FDA/CDER SBIA CHRONICLES
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GDUFA – Where Are We Now?

Since the implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA), the Office of Generic Drugs (OGD) has been busy! OGD received a record of 225 original abbreviated new drug applications (ANDAs) in December 2012, up more than 25% from the previous month. On top of this were 143 original amendments and 266 amendments to supplements.

GDUFA enables FDA to administer critical and measurable enhancements to the performance of the human generic drugs program and bring greater predictability and timeliness to the review of human generic drug applications.

GDUFA had some challenging goals when it was first introduced in September 2012. By September 30, 2017, GDUFA requires FDA to review and act on 90 percent of complete electronic original generic applications within 10 months after the date of submission. Let's take a look at how we are measuring up.

The FY 2013 GDUFA Performance Report to the President and Congress, which covers the period of October 1, 2012 through September 30, 2013, presents FDA's accomplishments for the first year of GDUFA and expectations for the future. As outlined in the GDUFA Performance Report, FDA has met all GDUFA program commitments for FY2013. FDA has:

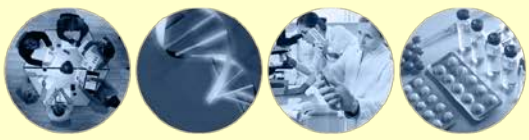
- Hired 291 employees (31% of the anticipated GDUFA program staff), exceeding the FY 2013 performance goal
- Implemented a number of improvements designed to enhance the efficiency of the review process and improve the quality of human generic drug submissions:
    - Published criteria for Type II active pharmaceutical ingredient (API) drug master file (DMF) completeness assessments (CA) and enhanced refuse-to-receive (RTR) standards to clarify FDA requirements for complete applications
    - Received over 1,500 DMFs requiring CAs; more than double the expected volume of 700
    - Launched a public list containing more than 1,000 Type II API DMFs that passed the CA and are available for reference
    - Issued more than 1,500 complete response (CR) letters reflecting full division-level review of deficiencies
    - Instituted routine policy on communicating easily-correctable deficiencies

Facilitated industry self-identification efforts, enabling fee calculation and improving the quality of generic industry supply chain information.

Engaged in outreach efforts to educate and inform industry participants and other stakeholders about GDUFA

Awarded $17 million in grants to advance FY 2013 regulatory science priorities, and developed FY 2014 regulatory science priorities based on significant input from stakeholders

- Built new information technology systems and expanded on existing systems and technology investments to promote efficiency, monitor human generic drug safety and efficacy, and streamline the human generic drug approval process



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- Made significant progress towards meeting the backlog requirement for pre-GDUFA applications pending on October 1, 2012. Of the 2,866 abbreviated new drug applications (ANDAs) and 1,882 prior approval supplements (PASs) pending on October 1, 2012, 868 and 752, respectively, received a first action (approval, tentative approval, CR, refusal to file (RTF), or withdrawal) as of September 30, 2013.

As outlined in the GDUFA Performance Report, FDA has met all GDUFA program commitments for FY2013

The Backlog: When GDUFA was implemented on October 1, 2012, there were a large number of generic applications that had been submitted to OGD, but had not been approved or received a tentative approval. "Backlog" refers to the pending ANDAs, ANDA amendments and ANDA PASs that had not received a minimum of a tentative approval as of October 1, 2012. One of GDUFA's goals is to review and act on 90% of this backlog by the end of FY 2017. In other words, GDUFA wants to reduce the backlog in the OGD.

OGD has made significant progress reducing the ANDA backlog and at the current rate, will reach 5-year GDUFA goals way ahead of schedule. At the end of FY 2013, the first year under which FDA has been subject to GDUFA guidelines, OGD took action on approximately 34% of backlogged ANDAs. These actions include full approvals, tentative approvals, withdrawals, refuse-to-receives and complete responses. As of Jan. 24, 2014, OGD has increased that number to nearly 45%, leaving a little more than 2,600 submissions awaiting action.

As OGD takes more actions on applications, the number of backlog applications requiring a first action will decrease. In December alone, OGD completed 174 actions, including 30 full approvals for generic drug products. For those of you that like numbers, we have posted monthly GDUFA stats on our website.

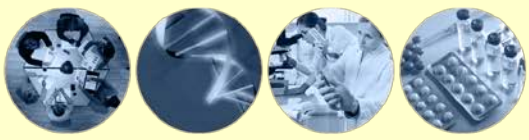
You may also find a whole lot of information on GDUFA in the presentations for our first *GDUFA and You Conference* from last year. Check out the sidebar for information on our upcoming conference on March 27/28th in Orlando, FL. Don't miss this great opportunity – it's not too late to register!

Improving the Quality of ANDA Submissions: FDA is establishing a public docket to receive input and suggestions from the public on ways to improve the quality of ANDAs and associated amendments and supplements. Specifically, FDA is interested in hearing about difficulties sponsors are having developing and preparing their ANDA submissions. FDA is also seeking input on how to best share suggestions for improving the quality of ANDAs with the generic drug industry. Improving the quality of ANDA submissions will result in more submissions accepted for filing, fewer amendments and easily correctable deficiencies (ECDs), and ultimately, more generic drug approvals.

FDA welcomes comments at any time, but we encourage submission of electronic or written comments to http://www.regulations.gov or the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 by March 24, 2014.

Happy Spring!
Renu Lal, Pharm.D.
CDER Small Business Assistance

Issues of this newsletter are archived at http://www.fda.gov/cdersmallbusinesschronicles



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