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Division of Dockets Management (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, MD 20852

Comments of the Patient, Consumer, and Public Health Coalition
on the Food and Drug Administration's Proposed Rule
"Supplemental Applications Proposing Labeling Changes for Approved Drugs
and Biological Products"
[Docket No. FDA-2013-N-0500]

As members of the Patient, Consumer, and Public Health Coalition, we are pleased to have the opportunity to strongly support the Food and Drug Administration's (FDA) proposed rule entitled, *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products* (78 Fed. Reg. 67985).

The proposed rule recognizes the importance of allowing generic drug manufacturers to update their labeling as new information becomes available. Patients and consumers deserve up-to-date information about the prescription drugs that they use, and it is therefore essential that all prescription drugs carry accurate safety warnings. Allowing generic drug manufacturers to update safety labels will help to improve the health of all Americans by providing the most current information about the risks and benefits of drugs.

Since the Supreme Court decided *Pliva v. Mensing* in 2011, patients who are harmed by a generic version of a prescription drug have been unable to seek relief from the drug's manufacturer. Millions of Americans rely on generic drugs to provide the same benefits as brand-name drugs at a lower cost. If the general public was aware that generic drug manufacturers could not provide the most up-to-date safety information on the label, and that patients could not seek legal redress if they were harmed by generic drugs for risks that were known but not on the label, this would certainly discourage patients from using generic medications. The result would be skyrocketing medical costs.

The FDA has post-approval requirements for brand-name and generic drugs. Currently, these requirements are not as effective as they should be because manufacturers of generic drugs are not allowed to initiate labeling changes when necessary. From a fairness and public health perspective, a patient's ability to seek redress when harmed by inadequately labeled drugs should not depend on whether they were harmed by a brand-name or generic version of a drug.

The proposed rule will give generic drug manufacturers the authority to initiate safety labeling changes through the Changes

Being Effected (CBE) process. The result will be to give patients access to the most up-to-date product labeling product information regardless of whether they choose a name-brand or generic drug.

Time is of the essence; the sooner drug manufacturers update their safety labels, the sooner consumers can be made aware of this information and make informed health decisions. Current regulations allow drug companies an indefinite period of time to update their safety labeling. In contrast, the proposed rule provides a clear framework to ensure that both the reference listed drug (RLD) and the abbreviated new drug application (ANDA) drug return to labeling uniformity in a timely manner. We strongly support the requirement that all manufacturers of a drug update their labels with new safety information within 30 days of FDA approving the labeling change.

The proposed rule is needed to help safeguard the health and safety of patients and consumers. In addition to the specific provisions of the rule, legal accountability is a powerful incentive for generic drug manufacturers to take post-market monitoring more seriously. We strongly urge the FDA to adopt the proposed rule in its current form, and to do so as soon as possible.

National Research Center for Women & Families
National Physicians Alliance

-- Paul Brown
Government Relations Manager
National Research Center for Women & Families
Cancer Prevention and Treatment Fund
1001 Connecticut Ave., NW, Suite 1100
Washington, DC 20036