October 24, 2015

Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Comment on Food and Drug Administration Draft Guidance "Nonproprietary Naming of Biological Products"

Submitted electronically via www.regulations.gov

Acting Commissioner Ostroff:

On behalf of the Lupus and Allied Diseases Association, Inc., and the millions of Americans struggling to live with and treat autoimmune conditions and other diseases of unmet need who are eagerly awaiting access to affordable, appropriate and safe therapies, I passionately urge you to adopt a policy of discernible names for all biological products including biosimilars and to issue final guidance that includes distinguishable nomenclature.

We thank you for the opportunity to provide our inimitable patient viewpoint regarding the naming of biological products. Lupus is an extremely complex, chronic inflammatory autoimmune disease affecting virtually any organ system of the body. Due to the heterogeneous nature of autoimmune diseases like lupus, no two cases are alike and treatment is highly individualized; *no one size fits all* products exist for our patients, their response to therapies is unique, contrary and at times adverse.

Because we represent patients who are distinctive and struggle daily with chronic, debilitating diseases, we have closely followed the biosimilar pathway to ensure that patient safety is given the utmost priority by the FDA as you finalize biological product regulatory policies. We applaud the FDA for releasing guidance proposing to distinguish biosimilars from both their reference products and other biosimilars by applying a nonproprietary name that includes an FDA-designated unique four-letter suffix. We believe it is essential that all biological products, including biosimilars, be clearly discernible from one another to ensure patient safety especially among products that have not been deemed interchangeable and to improve pharmacovigilance. Applying a meaningful suffix will avoid confusion with the original reference product and ensure accurate physician-patient communication, as well as reliability in the prescribing, dispensing and compliance processes of specific therapies.

Biosimilar drugs hold tremendous promise and therapeutic advantages for lupus and autoimmune patients just as biologic medicines have for millions of individuals living with life-threatening and life-diminishing diseases. As biosimilars become more readily available in the United States we want to ensure they are safe, efficacious, accessible, and affordable. We must remain vigilant in protecting patient safety while promoting unfettered access to vital and effective treatments.

Utilizing discernible meaningful suffixes rather than random suffixes for each biological product provides much-needed transparency by enabling better safety monitoring via tracking the therapy and tracing the product, promoting timeliness in addressing potential adverse events, and providing physicians with more information to recognize which products are likely to be safer or more effective in a specific patient.

Furthermore, distinguishable suffixes will facilitate pharmacovigilance which is essential when biological medicines are prescribed, as they may cause idiosyncratic reactions or immunogenic responses in lupus and autoimmune patients who can also be hypersensitive to changes in production methods or impurities. It is also important to recognize that adverse effects are difficult to predict and may only occur after many years of treatment. Distinguishable naming is particularly important with the advent of biosimilars in order for unexpected effects or adverse events to be attributed to the correct product and consequently non-interchangeable biosimilars are not inadvertently and/or inappropriately substituted.

Applying distinguishable names will be paramount in identifying exactly which medicine was received if an adverse event occurs since biologics and biosimilars in reality will be administered to patients suffering from serious, life-threatening diseases who take many concomitant medications and are not participating in a controlled clinical study.

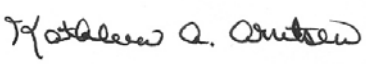
We believe that applying meaningful rather than suffixes devoid of meaning will create transparency, be easily recognized, reduce errors, and facilitate prompt and accurate association between adverse events and specific products. This clarity will aid in accurate product identification during prescribing, dispensing, and pharmacovigilance.

It is also our position that suffixes based on the name of a manufacturer, such as "-sndz", promote and maintain drug manufacturer accountability for their product regarding safety, efficacy, and quality. Using the license holder's name will reduce confusion, facilitate efficiency and enable the healthcare community to better address any potential adverse events. In order to minimize confusion the suffix should always reflect the name of the initial manufacturer even if the product is sold or licensed to another company.

We also believe that a biosimilar which has been determined to be interchangeable with its reference product be assigned a distinct suffix from the reference product to avoid inadvertent substitution. Interchangeability should be reflected on the label.

In conclusion, we thank you again for the opportunity to share our unique perspective as you evaluate final guidance and applaud the FDA for continually recognizing the importance of the patient voice during the drug review process.

Sincerely-



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