Food and Drug Administration
Office of the Commissioner
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-N-0500, Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products

Dear Sir/Madam:

In November 2013, the Food and Drug Administration (FDA) proposed to revise its regulations to allow generic drug manufacturers to initiate safety, efficacy, and dosing updates to their products' labeling. We strongly supported the FDA's *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products* when it was released, and we strongly support the rule moving forward expeditiously through the regulatory approval process now.

Requiring all prescription drugs to carry up-to-date 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. This new rule will enable generic drug manufacturers to revise drug labeling through the changes-being-effected (CBE-0) process, which currently permits brand-name manufacturers to update product labeling subject to simultaneous (instead of prior) review by the FDA. Extending this process to generic drug manufacturers will give physicians, patients, and their family members access to better and more accurate information about the risks and benefits of the medications they are taking, regardless of whether a drug is brand-name or generic.

Generic manufacturers currently are barred from providing new warning information, except in response to a brand-name update or FDA order. Most prescription drugs sold in the United States, however, are generic versions, and the brand-name manufacturer sometimes stops selling a drug after generic versions come on the market. The current system, which depends almost exclusively on brand-name manufacturers to maintain pharmacovigilance, no longer makes sense. Both brand-name and generic drug manufacturers must have the ability and duty to update drug labels expeditiously. Allowing generic manufacturers to initiate safety updates, as brand-name companies have done for 30 years, is essential for patients. Promptly updated warning labeling allows physicians and patients to make better informed health decisions and can help prevent serious harm to patients.

Recently, there have been attempts to unnecessarily delay or pull apart the proposed rule. One such alternative would prevent even brand-name manufacturers from promptly updating their safety information upon learning of an adverse event if a generic version has entered the market. If adopted, this proposal would be a significant step backward for consumer safety.

We urge you not to weaken the proposed rule and to move forward expeditiously in adopting it fully. Every day that the proposed rule is not in effect millions of patients and families face unnecessary health risks.

Thank you for your consideration.

Alpha-1 Foundation
American Medical Student Association
American Medical Women's Association
Annie Appleseed Project
Brain Injury Association of America
Breast Cancer Action
Center for Medical Consumers
Center for Science and Democracy at the Union of Concerned Scientists
Connecticut Center for Patient Safety
Consumer Federation of America
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COPD Foundation
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Lupus Foundation of America
MRSA Survivors Network
National Center for Health Research
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