



U.S. Food and Drug Administration
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Regulatory Information

Fact Sheet: New "Biosimilars" User Fees Will Enhance Americans' Access to Alternatives to Biologic Drugs

With the enactment of the Biosimilar User Fee Act of 2012 (BsUFA) on July 9, 2012, as part of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144), FDA will receive funding from the biopharmaceutical industry to help ensure Americans have timely access to biological products that have been demonstrated to be "biosimilar" to an FDA-approved biological product. Biosimilars are biological products that are highly similar to, or interchangeable with, an already approved biological product. The approval pathway for biosimilar biological products was authorized by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), which was intended to create price competition in the biologic drug marketplace. BsUFA, which establishes a new user fee program for biosimilars, authorizes user fees to support the review of marketing applications for biosimilar biological products.

The BPCI Act is similar in concept to the *Drug Price Competition and Patent Term Restoration Act of 1984* (a.k.a., the "Hatch-Waxman Act"), which enables approval of generic drugs based on their comparison to already approved drugs. Since 1984, FDA has approved more than 8,000 generic drugs resulting in hundreds of billions of dollars in cost savings to U.S. consumers.

Currently there are very few therapeutic alternatives to biological products, which are difficult to characterize because they are composed of highly complex molecules, sometimes hundreds of times larger than those of many other drugs.

Prior to being enacted into law, the provisions in the BsUFA legislation were, as directed by Congress, developed in consultation with companies that intend to make biosimilar products, patient and consumer advocates, health care professionals, and other public stakeholders. The law authorizes BsUFA funding for a five year period. The user fee funding from manufacturers provides FDA with supplemental funding for the Agency to hire new staff and to set and implement Agency processes to review and approve biosimilar versions of already-approved biological products.

Benefits to Americans:

- **Marketplace competition leading to potentially lower cost alternatives:** The approval pathway for biosimilar biological products can lead to marketplace competition and thereby help create less costly alternatives to the biological products currently on the market. BsUFA funding, which will provide the Agency with increased resources to review biosimilar biological product applications and provide feedback to companies seeking to develop biosimilar products, will help speed biosimilars to market.
- **Enhanced product access and consumer choice:** BsUFA funding, in providing FDA with increased resources to review biosimilar applications and provide feedback to sponsors, can help drive the development of multiple biological products to treat the same condition. If there is only one biological product available to treat a certain condition and there becomes an availability issue with that product, for instance a manufacturing problem that limits or stops production, patients who need treatment with that product might not be able to receive adequate therapy. The development of biosimilars creates the potential for multiple biological products available to treat a condition and thereby the potential for more access to biological products and more consumer choice.

Benefits to Industry:

- **Support to develop effective approval methods.** To generate an efficient approval process for biosimilars, FDA must expend significant resources in evaluating research and protocols for reviewing biosimilar applications and establishing the appropriate scientific methods necessary to help ensure that a biosimilar product will indeed be similar enough to an existing biological product. BsUFA funding will provide FDA with the necessary resources to enable the development of this important process.
- **Business development.** Biosimilars user fees have been designed to be distributed evenly and fairly across the biologic drug industry. The biologic drug industry has been supportive of these fees as a means of developing and implementing a process within FDA that can lead to enhanced opportunities for new product development and therefore serve as a benefit to their business.
- **Greater predictability.** In exchange for user fees from industry, FDA must strive to reach certain goals of efficiency in terms of the time it takes to review applications for biosimilar biological products. This provides manufacturers a higher degree of predictability in assessing when FDA will complete a review of their applications for biosimilars.

BsUFA Performance Goals and Efficiency Improvements:

- These goals include targets for FDA to review 70% of applications for biosimilars within 10 months of receipt in fiscal years 2013 and 2014, 80% in fiscal year 2015, 85% in fiscal year 2016 and 90% in fiscal year 2017. There are many other performance goals for FDA set forth in BsUFA, such as goal timeframes for holding meetings with manufacturers with biosimilar biological products in development. The BsUFA goals can be found at [FDA: Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 Through 2017](#)¹.

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