



GENERIC DRUG LABELING: why it matters for women

- Both brand and generic drug labels should reflect updated information on known safety risks, but currently only brand manufacturers are able to initiate this change.
- Women need updated safety and efficacy information to make informed health care decisions for themselves and their families.
- Generic drugs dominate the market and women deserve the same legal protections regardless of which drug they are prescribed.

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#samedrugsamestandards

#genericsmatter4women



GENERIC DRUGS: THE TRUE COST

Support the proposed *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products* rule and help protect women's health!

Requiring all prescription drugs to carry current and adequate safety warnings is essential for improving the safety and efficacy of all FDA approved drugs as well as for shoring up needed consumer safeguards and protections.

Accurate, up-to-date generic drug labels would provide the necessary information women need to ensure that they are accurately dosing and administering a drug at the appropriate levels, are aware of drug-drug interactions with other medicines they may be taking, and have access to critical warnings and precautionary recommendations alongside known side effects and adverse reaction related information.

As the health care decision-makers, not only for themselves but often for family members as well, women have a keen interest in ensuring that drug labels provide them with the most up to date information.

What will the proposed rule do?

- Gives generic drug manufacturers authority to initiate safety label changes through Changes Being Effected (CBE) process
- Provides a framework to ensure consistency between bioequivalent brand and generic drug labels
- Requires brand and generic manufacturers to update their labels within 30 days after a CBE supplement has been approved