September 21, 2018

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Docket ID: FDA-2018-N-2689 Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments

The undersigned organizations recognize and support the Food and Drug Administration's (FDA) goal to foster development of a robust biosimilars market that reduces prescription drug costs and offers patients access to more affordable therapies. We applaud the Agency for its leadership on biosimilars, especially in partnering with industry, patient, consumer, provider, and payor stakeholders as it implements its Biosimilars Action Plan. We are pleased to offer the following recommendations to increase competition and patient access through biosimilar medicines:

1. **Enhance the efficiency of FDA review of marketing applications for biosimilar and interchangeable products.**
   We are pleased to see the increase in approvals of biosimilar applications and the successful negotiation of the Biosimilar User Fee Agreement (BsUFA), which sets vital metrics for the review and approval process. We support the FDA's commitment and focus on improving the efficiency of review.

   In addition to the efforts already being made by the FDA, we encourage the Agency to work closely in dialogue with sponsors to review biosimilars using a case-by-case approach, and, when scientifically appropriate, eliminating unnecessary or duplicative requirements.

2. **Provide additional scientific or regulatory clarity regarding the FDA's regulation of biological products, including the Agency's review and approval of marketing applications for biological products**.
   We agree that greater clarity and guidance for industry will improve application quality and lead to faster approval of biosimilars. FDA has already made strides to provide guidance to industry and the scientific community about the approval criteria and requirements for biosimilar therapies. However, there is still more to be done to successfully communicate the Agency's current thinking. Specifically:

   - FDA's withdrawal of the guidance "Statistical Approaches to Evaluate Analytical Similarity" in June presents an opportunity for the Agency to update and reissue vital information to applicants.

- The Agency should establish the least burdensome data requirements for applicants that still meet the FDA's gold standard of safety and efficacy.

- We ask that the Agency clarify recent comments related to the requirement that originator biologics and biosimilars include a suffix in their non-proprietary names. Does this still represent the Agency's current thinking?

- We urge the FDA to finalize or issue revised guidance on interchangeability. The Agency can help increase marketplace competition by finalizing its guidance.

3. **Increase healthcare provider, patient, and payor understanding of biological products, including biosimilar and interchangeable products**.
   The FDA's current biosimilars education campaign and the continued inclusion of healthcare provider and patient understanding in the Agency's goals is vital to the success of the biosimilars market. We fully support the FDA's efforts to combat misinformation that undermines patient and provider confidence and inhibits uptake of lower cost biosimilars.

   We encourage the FDA to continue to prioritize education and to take aggressive steps to combat misinformation.

We appreciate the opportunity to submit these comments for consideration, and look forward to continued partnership with the FDA to foster a successful biosimilars market for America's patients.

Sincerely,

Academy of Integrative Pain Management
Academy of Managed Care Pharmacy (AMCP)
Allergy & Asthma Network
Alliance for Aging Research
America's Health Insurance Plans (AHIP)
American College of Physicians
American Consumer Institute
American Pharmacists Association (APhA)
Biosimilars Council, A Division of AAM
Cancer*Care*
Citizens Against Government Waste
Consumer Action
Cutaneous Lymphoma Foundation
CVS Health
Express Scripts
Frontiers of Freedom

Global Healthy Living Foundation
Healthcare Supply Chain Association (HSCA)
The Heartland Institute
Lung Cancer Alliance
The Mended Hearts, Inc.
National Association of Chain Drug Stores (NACDS)
National Consumers League
National Taxpayers Union
Ohio Public Employees Retirement System
Pharmaceutical Care Management Association (PCMA)
Prevent Cancer Foundation
Prime Therapeutics
Public Sector HealthCare Roundtable