DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

JAN 2 9 2014

The Honorable Kevin Yoder
House of Representatives
Washington, DC 20515

Dear Representative Yoder:

Thank you for your letter of September 20, 2013, cosigned by Representatives Valadao and Nunnelee, requesting information on the Food and Drug Administration's (FDA or the Agency) proposed regulatory changes being considered regarding the labeling of generic drugs. In your letter you expressed concern that the proposed changes might undermine a uniform Federal standard for drug labeling and ultimately affect public safety. We share your concern for public safety.

You specifically requested information related to:

- FDA's notice of proposed rulemaking (NPRM), which would "create parity between" generic and branded drugs (See RIN: 0910-AG94)
- A 2011 citizen petition (Docket Number FDA -2011-P-0675), which was filed with FDA seeking such a change
- FDA's recommendation to the Solicitor General related to the recently filed brief in the United States Supreme Court, (*Mutual Pharmaceutical Co. v. Bartlett*, 133 S.Ct. 2466 (2013)), which stated that "FDA is considering a regulatory change that would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances."

FDA issued the proposed rule Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,[1] If finalized, the rule would allow generic drug manufacturers, like brand name manufacturers, to independently update product labeling to reflect certain newly acquired safety information as part of the drug manufacturer's independent responsibility to ensure that its product labeling is accurate and up-to-date. We have attached the proposed rule for your further review.

FDA also issued a response to a citizen petition submitted by Public Citizen on generic drug labeling changes. The petition requested, among other things, that FDA amend its regulations to authorize generic drug manufacturers to revise their product labeling in a manner that differs from the corresponding brand drug through submission of a changes being effected supplement or a prior approval supplement. FDA granted the petition in part and denied the petition in part because the proposed rule, if finalized, would address some (but not all) of the petitioner's requests. The petition also requested that FDA amend the regulations to clarify that all generic

[1] See the *Federal Register*, Vol. 78 p. 67985, November 13, 2013.

drug manufacturers are required to report safety concerns to FDA as soon as they become aware of a clinically significant hazard. FDA denied this request because the current regulations already require such reporting and clearly apply to generic drug manufacturers.

The U.S. Supreme Court decided in *Pliva, Inc. v. Mensing,* 131 S.Ct. 2567 (2011) (*Mensing*) that state law tort claims against a generic drug manufacturer for failure to provide an adequate warning in product labeling were preempted by Federal labeling requirements for generic drugs. The Supreme Court did not adopt the position that the Federal government advocated in *Mensing*. At the request of the Supreme Court, the government filed an amicus brief in that case, addressing the issue of generic preemption. In that brief, the government stated its view that *failure-to-warn* claims against generic drug manufacturers were not categorically preempted because—although generic manufacturers currently may not make unilateral changes to the labeling—generic manufacturers can and must bring safety labeling information to FDA's attention and seek a labeling change when appropriate. However, the Supreme Court held that it was impossible for generic manufacturers to comply with both state and Federal law because they could not independently change their labeling under Federal law to accomplish what the Court found that state law required.

The Supreme Court's decision in *Mensing* prompted FDA to evaluate its current regulations. This decision, as well as the recent decision in *Mutual v. Bartlett*, may alter the incentives for generic drug manufacturers to comply with current statutory and regulatory requirements to conduct robust postmarket surveillance, evaluation, and reporting and to ensure that their product labeling is accurate and up-to-date. In the current marketplace, approximately 80 percent of dispensed drugs are generic drugs, and brand name drug manufacturers may discontinue marketing after generic drug entry. FDA believes it is time to provide generic drug manufacturers with the means to independently update their product labeling to reflect data obtained through postmarket surveillance, even though this will result in temporary labeling differences among products.

All drug and biologics manufacturers—generic as well as brand name—have an ongoing obligation to ensure their product labeling is accurate and up-to-date. The proposed rule would amend FDA's regulations to revise and clarify procedures for application holders to change the labeling of an approved drug or biologic to reflect certain types of newly acquired safety-related information in advance of FDA's review of the change. If this proposed rule is finalized, it would help ensure that health care professionals and the public have access to the most current safety information on the medications they use.

With respect to your request for a description of the resources expended on the proposed rule, this issue, and the proposed rule, involved complex legal and policy issues that required the active engagement of the Center for Drug Evaluation and the Center for Biologics Evaluation and Research as well as the Office of Chief Counsel and offices within the Office of Commissioner. As with other proposed rules, Executive Order 12866 required an analysis of impacts. Processing of the Federal Register document also involved staff time and resources.

With respect to your request for "a detailed listing of any non-government parties the FDA has met with regarding the proposal referenced in the Supreme Court brief and in the NPRM," FDA

generally declined requests for meetings related to this issue pending publication of the proposed rule. Other than through review of the petition described above and of the comments on the petition and of correspondence from members of Congress and the public, FDA did not consult with outside parties. While FDA generally does not participate in a dialogue during the development of proposed rules, there are occasions when FDA staff will participate in a listen-only session with interested parties. FDA's Chief Counsel and others met with Ms. Rooney (American Association for Justice), Mr. Forscey, and Mr. Blizzard on February 15, 2013. This information is publicly available at http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/PastMeetingsWithFDAOfficials/ucm340246.htm

The proposed rule issued on November 13, 2013, provides an opportunity for the public to submit comments on FDA's proposal to the public docket established for this rulemaking, and the comment period is being extended until March 13, 2014. We encourage you and other interested parties to review the proposed rule and submit comments to the public docket at www.regulations.gov established for this rulemaking (Docket No. FDA-2013-N-0500).

Thank you, again, for contacting us concerning this important matter. Please let us know if you have further questions. This letter also has been sent to your cosigners.

Sincerely,

Walter S. Harris, MBA, PMP
Deputy Commissioner of Operations and
Chief Operating Officer