



October 27, 2015

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-D-1543-0001: Nonproprietary Naming of Biological Products; Draft Guidance for Industry

Dear Sir or Madam:

On behalf of the 30 million Americans with one of the nearly 7,000 known rare diseases, NORD would like to thank the Food and Drug Administration (FDA) for the opportunity to provide comments on the Agency's Draft Guidance titled, "Nonproprietary Naming of Biological Products; Draft Guidance for Industry".

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services.

With nearly 7000 rare diseases identified and 30 million Americans affected, the population represented by NORD is extraordinarily heterogeneous. We believe strongly that every patient deserves the medical care that is best suited for their medical situation and that is most likely to give them the best results. Based on the reports we receive from member organizations, as well as individuals, it is increasingly difficult for rare disease patients to receive optimum care if any degree of customization to individual patients is required.

In light of this problem of access to optimum care, distinguishable names for biologics, including biosimilars, are critical in ensuring rare disease patients access personalized care. We are very pleased to see the FDA is proposing a policy to establish unique names for biosimilars, but we request that the FDA update the guidance to establish meaningful suffixes for biological medicines rather than the currently proposed random suffixes.

By establishing a unique naming system for biosimilars, the FDA is addressing three important concerns to the rare disease community. First, distinguishable names for biologics support the medical community's vital post-approval learning curve about which medicines are best for their rare disease patients. Health care providers need to know that a prescribed medicine was actually given to the patient and whether a substitution was made and to what alternative product. This can't be achieved unless biologic products—especially ones with similar therapeutic purposes—cannot be distinguished, tracked and studied.

Second, distinguishable names for biologics support surveillance and tracking of adverse events. Rare disease patients often do not respond to medications the same way other individuals might. Idiosyncratic reactions to medications occur frequently. Finally, distinguishable names for biologics reinforce a critical

distinction in the biosimilars law between biosimilars (similar not identical) and interchangeable biosimilars (similar but demonstrated to have comparable clinical results).

However, random four-letter suffixes to distinguish the name of a biologic product will only add complexity to the treatment of rare disorders. We ask, as a matter of clarity that will support optimal care for our patients, that FDA consider updating its draft guidance to establish meaningful suffixes for all biological medicines. A meaningful suffix will help to more readily identify each biologic medicine, leading to better tracking and tracing of a biologic medicine and facilitating a physician's use of the biologic.

We thank FDA for the opportunity to comment, and we look forward to working with FDA to ensure rare disease patients are able to obtain life-altering and even life-saving biologics and biosimilars. For questions regarding NORD or the above comments, please contact Paul Melmeyer, Associate Director of Public Policy, at pmelmeyer@rarediseases.org or (202) 588-5700, ext. 104.

Thank you in advance for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter L. Saltonstall". The signature is written in a cursive style with a horizontal line underlining the name.

Peter L. Saltonstall
President and CEO