



February 21, 2018

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock,

On behalf of the tens of millions of Americans living with psoriatic disease and arthritis, the National Psoriasis Foundation and Arthritis Foundation write to convey our appreciation for efforts made by the Food and Drug Administration (FDA) to advance innovative therapies that have significantly improved the health and quality of life for the patients we represent. Similar to improvements in treatment that resulted from the introduction of biologics, we are optimistic about the promise of biosimilars in advancing care. Biosimilars have the potential to increase access for psoriatic disease and arthritis patients, and we share the FDA's commitment to seeing that promise through.

Last fall, we were grateful to see the introduction of biosimilars educational materials focused on provider education. These tools will help prescribers familiarize themselves with biosimilars and, subsequently, increase opportunities for patients to access new treatments. Our organizations and others had discussed the value and importance of the FDA creating educational materials like these during a meeting with the FDA in May 2016, so it was exciting when these resources were released.

In addition, the educational materials will encourage conversations between patients and providers about biosimilars, interchangeability, and cost – important complements to our own efforts focused on raising awareness of biosimilars among our patient communities. Ultimately, we believe patients should have access to the full suite of therapies to treat their disease, and decisions on the appropriate treatment are best made between patients and their providers.

Many people with autoimmune diseases rely on biologic medications to manage their disease, and the FDA is vital to ensuring these products come to market safely. As such, we want to clarify our position on the recent [comments](#) submitted by Patients for Biologics Safety and Access. While we do not believe it was the intent of the coalition to question the FDA's processes and standards, we understand how some of the comments

could have been construed that way. We would like to acknowledge our support for the FDA's scientific standards in evaluating the safety and efficacy of biosimilars.

As organizations representing individuals with complex, chronic diseases, we thank you for inviting patients and patient organizations in to dialogue with the FDA on everything from patient focused drug development to benefit risk frameworks to patient and provider education. We appreciate the FDA listening to requests from the patient community, including the National Psoriasis Foundation and Arthritis Foundation, on the development of these new educational tools. We look forward to continuing our work with FDA as biosimilar therapies are developed and approved.

Sincerely,



Randy Beranek
President and CEO
National Psoriasis Foundation



Cindy McDaniel
Senior Vice President, Consumer Health
Arthritis Foundation