October 27, 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RE: Comment on Food and Drug Administration Draft Guidance “Nonproprietary Naming of Biological Products: Guidance for Industry”

Submitted electronically via www.regulations.gov

Dear Dr. Ostroff:

As the largest non-profit health organization addressing the needs of the more than 50 million adults and 300,000 children living with arthritis in the United States, the Arthritis Foundation welcomes the opportunity to provide written comments on the FDA draft guidance on nonproprietary naming of biological products. This guidance is of particular interest to the Arthritis Foundation, as one of the biosimilar products that would be affected – Celltrion’s infliximab – treats certain forms of arthritis.

The Arthritis Foundation supports a policy of unique names for all biological products, and is pleased that the FDA guidance would require unique names for the six biosimilar products that have been approved or currently have applications pending before the FDA. Since biosimilars are not identical to their reference biologics, we believe unique names are critical to distinguish biosimilar products from reference biological products. As these products enter the marketplace unique names will reduce confusion among prescribers, allow for transparency in substitution and notification, and support robust post-market surveillance. All of these issues are critical components for supporting patient safety.

Medically managing Arthritis is often complex and highly nuanced – one drug that works well for one patient may not work for another patient with the seemingly identical disease characteristics. One estimate of rheumatoid arthritis patients who took one of the three first-generation biologics for at least 6 months showed that between 40-50% of them failed to meet the American College of Rheumatology 50% improvement criteria.¹ Of patients who fail on a biologic, rheumatologists switch their patients to another biologic

¹ Renda-Baum, Regina; Wallenstein, Gene; Koncz, Tamas; Kosinski, Mark; Yang, Min; Bradley, John; Zwillich, Samuel. “Evaluating the Efficacy of Sequential Biologic Therapies for Rheumatoid Arthritis Patients With an Inadequate Response to Tumor Necrosis Factor-a Inhibitors.” Arthritis Research and Therapy. 13(1); 2011.
90% of the time.² It is our hope that biosimilars will add to the treatment options available for physicians, and given the complexity of arthritis-related diseases and disease management, we believe it is critical that both the prescriber and the patient know what medications are being dispensed.

The Arthritis Foundation would like to offer the following comments on the questions FDA posed in its draft guidance:

**Naming Convention**

The Arthritis Foundation supports the proposal to apply a suffix to both biosimilars and reference products. We believe it would create uniformity in tracking and reporting, and as stated in the draft guidance, it would “provide another critical tool for accurately identifying and facilitating pharmacovigilance for these products.”

The Arthritis Foundation also supports the proposal to make this naming convention retroactive, such that it would apply to biological products already on the market. For the reasons previously stated, this would ensure uniformity and lessen the possibility of error and confusion among prescribers, pharmacists and patients.

**Naming of Interchangeable Biological Products**

The Arthritis Foundation believes that all biological products should retain unique names, regardless of whether the product is a biosimilar or interchangeable biologic. Retaining the original suffix for a drug that is determined to be interchangeable is particularly important for the purposes of pharmacovigilance, since interchangeable drugs will be substitutable. Record keeping and notification are critical when drugs are substituted – the Arthritis Foundation believes that prescribers and patients should always know what drug is being dispensed. Sharing the same suffix as the reference drug could create confusion and make record keeping more difficult when a drug is substituted. We believe it would further lead to error and confusion if the routes of administration, dosages or number of indications are different than the reference product.

Ultimately, state legislatures will determine the regulations around substitution of an interchangeable biological product. 16 states and Puerto Rico have already passed legislation on biosimilars, and a number of others are currently considering legislation. Some legislation does not define whether notification should list the proprietary or nonproprietary name, and some legislation creates a pathway for the nonproprietary name to be used. For example, Michigan House bill 4437 states that “if the dispensed drug does not have a brand name, the pharmacist shall indicate the generic name or interchangeable biological drug product name of the drug product dispensed.”

² Ibid.
The broad range of legislative language across states could result in unintended consequences if FDA allows interchangeable biological products to share the same suffix as the reference product. Practically speaking, if a state allows the nonproprietary name to be used in the notification to the patient and prescriber upon substitution, and the interchangeable product shares the same suffix as the reference product, the prescriber and patient may have difficulty discerning which product was dispensed, particularly if there are multiple interchangeable products for a reference biologic.

We seek clarification from FDA on what mechanisms and safeguards would be put in place to ensure patients and prescribers clearly know what products are dispensed to treat their disease.

**Stakeholder Engagement and Education**

The Arthritis Foundation has made it a priority over the past year to educate people with arthritis about biosimilars and how these drugs might affect the treatment of their disease. We hosted a biosimilars education webinar that was well attended and is archived on the Foundation’s website. The AF could replicate this webinar, inviting FDA staff as guest speakers, and disseminate the webinar through various AF publications, our website, and our patient and provider partner organizations.

Other ideas for education include an FAQ that the AF could link to, tele-town halls for patients and patient advocacy groups, and a patient portal on the FDA website for patients to ask questions about biosimilars. The Arthritis Foundation is very interested in partnering with the FDA to help educate people with arthritis about the policies and guidances surrounding biosimilars.

Again, thank you for the opportunity to comment on the FDA nonproprietary naming of biological products draft guidance for industry. Please contact Sandie Preiss, Arthritis Foundation National Vice President of Advocacy and Access, at 202-887-2910 or spreiss@arthritis.org with questions or for more information.

Sincerely,

Sandie Preiss  
Vice President, Advocacy and Access  
Arthritis Foundation