WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, N.W.
Washington, DC 20036
202-588-0302

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

Re: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products—Proposed Rule
78 Fed. Reg. 67985 (November 13, 2013)
Docket No. FDA-2013-N-0500; RIN 0910-AG94

Dear Sir/Madam:

Washington Legal Foundation (WLF) takes this opportunity to submit additional written comments in response to the Food and Drug Administration's (FDA) proposal to amend its regulations governing procedures for application holders of an approved drug or biological product to make unilateral changes in the product labeling. WLF has twice filed written comments, once on March 13, 2014 and once on April 28, 2015, that were highly critical of FDA's proposal to allow permit holders of Abbreviated New Drug Applications (ANDAs) to unilaterally change product labels. Instead, WLF has supported a counterproposal suggested by the Generic Pharmaceutical Association (GPhA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) that would make FDA the source of uniform labeling across the industry. In light of press reports that FDA's decision on this issue is imminent, WLF is writing to renew our criticism of FDA's proposed rule change and to support the alternative put forward by GPhA and PhRMA.

As detailed in WLF's March 13, 2014 comments (attached), FDA's proposed rule change violates a fundamental principle of the Hatch-Waxman Act. That is, precisely because generic drugs are identical to the referenced brand-name drug in every pertinent respect, manufacturers of generic drugs are permitted to rely on safety and effectiveness data developed by brand-name manufacturers in their original NDA filings, and generic manufacturers need not compile their own data. Permitting such reliance reduces the time and cost of bringing generic products to the market.

Congress intended, and for the last 30 years FDA agreed, that this "sameness" principle extends to drug labeling. *See, e.g.*, 21 U.S.C. §§ 355(j)(2)(A)(v), (j)(4)(G). Congress determined that were the sameness principle no longer in place—*i.e.*, were generic manufacturers permitted to make unilateral changes in product labeling—there would not be any justification for excusing generic manufacturers from conducting the extensive product testing necessary to verify labeling information. If a manufacturer's labeling is unique, Congress concluded, it must conduct all research necessary to justify the labeling. The Federal Food, Drug, and Cosmetic Act (FDCA) does not authorize ANDA holders to revise the content of their product labeling unilaterally, and FDA lacks authority to grant such power. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

In addition, FDA's authority under the FDCA's misbranding provision and its authority to issue regulations for the "efficient enforcement" of the FDCA do not grant FDA the power to issue regulations that countermand an explicit provision of the FDCA. Should FDA finalize its proposal as it stands, the final rule will be unlikely to survive its inevitable court challenge.

WLF further explained in our March 13, 2014 comments that FDA's proposed regulatory changes are ill advised and would have a disastrous effect on the delivery of prescription drugs.

WLF does not claim significant medical expertise and thus does not fully comprehend the safety ramifications of FDA's proposal. We nonetheless respect the conclusions of numerous health officials who are not beholden to the plaintiffs' bar that the proposal will do nothing to advance patient safety and, to the contrary, is likely to lead to unnecessary confusion and uncertainty for the doctors who must decide whether the drug in question is appropriate for their patients. *See, e.g.*, March 6, 2014 letter to FDA from the Academy of Managed Care Pharmacy and 20 other groups ("[T]he proposed rule creates the regulatory framework whereby multiple different warnings can simultaneously exist in the marketplace for multiple generic versions of a drug. This would be inconsistent with FDA's longstanding, unwavering emphasis on consistency in drug labeling and potentially confusing for health care professionals.").

Further, the proposal would expose generic manufacturers to products liability litigation, adding expense and leading to increased prices for generic drugs. This result runs counter to the Hatch-Waxman Act's stated purpose of increasing access to low-cost drugs.

Finally, WLF strongly supports GPhA and PhRMA's alternative proposal because it would accomplish FDA's stated goals, would have no negative market effects, and falls comfortably within FDA's statutory authority. By designating FDA, the epicenter of safety and medical information, as the final arbiter of all labeling changes for prescription drugs, the GPHA/PhRMA proposal would create FDA's desired litigation parity (between generic and brand-name drug manufacturers) while avoiding the consumer confusion that would arise from non-uniform labeling. The resulting cost reductions across the entire market would further the Hatch-Waxman Act's goal of providing cheap, effective medications to the American public.

Therefore, Washington Legal Foundation respectfully requests that FDA withdraw its proposal to amend its regulations governing procedures for application holders of an approved

drug or biological product to make unilateral changes in the product labeling. It urges FDA to adopt GPhA and PhRMA's alternative proposal in its place.

Sincerely,

Mark S. Chenoweth
General Counsel

Gregory B. Herbers
Counsel