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BsUFA

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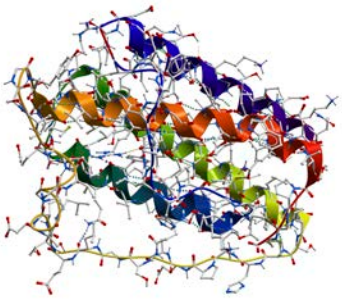


In exchange for user fees from industry, FDA must strive to reach certain goals of efficiency...

Having already discussed PDUFA (the Prescription Drug User Fee Act) and GDUFA (the Generic Drug User Fee Amendments) in past editions of our newsletter, we will now address CDER's third big 'UFA': BsUFA (the Biosimilar User Fee Act of 2012).

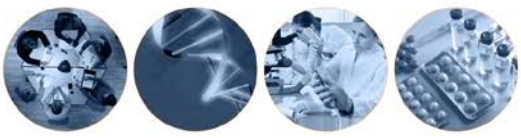
The Patient Protection and Affordable Care Act amends the Public Health Service Act to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. This pathway is provided in the part of the law known as the *Biologics Price Competition and Innovation Act of 2009* (BPCI Act). Under the BPCI Act, a biological product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to an already-approved biological product.

The implementation of an abbreviated licensure pathway for biological products can present challenges given the scientific and technical complexities that may be associated with the larger and typically more complex structures of biological products, as well as the processes by which such products are manufactured. Most biological products are produced in a living system such as a microorganism, or plant or animal cells, whereas small molecule drugs are typically manufactured through chemical synthesis.

The Federal Food, Drug, and Cosmetic Act, as amended by BsUFA, authorizes FDA to assess and collect fees for biosimilar biological products for fiscal years 2013 through 2017. FDA dedicates these fees to expediting the review process for biosimilar biological products. Biosimilar biological products represent an important public health benefit, with the potential to offer life-saving or life-altering benefits at reduced cost to the patient. BsUFA facilitates the development of safe and effective biosimilar products for the American public.

Performance Goals: In exchange for user fees from industry, FDA committed to meeting certain review performance goals 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. FDA review performance goals under BsUFA include:

- FDA review of 70% of original applications for biosimilars within 10 months of receipt and resubmitted applications for biosimilars within 6 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.
- FDA review and action on 90% of original supplements with clinical data within 10 months of receipt, and of resubmitted supplements with clinical data within 6 months of receipt.
- FDA review and action on 90% of manufacturing supplements within 6 months of receipt.
- FDA notification to the applicant of issues identified during the filing review for original biosimilar biological product applications and supplements with clinical data within 74 calendar days from the date of FDA receipt of the original submission.
- FDA notification to the applicant of planned review timelines for original biosimilar biological product applications and supplements with clinical data within 74 calendar days from the date of FDA receipt of the original submission.



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There are many other performance goals for FDA set forth in BsUFA, such as goal timeframes for the review of proprietary names, major dispute resolution, clinical holds, special protocol assessments, and meeting management. Details regarding the BsUFA goals are outlined in the Biosimilar Authorization Performance Goals and Procedures Fiscal Years 2013 through 2017 document.

Fees: BsUFA authorizes the FDA to assess and collect fees for activities in connection with biosimilar biological product development, applications for approval of biosimilar biological products, establishments where such products are manufactured in final dosage form, and biosimilar biological products.

BsUFA includes Biosimilar Biological Product Development (BPD) fees for products in FDA's BPD Program. BPD fees consist of the initial BPD fee, the annual BPD fee, and the reactivation fee. The BPD fee is an annual per-product fee, not a per-meeting or per-review activity fee.

Application and supplement fees, unless waived, are due upon submission of the application or supplement.

The establishment fee is an annual fee for each biosimilar biological product establishment listed in the approved biosimilar biological product application as an establishment that manufactures the biosimilar biological product in final dosage form. Each biosimilar biological product establishment is assessed only one establishment fee per fiscal year, notwithstanding the number of biosimilar biological products manufactured at the establishment. This fee does not apply if the establishment listed in the application does not engage in the manufacture the product during the fiscal year. In addition, if more than one applicant lists the same establishment in a biosimilar biological product application, the establishment fee for the fiscal year is divided equally among the applicants whose biosimilar biological products are manufactured by the establishment during the fiscal year.

Product fees are assessed annually for eligible products. They are assessed on each person who is named as the applicant in an approved biosimilar biological product application.

Fee schedule for fiscal year 2013

Fee Category	Fee Rates for FY 2013
Initial BPD	$195,880
Annual BPD	$195,880
Reactivation	$391,760
Biosimilar Biological Product Applications	
Requiring clinical data	$1,958,800*
Not requiring clinical data	$979,400*
Biosimilar Biological Product Supplement requiring clinical data	$979,400
Biosimilar Biological Product Establishment	$526,500
Biosimilar Biological Product	$98,380

***** If a sponsor that submits a biosimilar biological product application has previously paid initial BPD, annual BPD, or reactivation fees for the product that is the subject of the application, the fee for the application is reduced by the cumulative amount of these previously paid fees.

Specific information about BsUFA and the fees, including when they should be paid, how to pay them, fee amounts, exceptions, waivers, refunds, and penalties is located here and here. For more information about biosimilars, refer to the FDA Biosimilars Webpage.

Until next time,

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