ALERTS AND UPDATES

FDA Announces Draft Guidance for Industry on User Fee Waivers, Reductions and Refunds for Drug and Biological Products

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The U.S. Food and Drug Administration (FDA) announced in the *Federal Register* on March 14, 2011, the availability of a "Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products" (the "Draft Guidance"). Comments on the Draft Guidance may be submitted through June 13, 2011.

Revising the FDA's 1993 draft interim guidance on waivers of and reductions in user fees, the Draft Guidance addresses requests for waivers, refunds and reductions of user fees under sections 735 and 736 of the Food, Drug, and Cosmetic Act (FD&C Act). These provisions allow the FDA to levy application fees on certain human drug and biological product applications or supplements. Annual product or establishment fees may also be imposed for certain approved drugs, approved biological products or facilities in which those products are made.

The Draft Guidance describes the types of waivers and reductions, as well as the eligibility criteria and procedures for applying for a waiver or reduction. Waivers are available if the waiver or reduction is necessary to protect the public health, the assessment of the fee presents a significant barrier to innovation, or the applicant is a small business submitting its first human drug application. Although waivers or reductions may also be available if the fees imposed exceed the costs of conducting the human drug-application process, that type of waiver is not addressed in the Draft Guidance.

The Draft Guidance also identifies several products that are exempt from fees, including orphan designated products; applications by state or federal agencies for drugs that are not distributed commercially; or applications or supplements withdrawn before any substantial work is performed on the application or supplement. Finally, the Draft Guidance describes the procedure for submitting requests for waivers, reductions and refunds. Requests for waivers or reductions—for application, product or establishment fees—must be submitted no later than 180 calendar days after the fee is due, and they may be submitted in advance to avoid having to pay the fee. The FDA recommends that advance requests should be submitted three to four months before submission of the application or before the product and establishment fees are due.

For Further Information

If you have any questions about this *Alert*, please contact Frederick (Rick) R. Ball, any member of the Pharmaceutical, Pharmacy & Food industry group or the attorney in the firm with whom you are regularly in contact.