ALERTS AND UPDATES

FDA Issues Draft Guidance for Industry Tablet Scoring

September 2, 2011

On August 31, 2011, the U.S. Food and Drug Administration ("FDA") issued a draft guidance for sponsors of new drug applications ("NDAs") and abbreviated new drug applications ("ANDAs") providing criteria for evaluating and labeling of tablets that have been scored. The FDA considers tablet scoring when determining whether a generic drug product is the same as the reference listed drug ("RLD"). Patients often use scoring to facilitate the splitting of a tablet into fractions when less than a full tablet is the desired dose. The Center for Drug Evaluation and Research's (CDER) Drug Safety Oversight Board considered the practice of tablet-splitting, and the FDA conducted internal research on splitting. The FDA then issued the draft guidance's guidelines and criteria to help ensure safety and effectiveness in drug products that are scored and subsequently split. The guidance includes requirements that the dosage amount after splitting not be below the minimum therapeutic dose, recommendations regarding post splitting safety, recommendations related to modified release products, stability requirements post-splitting, risk assessment testing and patient population testing. It recommends that scoring for generic product by the same as the RLD. Finally, it includes criteria for the label and labeling.

For Further Information

If you have any questions concerning this draft guidance, please contact Frederick R. Ball, any other member of the Pharmaceutical, Pharmacy and Food industry group or the attorney in the firm with whom you are regularly in contact.