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FDA also required a first submission of “self-identification” by December 3, 2012. That included facilities that are required to pay fees, such as active pharmaceutical ingredient (API) facilities, but also covered other categories, such as “Bioequivalence (BE)/bioavailability (BA) sites that are identified in a generic drug submission and conduct clinical BE/BA testing, and/or in vitro BE testing.” These sites are not currently subject to FDUFA facility fees; one can only speculate the reasons for this is that these sites may become targets for facility fees in the future.

Other fees were established and increased in the current fiscal year as follows:

	FY 2013	FY 2014
DMF Fee:	\$21,340	\$31,460
ANDA Fee:	\$51,520	\$63,860
PAS Fee:	\$25,760	\$31,930
Domestic FDF facility:	\$175,389	\$220,152
Foreign FDF facility:	\$190,389	\$235,152
Domestic API facility:	\$26,458	\$34,515
Foreign API facility:	\$41,458	\$49,515

Foreign facility fee differential: \$15,000

An early consequence was the inclusion on an arrears list and bills received from FDA to firms that did not believe they were subject to these provisions since they were not involved. In some cases, FDA had been informed that the location was a “potential” site to be used in an ANDA, although the sponsor had not contracted for the actual use of the facility, since they were unaware they had been identified by a potential customer and were very unhappy to be billed for the privilege.

FDA’s intent to enforce these provisions was shown in a Warning Letter issued to C.P.M. Contract Pharma GMBH & Co. in Feldkirchen-Westerham, Germany on September 1, 2012. On the publicly available arrears list, the letter noted:

“Failure to correct these violations promptly may result in regulatory action, including but not limited to seizure or injunction without further notice. Your facility may also be placed on the list of facilities that manufacture drugs that are refused admission into the United States.”

Generic manufacturers have also seen an increase of FDA inspections, particularly overseas, funded by FDUFA. These have been followed by compliance actions, including Warning Letters.

Finally, an unintended problem facing those subject to FDUFA (as well as the other user fees) is that the Office of Management and Budget has determined that the user fees are subject to the same sequestration rules that cut FDA appropriations. So industry is now paying fees that are not available to the agency, which must still try and meet the goals agreed to in negotiations. These programs are popular with both parties, and it is hoped that a legislative fix will emerge.

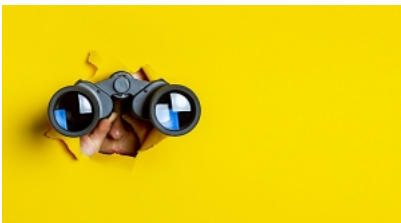
All of the user fee programs have included a “sunset” provision that requires reenactment every five years. Contract manufacturers and others that may not have been active participants would be wise to participate when the process for renewal begins. **CP**

Mark Elengold
FDA Strategies

Mark Elengold is president of FDA Strategies LLC. He served as the Deputy Director of the FDA’s Center for Biologics Evaluation and Research until his retirement in 2005, and is now a frequent speaker on regulatory and compliance activities, Good Manufacturing Practices (GMPs), and FDA application review procedures, including electronic submissions. He can be reached at mark@fdastrategies.com.



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