NATIONAL CONSUMERS LEAGUE
1701 K Street, NW, Suite 1200 Washington, DC 20006
Main: (202) 835-3323 Fax: (202) 835-0747 www.nclnet.org

Comments of the National Consumers League
September 21, 2018

Docket No. FDA–2018–N–2689

Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments

Founded in 1899, the National Consumers League (NCL) has long been concerned with ensuring patient access to safe, effective, and affordable medications. NCL is a strong supporter of biosimilars, and commends the Food and Drug Administration's (FDA) Biosimilars Action Plan. We recognize that the entry of biosimilars into the U.S. market presents an opportunity to broaden patient access to life-saving biologic treatments while bolstering competition, reducing costs, and realizing better health outcomes. Biologics are a manifestation of revolutionary advancements in the development of therapies for patients with debilitating and deadly diseases such as diabetes, multiple sclerosis, rheumatoid arthritis, and various forms of cancer. Unfortunately, the price for these complex therapies is often prohibitive for the vulnerable patients who need them the most – with some costing upward of several hundred thousand dollars per year. Biosimilars provide a less expensive alternative to their reference products, offering the same potency and therapeutic benefits at a fraction of the price. Similar to the dynamic relationship of generic and brand name drugs, the presence of biosimilars will not only encourage patient choice, but also boost market competition and drive down costs.

NCL is pleased to offer these comments on ways in which the FDA can facilitate competition and innovation in the biological products marketplace:

Continue to Hire and Retain a Highly Qualified Biological Product Review Staff

In order to promote continued innovation and investment in the biological product marketplace, FDA must continue to recruit, hire, and retain highly trained and qualified technical and scientific experts to efficiently conduct reviews of biological products. This includes continuing to hire scientists with analytical expertise.

Prioritize Reviews of Novel Cures and Biosimilars

In order to best serve the needs of patients, FDA should prioritize the review of new cures and biosimilars.

Ensure Appropriate Access to Reference Products for Testing

NCL commends the FDA for its decision to publish a list of restricted access abusers, and encourages the agency to ensure that reference product makers do not inappropriately block biosimilar manufacturers' access to necessary product samples.

Finalize Guidance on Interchangeability

In order to promote the development of interchangeable biologics, NCL urges the FDA to finalize its guidance on interchangeability. FDA should also further clarify the utility and relevance of the interchangeability designation. This will help to drive utilization of interchangeable biologics and drive down costs.

Enhance the Purple Book

To encourage biosimilar development, the Purple Book should include the date of first licensure and the reference product exclusivity expiry date.

Increase Healthcare Provider, Payor, and Consumer Education about Biologics and Biosimilars

NCL appreciates FDA's biosimilars education campaign and believes that more needs to be done to educate health professionals, payors, patients, and caregivers about biologics, biosimilars, and interchangeability in order to enhance the understanding and acceptance of biosimilars in the treatment of disease. FDA should partner with healthcare professional, patient, and consumer organizations to develop and deliver additional educational materials and messaging. It is also critical for the FDA and stakeholders to continue to combat misinformation that undermines provider and patient confidence in biologics and biosimilars.

NCL appreciates the opportunity to submit these comments. We look forward to continuing to work collaboratively with the FDA, the advocacy community, and industry stakeholders to ensure that consumers and patients have expanded and affordable access to the safe and effective biologic and biosimilar medicines they need to maintain their health and enjoy a positive quality of life.