs. Under the proposal, drug labeling would explain, based on available information, the potential benefits and risks for the mother and the fetus, and how these risks may change during the course of pregnancy.

In the 1990s, the FDA recognized the shortcomings of pregnancy and breastfeeding information in prescription drug labeling and began reviewing ways to improve the information. The agency held public meetings and focus groups to obtain comment on the current labeling from health care professionals and scientific experts. Current labeling uses a letter category system to describe the risks of drug use during pregnancy. Stakeholders have said the letter category system leads to an inaccurate and overly simplified view of these risks, and does not facilitate updating of labeling as new information becomes available.

The proposed rule would remove the letter categories from the pregnancy section of prescription drug labeling. The newly designed format, for the pregnancy section of the labeling would have three sections:

- The first section, called the "Fetal Risk Summary," would describe what is known about the effects of the drug on the fetus, and if there is a risk, whether this risk is based on information from animals or humans. The proposal calls for a risk conclusion based on the available data and provides a number of examples depending on the quality and quantity of that data. For example, one risk conclusion might be: "Human data indicate that (name of drug) increases the risk of cardiac abnormalities." This would be followed by a summary of the most important data on the drug's effects.
- Another section, called "Clinical Considerations," would include information about the effects of the use of the drug if it is taken before a woman knows she is pregnant. This section also would feature discussions about the risks of the disease to the mother and the baby, dosing information, and tell how to address complications.
- The third section, under the heading "Data," would describe in more detail the available data regarding use of the drug in humans and from animal studies that were used to develop the Fetal Risk Summary.

The pregnancy section would also include information about whether there is a pregnancy exposure registry for the drug. Pregnancy exposure registries collect and maintain data on the effects of approved drugs that are prescribed to and used by pregnant women.

The lactation (breastfeeding) section of prescription drug labeling would use the same format as the pregnancy section. The lactation section would provide information about using the drug while breastfeeding, such as the amount of drug in breast milk and potential effects on the breastfed infant.

Certain newly approved drugs would use the new pregnancy and lactation labeling format, while labeling for previously approved drugs will be phased in gradually under FDA's recent Physician Labeling Rulemaking.

Electronic comments can be submitted within 90 days via the Federal Documents Management System/eRulemaking portal at www.regulations.gov. The FDA will carefully consider the comments in preparing a final rule.

For more information, visit: http://www.fda.gov/cder/regulatory/pregnancy_labeling/default.htm

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