User fees, biosimilars on FDA priority list for 2016

By Erica Cribbs, Gretchen Harper and April Schweitzer

The U.S. Food and Drug Administration’s (FDA’s) Center for Drug Evaluation and Research (CDER) director, Janet Woodcock, outlined the agency’s priorities for the coming year at the FDA/Centers for Medicare and Medicaid (CMS) Summit for Biopharma Executives on December 14–15. CDER, a sub-agency within the larger purview of the FDA, regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs, thereby ensuring that safe and effective drugs are available to improve the health of the U.S. population.

User fees

Along with its daily operations, CDER plans to prioritize significant projects in 2016, including negotiating the sixth re-authorization of the Prescription Drug User Fee Act (PDUFA), continuing to streamline the process for new drug applications and implementing its biosimilars program.

CDER plans to undergo negotiations with industry stakeholders in order to reauthorize the PDUFA, which is set to expire in September 2017. The PDUFA, as initially passed in 1992, set out to reform the drug review process and to speed the delivery of new drugs to consumers, while preserving the FDA’s high standards related to quality and safety. Under the PDUFA, drug-makers are required to allocate extra financial resources, or user fees, in order to supplement congressional appropriations to the FDA. The user fees are then used in conjunction with the appropriations money to help fund and accelerate the FDA’s drug-approval process. As part of the upcoming reauthorization process, the FDA (through CDER) must engage in negotiations with drug-makers and industry stakeholders and agree to certain performance goals to enhance the drug review process.

Biosimilars

As drug costs continue to soar, there is a pressing need to cut costs and expand patient access to expensive treatments. Pursuant to the Affordable Care Act, FDA has authority (through CDER) to

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1 Inst. for Int'l Research, IIR USA, *FDA/CMS Summit for Biopharma Executives* (last visited December 23, 2015).

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approve imitations of biological products, including biosimilars.\textsuperscript{4} A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an already-approved biological product, or a reference product.

The FDA implemented its biosimilars program earlier this year to establish a pathway for the clinical approval of drugs that may be lower in cost than their brand-name counterparts. CDER approved the first biosimilar drug in March and issued draft guidance on nonproprietary naming in August.\textsuperscript{5} The draft guidance proposes that reference products and biosimilars have nonproprietary names that share a core drug substance name and an FDA-designated suffix that is unique for each product.\textsuperscript{6} The agency stated that it has received numerous comments on its draft guidance as questions remain from stakeholders concerning the biosimilars program. CDER plans to issue further guidance and regulations in 2016 in order to clarify the program and continue its success.

**Sentinel network**

In 2007, Congress passed the FDA Amendments Act mandating the FDA to establish an active surveillance system for monitoring drugs, using electronic data. The Sentinel Initiative is the FDA’s response to such mandate. The goal of the Sentinel Initiative is to create and implement a surveillance system that will ultimately be used to monitor all FDA-regulated products. Developing a sustainable system has led to many questions of significant public interest, including issues regarding governance, privacy, data standards and public availability of results. In 2016, CDER plans to work to integrate the Sentinel Network into routine drug safety activities.

Other initiatives that CDER has planned for 2016 include the following:

- Reevaluate regulations on drug advertising in light of current First Amendment jurisprudence;
- Issue draft guidance on generic versions of abuse-deterrent opioid formulations;
- Continue drug label improvement initiatives;
- Streamline clinical trial monitoring and data cleaning practices;
- Continue to implement statutory provisions on track and trace legislation; and
- Continue to push standards development and standardized electronic submissions to CDER and utilize electronic health data.\textsuperscript{7}

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\textsuperscript{4} U.S. Food & Drug Admin., \textit{Biosimilars} (last visited December 23, 2015).
\textsuperscript{6} Id.
\textsuperscript{7} Regulatory Affairs Professionals Society, \textit{CDER’s Woodcock Outlines Priorities for 2016} (last visited Dec. 22, 2015).