ALERTS AND UPDATES

FDA's Interim Final Rules for the Food Safety Modernization Act

May 6, 2011

The U.S. Food and Drug Administration (FDA) issued two interim final rules, published in the *Federal Register* on May 5, 2011. The first rule implements section 207 of the Food Safety Modernization Act (FSMA) related to the criteria for ordering administrative detention of human or animal food. The second implements section 304 of the FSMA related to additional requirements under the prior notice of import of food. Both interim final rules have an effective date of July 3, 2011.

The first rule, "Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption," implements section 207 of the FSMA. Under the new rule, FDA can order administrative detention "if there is reason to believe that an article of food is adulterated or misbranded" for 20 calendar days with a possible 10-calendar-day extension. FDA did not define "reason to believe," but stated the decision would be made on a case-by-case basis. FDA anticipates it is more likely to use administrative detention under the new rule because the old rule required an FDA officer or qualified employee to find "credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals." FDA has stated that it anticipates situations of detention under the new rule would be analogous to the situations in which the FDA would order a Class II recall. The FDA has requested comments and has stated that interested parties have 90 days in order to provide their comments on this interim final rule.

On the same day, FDA issued a second interim final rule and request for comments related to its regulations on prior notice of imported food. This interim final rule implemented section 304 of the FSMA and now requires a person submitting prior notice of imported food for animals to report "any country to which the article of food has been refused entry." This interim rule is also effective on July 3, 2011. FDA has allowed 30 days for persons to submit comments on this interim final rule.

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.