



**Statement of Sally Greenberg, Executive Director
National Consumers League**

Docket No. FDA-2015-N-3326

**Biosimilar User Fee Act: Public Meeting
October 20, 2016**

Introduction

The National Consumers League (NCL) appreciates the opportunity to deliver these comments on the reauthorization of the Biosimilar User Fee Act for fiscal years 2018 through 2022 (BsUFA II). My name is Sally Greenberg, Executive Director of NCL. Founded in 1899, the National Consumers League has long been concerned with ensuring the safety of foods and drugs. Among NCL's top priorities are ensuring the safety, effectiveness, and appropriate use of both prescription and over-the-counter (OTC) drugs, and medication adherence, which we have helped to advance through our *Script Your Future* Campaign.

BsUFA II Review Goals and User Fee Revenue

The National Consumers League is a strong supporter of biosimilars, since they help to provide less expensive biological products for patients with serious diseases, such as rheumatoid arthritis, multiple sclerosis, and cancer. Since 2012, BsUFA has helped to provide FDA with the resources the agency needs to enhance the science-based review of new biosimilars. User fees are integral to the FDA's ability to review drugs and biologics in a timely manner, since the agency is woefully underfunded. To make matters worse, due to a .5% Across-the-Board (ATB) cut included in the Continuing Resolution, the FDA will experience a \$2.5 million cut in funding over the 10-week period until December 9. It is clear that user fees are necessary for the FDA to carry out its drug and biologic review functions.

BsUFA II lays out ambitious FDA review goals as detailed in the Goals Summary Tables on page 5 of the commitment letter. To meet these review goals, BsUFA II proposes to generate a total of \$45 million in user fee revenue for FY 2018. However, FDA can also raise the user fee amounts by no more than \$9 million in FY 2018 to reflect an updated assessment of the BsUFA workload. NCL supports FDA's ability to set increased BsUFA fees, and urges the agency to ensure that the fees are sufficient to offset the increased workload required under the BsUFA II agreement.

The Need for FDA to Remain Independent and Not Compromise its High Standards for Safety, Efficacy, and Quality of Biological Products

As BsUFA II goes through the reauthorization process, NCL urges the FDA to remain mindful of the concerns expressed by some that because industry pays user fees, industry thereby controls the FDA's agenda and process. It is critical for the agency to act independently of industry influence and to uphold its high standards for safety, efficacy, and quality of biological products.

Positive Features of BsUFA II

In reviewing the proposed BsUFA II User Fee Agreement, NCL notes that it has many good features, including the following:

Enhanced Communication and Meetings between the FDA and Product Sponsors

NCL supports BsUFA II's emphasis on improving communication between FDA and product sponsors, with the goal of promoting the efficiency and effectiveness of the first cycle review process and minimizing the number of review cycles necessary for approval of 351(k) applications. BsUFA II will allow for additional communication between FDA review teams and the applicants of biosimilar biological products in the form of pre-submission meetings, mid-cycle communications, and late-cycle meetings, while also adding 60 days to the review timeframe to accommodate this additional interaction. BsUFA II also updates meeting management practices to provide FDA and sponsors sufficient time to review each other's materials and provide the necessary feedback for informed discussions.

Biosimilars Unit

NCL supports the establishment of a Biosimilars Unit to provide a focal point of coordination to facilitate scientific coordination, policy development resources, operations management, program governance, internal training, educational outreach, and enhanced communication related to biosimilars.

Guidance Development

NCL applauds FDA's commitment in BsUFA II to issue guidance documents on several issues related to biosimilar biological product development in order to provide clarity to industry and other stakeholders on agency expectations. NCL believes that of particular importance are FDA guidances on demonstrating interchangeability with a reference product and labeling for biosimilar biological products.

Improving FDA Hiring and Retention of Review Staff

Improving FDA's ability to hire and retain a highly qualified biological product review staff is one of the most important components of BsUFA II. In order to carry out its mission to protect and advance the public health, FDA must be able to hire and retain highly trained and qualified technical and scientific experts to efficiently conduct reviews of drugs and biologics. Many physicians and scientists are committed public servants, and FDA has a long history of attracting these talented and highly educated professionals. NCL agrees with the FDA that the agency must find the means to continue to hire and retain such talent.

Enhancing Capacity for Biosimilar Guidance Development, Reviewer Training, and Timely Communication

In addition to the emphasis on guidance development, NCL supports BsUFA II's commitment for the FDA to develop and deliver timely, comprehensive training to all CDER and CBER review staff and special government employees involved in the review of 351(k) BLAs; deliver timely information to the public to improve public understanding of biosimilarity and interchangeability; and deliver information concerning the date of first licensure and the reference product exclusivity expiry date, to be included in the Purple Book. With regard to education, NCL believes that there is an urgent need for health professional and consumer education about biologics and biosimilars to enhance the understanding and acceptance of biosimilars in the treatment of disease.

Conclusion

NCL appreciates BsUFA II's role in continuing to improve the efficiency of the science-based FDA review process for biosimilars. We are pleased to have the opportunity to work with the FDA and to offer comments on the BsUFA II User Fee Agreement. 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 medicines they need to maintain their health and enjoy a positive quality of life.