March 13, 2014

Janice L. Weiner
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Building 51, Room 6304
Silver Spring, MD 20993-0002

Docket No. FDA-2013-N-0500

Dear Ms. Weiner,

We are pleased to have the opportunity to submit comments in support of 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 undersigned groups applaud the FDA for taking this critically important step towards enabling generic drug manufacturers to unilaterally update their labeling in appropriate circumstances. It is critically important that *all* prescription drugs carry current and adequate safety warnings. Allowing generic drug manufacturers to update safety labeling will go a long way towards improving the health and safety of Americans by ensuring that the public remains appropriately informed of drugs' risks and benefits.

Consumers deserve a uniform set of rules around the prescription medications that they depend on. However, since the Supreme Court decided *Pliva v. Mensing* in 2011, this has not been the case. Consumers who are harmed by the generic version of a prescription drug have been unable to seek relief from the drug's manufacturer because the Court held that generic manufacturers could not be held responsible for inadequate labeling because they lack authority to update their warning labels, even if they become aware of new safety problems. Today, Americans may be unaware that the prescription drug prescribed by their doctor could cause harmful complications because of limitations that do not allow generic drug manufacturers to update their labels to accurately reflect all of the side effects or risks. An individual's ability to seek redress when impaired by inadequately labeled drugs should not depend on whether they were injured by a brand name or generic version of a drug. The finalization of this rule will create long overdue parity among generic and brand name prescriptions.

Generic Drugs Make Up a Substantial Portion of the Prescription Drug Market

Millions of Americans rely on generic drugs to provide the same results as brand prescription drugs at a lower cost. Since 1984, when the Hatch-Waxman Amendments were enacted, sales of generic drugs have increased dramatically and now represent the majority of prescription drugs sold in the United States. Once generic drug products enter the market, they quickly replace the

reference listed drug (RLD). Typically, around 90% of all prescriptions get filled with generic drugs within months of their introduction into the marketplace.[1] Furthermore, state generic substitution laws, lower insurance reimbursement rates and other incentives help to ensure that consumers take a generic prescription medication when one is available. Every state in the country either has a mandatory or permissive generic substitution law on the books.[2] Once a generic is released, the manufacturer of the RLD typically loses much of its incentive to stay on top of emerging safety information regarding its drug because sales have become so small. In many cases, the RLD holder will simply withdraw from the market, leaving no one to reliably initiate labeling changes in response to emerging risk information. Despite the fact that generic drug manufacturers often control most of the drug's market share, under current regulations, they are precluded from updating safety information when new health risks are discovered and immediately providing that information to consumer. This poses a risk to Americans who deserve to have confidence that generic drugs are the same as their brand counterparts in all significant respects.

Generic Drug Manufacturers Have Always Been Obliged to Monitor the Safety of Their Products

Consumer well-being should be at the forefront of the creation of any new drug and should remain a priority once a prescription is on the market. There are numerous post-approval requirements that manufacturers of both brand name and generic drugs must meet to ensure products remain safe and effective as labeled.[3] All drug manufacturers must conduct regular pharmacovigilance to stay current on information regarding their products and ensure that their products remain safe and effective as labeled.[4] For example, a manufacturer must "promptly review all adverse drug experience information obtained . . . from any source . . . including reports in the scientific literature" and submit adverse event reports to FDA.[5] Each year, manufacturers must report to FDA a "summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product" and they must describe to FDA "the actions the applicant has taken or intends to take as a result of this new information."[6] The FDA has repeatedly reaffirmed these obligations including in the preamble to the proposed rule being discussed here and all drug manufacturers, including generic drug manufacture's, should be following them.[7] Notwithstanding, the requirements around monitoring are not as effective as they could be because producers of generic drugs are powerless to initiate labeling changes when necessary.

The FDA's Proposed Rule Increases Public Safety Through Clarity and Accountability

[1] HHS, *ASPE Issue Brief: Expanding the Use of Generic Drugs* 3-4 (2010). ("ASPE Issue Brief").
[2] *See* Judith K. Hellerstein, *The Importance of the Physician in the Generic versus Trade-Name Prescription Decision*, 29 RAND J. Econ. 108, 109 (1998). ASPE Issue Brief, *supra* note 1.
[3] 21 U.S.C. § 355(k).
[4] *See* 21 U.S.C. § 355(k).
[5] 21 C.F.R. §§ 314.80 (NDA holders) and 314.98(a) (ANDA holders).
[6] 21 C.F.R. §§ 314.81(b)(2)(i) (NDA holders) and 314.98(c) (ANDA holders).
[7] 78 Fed. Reg. 67986.

The proposed rule will remedy this accountability gap by providing the authority to generic drug manufacturers to initiate safety labeling changes through the Changes Being Effected (CBE) process. By allowing generic drug manufacturers to initiate labeling changes through the CBE process, consumers and health care professionals will have access to the most up-to-date product labeling information regardless of whether they choose to use a name brand or generic drug. Allowing generic drug manufacturers to update safety labeling ensures that consumers can be made aware of all new safety information pertaining to a generic drug in a timely fashion.

At the same time, the rule provides a clear framework to ensure that both RLD and the abbreviated new drug application (ANDA) return to labeling uniformity in a clear and concise timeframe. Requiring all manufacturers of a drug, both the generic and the brand, to update their labels with new safety information within thirty days of FDA approving the labeling change is a significant improvement over current regulation that allows drug companies an indefinite period of time to update their safety labeling. This timeframe will improve the speed and orderliness in which all manufacturers of a drug update their safety labeling after one manufacturer has a CBE supplement approved by the FDA. The sooner drug manufacturers update their safety labels with the most up-to-date information, the sooner consumers can be made aware of this information and can make the best decisions for the health of themselves and their families.

The proposed rule takes welcomed steps to make drug labeling safety information more accessible to the public through the utilization of technology. Allowing health care providers and consumers to have access to safety information posted on one unified website during the FDA review process will enable faster communication of important safety information directly to health care providers and consumers. Previously, finding a drug safety label could be a daunting task for either a consumer or a health care provider. Posting this information on the web provides an additional layer of safety for anyone taking a prescription medication and will help equip health care providers and consumers with the best possible information to avoid adverse outcomes.

Conclusion

Thank you for the opportunity to submit comments in response to the FDA's proposed rule on *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*. We believe the proposed rule offers a myriad of increased protections to consumer safety and health. Moving forward, all drug manufacturers, including generic drug manufacturers, should actively engage in monitoring the safety of their products and have the ability to keep the public appropriately informed of a drugs' risks and benefits. Consumers should never again have to rely on outdated safety labels for something as essential as medications; and, parity should be instated so consumers who are adversely harmed by generic drugs can access the courts. Legal accountability serves as a powerful incentive for generic drug manufacturers to take their legally required safety monitoring seriously. Together, these new requirements will provide consumers with clear, safe and accurate drug information and help Americans make the best decisions for themselves and their families. We strongly urge the FDA to adopt the proposed rule in its current form as quickly as possible.

Sincerely,

Alpha-1 Association
Alpha-1 Foundation
American Autoimmune Related Diseases Association
Brain Injury Association of North America
COPD Foundation
Lupus Foundation of America
National Eczema Association
National Latina Institute for Reproductive Health
National Multiple Sclerosis Society
National Psoriasis Foundation
National Women’s Law Center
Prevent Blindness America
Reproductive Health Technologies Project
Service Employees International Union (SEIU)
Sjogren's Syndrome Foundation