May 7, 2019

Commissioner Norman E. Sharpless, M.D.
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Submitted via: https://www.regulations.gov

Re: [FDA-2013-D-1543] Nonproprietary Naming of Biological Products: Update

Dear Acting Commissioner Sharpless,

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and rheumatology inter-professional team members, appreciates the opportunity to comment on the Nonproprietary Naming of Biological Products: Update - Guidance for Industry. The ACR applauds the Food and Drug Administration (FDA) for issuing draft guidance that would require separate and distinct suffixes for new biosimilars and biologic therapies, and we encourage the agency to continue to implement the policy as presented in the March 2019 updated guidance. We believe this naming protocol will help to ensure patient safety and transparency.

Distinct, unambiguous, and preferably meaningful and therefore memorable, names are essential to allow pharmacovigilance for rare events. In addition, non-distinguishable naming could lead to confusion in prescribing these drugs for non-approved indications, as many biologics have separate FDA approval for different conditions that are non-overlapping. For example, Rituximab is FDA-approved for treatment of a type of cancer (non-Hodgkin’s lymphoma), rheumatoid arthritis and other less common diseases, whereas biosimilar rituximab-abbs is not FDA-approved to treat rheumatoid arthritis. The treatment regimen and dosing varies depending on the disease state and patient population being treated. Clearly defined and unequivocal naming is required to safeguard accurate prescribing of biosimilars for specific diseases. Widespread use of less costly biological products will require confidence in their use among physicians and patients. This will only occur with transparent naming and prescribing practices. Easily distinguishable naming of biosimilars is required to avoid errors in prescribing and promote pharmacovigilance for each individual biosimilar.

The ACR supports the FDA’s recommendation of distinct suffixes for both biosimilars and reference biologics, so as to prevent prescribers from perceiving that drugs with suffixes are less safe or effective. One of the ACR’s top priorities is to ensure that more affordable treatments reach our patients as quickly as possible, so we applaud the FDA’s measured and thoughtful approach to addressing provider confidence concerns while also prioritizing the safety of patients. The American College of Rheumatology appreciates the work that the FDA
does and the opportunity to respond to this draft guidance. We look forward to being a resource to you and to working with the agency. Please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs, at kamodeo@rheumatology.org or (202) 210-1797 if you have questions or if we can be of assistance.

Sincerely,

[Signature]

Colin C. Edgerton, M.D.
Chair, Committee on Rheumatologic Care
American College of Rheumatology