



March 13, 2014

Margaret A. Hamburg, M.D. Commissioner
Food and Drug Administration
Health and Human Services Department
Rockville, MD 20852

Submitted via regulations.gov

Re: Supplemental Applications Proposing Labeling Changes for Approved Drugs
and Biological Products FDA Docket No. FDA-2013-N-0500 and RIN 0910-AG94

Dear Commissioner Hamburg:

Thank you for the opportunity to comment on the proposed rule on Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products. AARP is a nonprofit, nonpartisan organization, with a membership of nearly 38 million, that helps people turn their goals and dreams into real possibilities, strengthens communities and fights for the issues that matter most to families such as healthcare, employment and income security, retirement planning, affordable utilities and protection from financial abuse.

AARP believes that it is critically important that all prescription drugs carry current and adequate safety warnings. AARP also believes that consumers who are injured by generic drugs should have the same legal rights as consumers who are injured by brand name drugs. We commend the Food and Drug Administration (FDA) for its efforts to enable generic drug manufacturers to make labeling changes so that consumers and prescribers have the most up-to-date and accurate safety information for their prescription drugs.

AARP was extremely concerned by the Supreme Court's ruling that generic drug manufacturers could not be held liable for patient injuries due to inadequate safety information on product labeling because current FDA regulations do not allow generic drug manufacturers to unilaterally update their warning labels (*PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011)). As noted in AARP's amicus brief in *PLIVA v. Mensing*¹, "Generic drug companies are often in the best position to discover, assess, and take early action to address risks that come to light after the name-brand drug's period of patent exclusivity has ended because, once generic drugs are available, they often have the majority market share for the drug. ... Generic drug manufacturers are already subject to the same requirements as name-brand drugs regarding the "reporting and recordkeeping of adverse drug experiences." 21 C.F.R. § 314.98(a). They should not be immune from liability under

¹ Brief of Public Citizen and AARP as Amici Curiae Supporting Respondents, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, and 09-1501)

state law if they fail to take reasonable steps to ensure that consumers are properly warned about risks from their products.”

The current lack of parity in brand name and generic drug manufacturers’ ability to update labeling raises serious safety concerns in the current marketplace, where approximately 80 percent of drugs dispensed are generic and, in some instances, the brand name manufacturer exits the market entirely after generic entry. It is essential for generic drug manufacturers to be able to make appropriate updates to their labeling without having to wait for changes to be initiated by a brand name drug manufacturer.

We have reviewed the process FDA laid out in its proposed rule that would allow generic manufacturers to make updates to their labeling when new safety information becomes available. Under the proposed rule, Abbreviated New Drug Application (ANDA) holders would be able to immediately change their labeling when they get new safety information after submitting a “Changes Being Effectuated” (CBE) supplement to FDA for review and to brand name manufacturer. The new labeling information would be posted to an FDA web page so that it is available to other manufacturers, providers, and consumers. Once the agency approves the change it would also be cleared for the brand name drug, and any other ANDA holders for the same drug product would have to make conforming labeling changes within 30 days.

While AARP wholeheartedly supports the goal of ensuring new drug safety information is available to consumers as quickly as possible, we do have some concerns that the proposed rule could lead to inconsistent labeling information on multiple versions of equivalent drugs for a substantial period of time. The resulting confusion could affect confidence in generic drugs and complicate decision-making conversations between providers and consumers about appropriate drug therapies based on their safety, efficacy and quality.

In addition, while we acknowledge that the new CBE process could speed up the time it takes for generic drug labels to be updated following the approval of a brand name drug’s labeling change, it remains unclear how many of these new CBE supplements will be submitted and whether FDA will have the necessary resources to process them expeditiously. Therefore, we believe it will be critical for FDA to closely monitor how generic drug manufacturers and other stakeholders react to the new process and reevaluate how it is working to determine whether any adjustments or improvements are needed.

Thank you for the opportunity to comment on this important proposed rule. If you have any questions, please do not hesitate to contact KJ Hertz on our Government Affairs staff at khertz@aarp.org or 202-434-3770.

Sincerely,

A handwritten signature in black ink, appearing to read "David Certner", with a stylized flourish at the end.

David Certner
Legislative Counsel and Legislative Policy Director
Government Affairs