Alerts and Updates

FDA Sends Prescription Drug User Fee Act V to Congress for Reauthorization

January 23, 2012

The Prescription Drug User Fee Act (PDUFA) allows the U.S. Food and Drug Administration (FDA) to collect fees from drug manufacturers to facilitate reviewing their new drug applications. In a statement released January 13, 2012, the FDA said it had completed and transmitted to Congress for reauthorization its recommendation for three user fee programs under the PDUFA "that will help speed safe and effective drugs and lower-cost generic drug and biosimilar biological products to patients."[1] The FDA's recommendations, reached after consultation with drug industry representatives and patient/consumer advocates, are promulgated in the fifth reiteration of the PDUFA, PDUFA V. FDA Commissioner Margaret A. Hamburg, M.D., stated: "These final recommendations offer a great example of what can be achieved when the FDA, industry and other stakeholders work together on the same goal."

PDUFA was enacted by the U.S. Congress in 1992 and must be reauthorized every five years. The current PDUFA IV program will expire on September 30, 2012, unless reauthorized by Congress. PDUFA provides that the FDA is entitled to collect a substantial application fee from a drug manufacturer at the time a New Drug Application (NDA) or a Biologics License Application (BLA) is submitted. In addition, product and establishment fees, set by statute, but adjustable each fiscal year based on inflation and workload, are due annually on October 1. Human drug applications meeting conditions for orphan drug or indication are exempt. The fees collected under the PDUFA are to be used for drug approval activities in the Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER). In return, the FDA commits to meet certain performance benchmarks related to review times and drug launches, thus benefitting drug manufacturers. Since enactment, PDUFA has contributed to the approval of more than 1,200 new medicines.

PDUFA V[2] includes a traditional prescription drug user fee program and two new user fee programs for human generic drugs and for more complex biosimilar biological products that were modeled on the successful PDUFA program "which has ensured a predictable, consistent, and streamlined premarket program for prescription drugs," Hamburg said.

The FDA said it receives 800 to 900 new generic drug-related applications annually. According to the Generic Pharmaceutical Association (GPhA), the FDA has a backlog of more than 2,000 generic drug applications awaiting review. The proposed new Generic Drug User Fee Amendments of 2012 (GDUFA[3]), supported by the GPhA, would help eliminate the review backlog and ensure consumers get timely access to safe, high-quality and effective generic drugs accounting for two-thirds of all U.S. prescriptions. Hamburg said: "At a time of greater budgetary constraint, user fees provide a critical way for leveraging appropriated dollars, ensuring that FDA has the resources needed to conduct reviews in a timely fashion." Similarly, Ralph Neas, CEO of GPhA, said: "This program, as negotiated [between GPhA and the FDA], will result in expedited access to low-cost, high-quality generic drugs for Americans and will further safeguard the quality and accessibility of our nation’s drug supply."

The GDUFA includes provisions for the following fees: (1) a one-time backlog fee, (2) a drug master file fee, (3) a new drug application and prior approval supplemental filing fee and (4) a generic drug facility and active pharmaceutical ingredient facility fee. Starting with fiscal year 2013, the FDA proposes to collect from generic drug manufacturers $299 million in fees annually ($50 million allocated to a one-time backlog fee) to hire additional personnel for reviewing generic drug applications. In return, the FDA will strive to review 90 percent of the generic drug applications within 10 months after submission. Failure to timely pay the GDUFA fees results in stiff penalties under the proposed statutory language. The traditional prescription drug user fee program is expected to provide the FDA with $712.8 million in fees annually, from 2013 to 2017.

The new proposed Biosimilar and Interchangeable Products User Fee program is intended for products approved under new section 351(k) of the Public Health Service Act (PHSA), as amended by the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which, as part of President Obama's healthcare reform law, provides a new abbreviated approval pathway for biosimilar products. A biosimilar is a biological product that is highly similar to a reference biological product, notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product.

The Biosimilar User Fee Act of 2012 (BUFA[4]), negotiated between biopharmaceutical companies, the Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Industry Organization (BIO) and the FDA includes provisions for: (1) a biosimilar development program fee (initial fee and annual fees thereafter), (2) a biosimilar biological product application and supplement fee, (3) a biosimilar biological product establishment fee and (4) a biosimilar biological product fee. Fees will be set by the Secretary in advance of each fiscal year. Under the BUFA, user fees for biosimilar product applications will be comparable to fees imposed by standard BLAs submitted under preexisting section 351(a) of the PHSA. Collected fees will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities. Of particular note, the biosimilar application fee will be waived for a small business submitting its first biosimilar biological product application.

On February 7, 2012, Congress has scheduled a hearing on the new user fee programs for generic drugs and biosimilars. BIO President and CEO Jim Greenwood urged Congress to promptly reauthorize the PDUFA and said in a statement:

BIO strongly supports the PDUFA V recommendations as they will enhance the drug development and review process through increased transparency and scientific dialogue, advance regulatory science, and strengthen post-market surveillance. Most importantly, PDUFA V will provide patients and doctors with earlier access to innovative new therapies.

It is expected that Congress will quickly reauthorize PDUFA V. Meanwhile, the FDA is working on the completion of the much-anticipated guidelines addressing scientific and regulatory requirements for biosimilar approval and providing the biosimilar manufactures a clear framework to pursue the abbreviated biosimilar pathway for bringing biosimilars to market.

For Further Information

If you have any questions about this *Alert*, please contact Siegfried J.W. Ruppert, Ph.D.; Vicki G. Norton, Ph.D.; Lee Crews, Ph.D.; L. Norwood "Woody" Jameson; any member of the Intellectual Property: Generic Pharmaceuticals Practice Group; or the attorney in the firm with whom you are regularly in contact.

Notes

1. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm287723.htm.
2. http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM287747.pdf.
3. http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM287735.pdf.
4. http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM287749.pdf.