[Alerts and Updates]

FDA Issues Draft Guidance Regarding the Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications

April 17, 2009

On April 17, 2009, the FDA issued a Draft Guidance for Industry titled *Submission of Summary Bioequivalence Data for ANDAs*. The draft guidance provides information for applicants submitting bioequivalence studies. The draft guidance is pursuant to the FDA's January 16, 2009, final rule that required an Abbreviated New Drug Application ("ANDA") applicant to submit data from all bioequivalence studies the applicant conducted on a drug product formulation submitted for approval. The submissions must include studies that demonstrate and studies that fail to demonstrate that a generic product meets the current bioequivalence criteria.

The April 17 draft guidance includes information on the following subjects:

- The types of ANDA submissions covered by the new regulations on bioequivalence studies;
- A recommended format for summary reports of bioequivalence studies; and
- What formulations FDA considers the "same drug product formulation."

The draft guidance applies to bioequivalence studies conducted for ANDAs during both pre-approval and post-approval periods. FDA seeks comments on the draft guidance.

For Further Information

If you have questions concerning this draft guidance or would like more information, please contact Frederick R. Ball, any of the other health law lawyers in the Pharmaceutical & Biotechnology industry group or the attorney in the firm with whom you are regularly in contact.