American Autoimmune Related Diseases Association (AARDA)

Arthritis Foundation (AF)

Committee of Ten Thousand (COTT)

Crohn's and Colitis Foundation of America (CCFA)

Dystonia Medical Research Foundation (DMRF)

GDS/CIDP Foundation International

Hemophilia Federation of America (HFA)

Hepatitis Foundation International (HFI)

Immune Deficiency Foundation (IDF)

International Foundation for Autoimmune Arthritis

Jeffrey Modell Foundation

Lupus and Allied Diseases Association (LADA)

Lupus Foundation of America

National Alliance on Mental Illness (NAMI)

National Organization for Rare Disorders (NORD)

National Psoriasis Foundation (NPF)

Platelet Disorder Support Association (PDSA)

Pulmonary Hypertension Association (PHA)

RetireSafe

Scleroderma Foundation

Spondylitis Association of America

United Spinal Association

US Hereditary Angioedema Association (US HAEA)

US Pain

Patients for Biologics Safety & Access

Robert Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Docket No. FDA–2015–N–3326 Comments Submitted on "Biosimilar User Fee Act; Public Meeting"

Submitted electronically via www.regulations.gov

October 19, 2016

Dear Commissioner Califf:

PBSA has long taken the position that in order to protect patient safety, assure transparency, and build consumer confidence in biosimilars, FDA should promptly publish final guidance on key issues such as naming, labeling and interchangeability, and incorporate in these guidances the views and priorities of patients. In the last two years, FDA has issued draft guidance on naming and labeling and received public comment. In response to questions from PBSA and others, FDA has stated repeatedly that it is working to promptly finalize the naming and labeling guidance, and expects to publish draft guidance on interchangeability in 2016. However, while FDA has now approved four biosimilars and has many more applications under active review, FDA is substantially delaying its timelines for getting out these key patient safety safeguards. This is also troubling as it comes in the wake of recent announcements by major insurers to force mass switching of stable patients to non-interchangeable biosimilars.

In late September, FDA released the Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, commonly referenced as the "commitment letter". It contains steps and actions FDA is committed to take as a part of the process for reauthorizing the Biosimilar User Fee Act (BsUFA) which expires in September 2017.

The agreement identifies substantially later deadlines for issuing and finalizing key patient safety guidelines. Among other things, it establishes **December 31, 2019** (over 3 years from now) as the goal for completing a final guidance on the crucial issue of interchangeability. However, the date is just a goal. There is no enforcement mechanism for this "deadline". It is just a goal.

PBSA is very concerned by the substantially delayed timelines announced by FDA for completing crucial patient safety guidelines for the review and approval of biosimilar drugs. New deadlines for final guidances on naming and labeling of biosimilars and the safety and efficacy standards required for biosimilars to be approved as interchangeable now may not be completed for years. Earlier this

year FDA stated that it expected to complete draft interchangeability guidance in 2016 and said that final guidance on naming and labeling was forthcoming shortly. Dr. Janet Woodcock in September 2015 testimony before the Senate HELP Committee stated that FDA would "try to get the guidances out expeditiously". However, the newly stated goal for final guidance on interchangeability is not until December 31, 2019.

While we understand the complexities of the issues involved and limited resources available to FDA, we find these new goals unacceptable. FDA has now given approval of four biosimilars and has many other applications under active review without final guidance on naming and labeling of biosimilars. While we are pleased there has been draft guidance issued on naming and labeling, completion of final guidance on all these key patient safety issues should be FDA's top priority in implementing the law. Timely guidance on these crucial issues is necessary to ensure patient safety and to build patient confidence in this new category of therapies.

Delay on issuance of and interchangeability guidance is even more concerning to patients given the recent steps taken by major insurance and pharmaceutical benefits managers in the absence of such guidance. While none of the four biosimilars were approved as interchangeable products by FDA, these payers are moving forward with plans in 2017 that could result in switching patients who are stable on their treatments to non-interchangeable biosimilars.

Earlier this year, CVS Caremark, which covers 75 million individuals, released an aggressive plan that could result in switching patients on stable treatments to non-interchangeable biosimilars absent any guidance on what constitutes interchangeability for biosimilars. In August, CVS announced that it will begin implementing this policy by dropping the biologic Neupogen from its 2017 formulary and replacing it with the non-interchangeable biosimilar Zarxio. In September, United Health Care, which insures 25 million Americans, also announced that its 2017 formulary will drop coverage of Neupogen and replace it with Zarxio.

PBSA has previously called for concrete steps to protect patients from unsafe non-medical switching of their treatments. PBSA now calls on FDA to speed up its work on these crucial guidance documents and stand by its previous estimates to complete draft interchangeability guidance this year. Additionally, FDA should issue final guidance on naming and labeling that take into account patient comments and suggestions by the end of this year.

Thank you for your consideration of our views.

Sincerely,

Lawrence A. LaMotte

On behalf of Patients for Biologics Safety and Access

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