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User Fees for Generic Drugs - What are the Issues?

By Peter S. Reichertz

On August 9, 2010, the Food and Drug Administration ("FDA") published a notice announcing a public meeting to be held September 17, 2010, "to gather stakeholder input on the development of a generic drug user fee program." *See* 75 Fed. Reg. 47,820-21. FDA also requested submission of written comments on issues relating to assessment of user fees for generic drugs, which can be submitted by no later than October 17, 2010.

While FDA acknowledged most "[n]ew legislation would be required" for it to establish and collect user fees, the Obama Administration has already included generic drug user fees in its fiscal 2011 budget. So the possibility for assessment of user fees for generic drugs seems to be greater than in the past, as it is the only other major type of medical product that is subject to an FDA approval process for which user fees are not currently assessed.

FDA has identified the issues as follows:

1. How, if at all, should a generic drug user fee program differ from FDA's existing user fee programs, including the Prescription Drug User Fee Act ("PDUFA"), the Animal Drug User Fee Act ("ADUFA"), the Medical Device User Fee and Modernization Act ("MDUFMA") and Tobacco Product User Fees?

2. What should a generic drug user fee program look like or how should a generic user fee be structured? (User fees for brand name drugs include a one-time fee for a new drug application and annual fees for marketed products and facilities at which these products are produced. Should the generic drug fees follow the same structure? If not, what are the unique aspects of the generic drug industry or market that should be considered and how might these impact a proposed user fee plan?).

3. Are performance goals recommended for FDA. If so, what performance goals would you recommend for FDA? If not, why not?

4. Should all applications pay the same fees and be subject to the same goals? (For example, should applications for more complex products pay a higher application fee to reflect the

additional regulatory efforts they entail? Should such differences be captured through differential goals?)

5. Including applications for which exclusivities would prevent current marketing, and applications that are awaiting responses from sponsors for noted deficiencies, there is a current queue of over 2,000 applications under review, and approximately 800 new applications submitted each year. How should a generic drug user fee program address applications currently awaiting FDA review?

6. PDUFA currently supports oversight of post-marketing safety of drugs. What kind of support, if any, should a generic user fee provide for post-marketing safety?

So what are some of the other specific issues most generic drug user fees raise? A few issues, among many, stand out.

Many Abbreviated New Drug Applications ("ANDAs") for generic drug products contain bioequivalence ("BE") data; others do not (for example, certain oral dosage form drugs rated AA by FDA and many injectable drugs). Given that no bioequivalence data are needed for review of these products, should not such ANDA's be subject to a reduced user fee as opposed to those that contain BE data?

In addition, as opposed to the NDA process, FDA usually requires a separate ANDA for each dosage strength of a product. Since much of the data is common in such applications, should not FDA either be forced to change its rules to allow bundling of dosage strengths in one application or to provide for reduced user fees where a ANDA applicant submits several ANDA's for different dosage strengths of the same product? (FDA bundles dosage strengths in full NDAs).

Furthermore, ANDA's differ in complexity in other ways. As the recent approval of a generic of LOVENOX shows, FDA may require significant additional data beyond a simple BE study and CMC data to obtain approval of an ANDA of a complex drug product. Should not ANDA's for such products, which obviously take significantly more review time, be subject to additional user fees?

What about supplements? While FDA cites the queue of 2,000 ANDA applications under review, it says nothing about the enormous backlog of supplements. Should FDA charge user fees to expedite the review of ANDA supplements? Should the fees be determined based on the type and complexity of the supplement? A supplement for a change in labeling may involve insignificant review time, while one making a Chemistry Manufacturing Controls ("CMC") change may require significant resources.

With NDA products, FDA charges annual product fees. For fiscal 2011, the annual product fee for an NDA product will be $86,520. In addition, every establishment manufacturing an NDA product must pay an establishment fee, which in fiscal 2011 will be $497,200. (See 75 Fed. Reg. 49,952-57, August 4, 2010). Sales of many generic drugs would not be sufficient to make it economically worthwhile to market or obtain approval of a generic product if similar fees were charged for generic drug manufacturing establishments and for products. Sales of generic drug

products can vary greatly from manufacturer to manufacturer. Is charging the same user fee for a company that has 1% of the market fair when another manufacturer has over 50% of the market? Should generic drug annual fees – if assessed - be based on sales, rather than a figure divided equally among manufacturers? If not, the policy could actually decrease competition in the generic drug market, and lead to higher prices. In addition, what if an ANDA is approved but the product is not marketed? Should such an ANDA applicant be charged an annual product fee?

On the issue of what to do regarding currently pending applications, it seems unfair to charge for review of applications that have been tentatively approved and are awaiting approval following expiration of patent or market exclusivity. With regard to other pending ANDAs, should not those applicants be given an option as to whether their applications should be charged a user fee and given priority in review? If a company knows it is not a first filer and another generic product or products will have 180 days exclusivity, it may not be worth it to that later filing applicant to pay a user fee.

And, as to performance goals, one questions why the performance goals for ANDA products should be any different from those for NDA products, given the requirement in the Federal Food Drug and Cosmetic Act that FDA review applications in 180 days.

These are but some of the issues of the real issues facing the generic drug industry as user fee are considered.

Interested persons may submit either electronic or written comments to FDA by October 17, 2010 Written comments may be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, or one can submit electronic comments to http://www.regulations.gov.

Authored By:

Peter S. Reichertz
(202) 772-5333
preichertz@sheppardmullin.com