U.S. FOOD & DRUG ADMINISTRATION

August 29, 2017

Lee Ann C. Stember
President
National Council for Prescription Drug Programs
9240 E. Raintree Drive
Scottsdale, AZ 85260

Dear Ms. Stember:

Thank you for your kind letters of March 17 and May 25, 2017, congratulating Secretary Price and Commissioner Gottlieb on their confirmations. I have been asked me to respond on their behalf.

In your letters, you referenced the Food and Drug Administration's (FDA or the Agency) January 2017 final guidance entitled "Nonproprietary Naming of Biological Products." You note that you have expressed concerns about the costs associated with certain aspects of the guidance. FDA has carefully considered the appropriate naming convention to help ensure the safety of patients receiving biological products, enhance patient and prescriber confidence, and maximize the success of biosimilar and interchangeable biological products. As stated in the guidance, FDA is continuing to consider, among other issues, the process for implementation of the naming convention for previously licensed products. I assure you that, to implement the guidance, the Agency will continue working with stakeholders, including, as appropriate, drug manufacturers, prescribers, pharmacies, hospitals and health systems, informatics providers, and patient groups.

On behalf of HHS and FDA, I would like to convey my appreciation for your concerns. Thank you, again, for contacting us and for your continued interest in this important matter.

Sincerely,

Lauren Silvis
Chief of Staff

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