

FDA Grants Public Citizen Petition, Issues Proposed Rule on Generic Drug Safety

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We are extremely pleased that the Food and Drug Administration (FDA) today issued a proposed rule to revise FDA regulations about generic drug labeling. When finalized, the revisions will fill a regulatory gap that poses a risk to patient safety. The proposed rule will allow generic drug manufacturers to "change the labeling of an approved drug or biologic product to reflect certain types of newly-acquired safety-related information in advance of FDA's review of the changes." When finalized after public comments, the rule will provide added protection to the tens of millions of people who regularly use generic drugs.

Many potential hazards are not discovered until years after drugs have been on the market, as documented in a recent Public Citizen report, yet, currently, generic drug manufacturers can do little to warn doctors and patients about newly discovered information, putting patients at risk. The new rule should remedy this public health problem.

Under current FDA regulations, generic manufacturers cannot update their products' labeling, even if they become aware of a potential risk not stated in the labeling. In contrast, brand-name drug manufacturers can update warnings and precautions before getting FDA approval.

In August 2011, Public Citizen submitted a citizen petition to the FDA asking it to revise its labeling rules to fill the safety gap. While formally the FDA stated in a letter that it was granting our petition in part, the agency has approved the critical issues addressed in our petition.

The proposed rule creates parity between brand-name drug manufacturers and generic drug manufacturers with respect to revising drug labeling to provide information about newly discovered risks. It would address requirements that all manufacturers of the same drug submit conforming labeling revisions after the FDA has approved a revision by one manufacturer of that drug.

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