Alerts and Updates

FDA EXTENDS COMMENT PERIOD FOR STRATEGIES TO ADDRESS ANIMAL DRUG PRODUCTS MARKETED IN THE U.S. WITHOUT APPROVAL

February 23, 2011

On December 20, 2010, the U.S. Food and Drug Administration (FDA) issued a notice in the *Federal Register* that indicated its concern about the safety and effectiveness of marketed animal drug products that do not have approval or other legal marketing status. In general, the FDA stated these types of unapproved animal drugs included, but were not limited to,
"[i]njectible vitamins; various topical solutions; shampoos, and liniments; electrolyte and glucose solutions, and antidotes." The FDA included anti-effective and other animal drug products marketed in the United States that do not have approval or other legal marketing status.

The FDA sought comment because it recognized that a significant number of unapproved animal drug products were being used to treat animals. In particular, the agency requested comment on how to expand approval of marketed animal drug products, including the use of monographs and the use of publicly available information for approval.

On February 18, 2011, the FDA extended the comment period to April 19, 2011.

For Further Information

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