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Client Alert

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Generic Drug User Fees and Why People Care?

For the past year, the Food and Drug Administration (FDA) has been seeking stakeholder input, from both the public and pharmaceutical industry itself, on establishing a generic drug user fee program, similar to the other user fee programs that currently exist for prescription drugs, medical devices, tobacco products and animal drugs. The agency itself has reported problems with a backlog of generic drug applications due to scarce resources at the agency level and increasing budgetary constraints. The supplementary revenues from a new generic drug user fee program would undoubtedly allow the FDA to hire additional staff and improve the process for generic drug application review.

Although statistics suggest that more than two-thirds of all prescriptions dispensed in the United States are for generic drugs, the median time for review of a generic drug application has increased, slowing down the process for bringing new generic drug products to market. Several larger generic companies have supported a user fee program, noting that the generic drug industry can only benefit from paying such fees in order to provide the resources that FDA needs to prevent further delays in the generic drug application review process. More timely review will ensure that a greater number of generic products can make it to market for consumers.

Although the establishment of any new user fee program will require new legislation and congressional action, the FDA will certainly play a part in outlining the scope and structure of any generic drug user fee program to be developed. As part of the consideration of the implementation of such a fee program, the agency in its September 17, 2010, public meeting notice on the subject asked for comment on the following questions:

1. How, if at all, should a generic drug user fee program differ from the existing user fee programs?

2. How should the generic user fee program be structured (i.e., as a one-time fee for a new generic drug application and annual fees for marketed products and facilities), and should any unique characteristics of the generic drug market be considered in developing a user fee program?

3. Should the FDA have performance goals, and if so, what should be the performance goals?

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4. Should user fees be the same across the board or should they vary (i.e., based on the complexity of the generic drug application or the agency resources required for such review)?

5. Should all applications be subject to the same goals?

6. How should any user fee program developed address applications currently awaiting FDA review?

7. What kind of support, if any, should a generic user fee provide for post-marketing safety?

As part of the growing national interest in reducing medical costs, increased access to generic drugs will likely play a large role by providing consumers with options for cost-efficient care. The FDA indicates that it will work with generic drug makers to develop fees that are fair, but that will ensure more timely review and approval of generic drug applications.

Many factors will drive this process. Both the FDA and the industry are vested in streamlining the user fee program. Answering the questions posed at the September 17, 2010, meeting will take much give-and-take between the industry and the FDA, but again, both sides have common interests in having this process work to ensure an efficient and fair fee system is in place as soon as possible.