Alerts and Updates

FDA DRAFTS PHARMA INDUSTRY GUIDANCE FOR POSTMARKETING STUDIES AND CLINICAL TRIALS

April 14, 2011

The U.S. Food and Drug Administration (FDA) announced in the *Federal Register* on April 1, 2011, the availability of a Draft Guidance for Industry titled "Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act" (the "Draft Guidance"). Comments on the Draft Guidance may be submitted at any time.

The Draft Guidance addresses the implementation of section 505(o)(3) of the federal Food, Drug, and Cosmetic Act (the "FD&C Act"), added by section 901 of the Food and Drug Administration Amendments Act of 2007. Section 505(o)(3) authorizes the FDA to require postmarketing studies and clinical trials for prescription drugs approved under the FD&C Act and biological products approved under the Public Health Service Act, either at the time of approval or postapproval if the FDA becomes aware of new safety information. "New safety information" is defined to include information about a serious risk or unexpected serious risk associated with the use of the drug, or the effectiveness of the approved risk evaluation and mitigation strategy for the drug since the last assessment.

The Draft Guidance states that the FDA will require a postmarketing study or clinical trial when the decision to require such study or trial is based on appropriate scientific data and where adverse-event reporting (for postmarketing studies) or a postmarketing study (for clinical trials) would be insufficient to meet one of the purposes for either. Under section 505(o)(3)(B), the purposes for a postmarketing study or clinical trial may be:

1. to assess a known serious risk related to the use of the drug;

2. to assess signals of serious risk related to the use of the drug; or
3. to identify an unexpected serious risk when available data indicate a potentially serious risk.

If these conditions are met, a postmarketing study or clinical trial may be required as a postmarketing requirement, and the FDA may describe the study or trial, including how it will be conducted, the population and the indication. The FDA may also require a postmarketing study or clinical trial if it becomes aware of a risk and believes it is serious, but requires additional knowledge to determine the appropriate response to the risk. Applicants may appeal the imposition of a postmarketing study or clinical trial through the dispute resolution procedures that are described in the "Guidance for Industry Formal Dispute Resolution: Appeals Above the Division Level."

The Draft Guidance also identifies the reporting requirements under section 505(o)(3). An applicant is required to provide a timetable for completion for the postmarketing study or clinical trial, periodic reports on the status of the postmarketing study or clinical trial, and each postmarketing study or clinical trial that is "otherwise undertaken by the applicant to investigate a safety issue." Applicants may already be submitting such reports under existing regulations. Failure to comply with the reporting requirements and other requirements of section 505(o)(3)(E)(ii), however, may result in enforcement action, unless the applicant can show good cause.

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.