Pregnant Women to Benefit from Better Information

The Food and Drug Administration (FDA) has taken action to give women and their health care professionals better information about the effects of medicines when used by a woman who is pregnant or breastfeeding.

The action is a proposed rule, published May 29, 2008, that would require major changes to the sections of prescription drug labeling (the prescribing information) concerning pregnancy and lactation (secretion of breast milk).

Why FDA is Taking Action

FDA wants women and their health care professionals to have the most useful and up-to-date information about the benefits and risks of medications when used during pregnancy and while breastfeeding.

"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 breastfeeding infants will benefit," says Rear Adm. Sandra Kweder, M.D., Deputy Director of FDA's Office of New Drugs.

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The new labeling will provide better information about a drug's risks to the expectant mother, the developing baby, and the breastfed infant.

Women and health care professionals need to be armed with available information on the effects of drugs when used in pregnancy because

- women take an average of three to five drugs during pregnancy
- many pregnant women have medical conditions, such as asthma, high blood pressure, depression, or diabetes, that require them to continue taking drugs they were on before pregnancy
- new medical problems may begin or old ones may get worse during pregnancy, requiring drug treatment
- a woman's body changes throughout the term of her pregnancy, which can affect the dose she needs of a particular drug
- a woman will often need and take medications while she is breastfeeding, potentially exposing her child to the effects of these medications
- about half of the six million pregnancies in the United States each year are unplanned, exposing women to drugs before they know they are pregnant; improved labeling will help with assessing the risks of unintended drug exposure to the developing baby.

Labeling Background

The current standard for information on pregnancy and lactation in drug labeling dates back to 1979. It categorizes the risks of taking a drug during pregnancy under a five-letter system. Over the decades, medical experts have criticized the category system as confusing, overly simplistic, and not reflective of newer studies and medical knowledge.

Over the last 10 years, FDA has responded to this criticism by

- holding public meetings
- conducting focus groups
- assembling advisory committees
- inviting comments from health care professionals, scientific experts, consumer advocates, and others

Through these activities, FDA concluded that drug labeling needed major changes to improve the quality of information about a drug's effect on pregnancy and lactation.

Look of the New Labeling

Under the proposed rule, the current drug labeling format and category system would be replaced with a new format that gives more detailed information in the pregnancy and lactation sections. The new labeling will provide better information about a drug's risks to the expectant mother, the developing baby, and the breastfed infant. The labeling will also discuss the data about these risks, including information from pregnancy exposure registries.

Pregnancy exposure registries collect and maintain data on the effects of drugs and vaccines that are used by pregnant women. These registries do not require women to take an experimental drug or a drug they would not ordinarily take. Instead, the registries collect information on the effects of already approved drugs prescribed to pregnant women by their doctors. FDA encourages drug companies to maintain pregnancy exposure registries.

If you are pregnant and want to know more about participating in a pregnancy exposure registry, visit *www.fda.gov/womens/registries/default.htm.*

What's Next?

After a 90-day comment period, FDA will consider all comments and prepare a final rule. FDA

For More Information

Pregnancy and Lactation Labeling
www.fda.gov/cder/regulatory/pregnancy_labeling/default.htm

Pregnancy Information from FDA's Office of Women's Health
www.fda.gov/womens/healthinformation/pregnancy.html