ALERTS AND UPDATES

New FDA Guidance for Industry on Implementation of Fee Provisions of the Food Safety Modernization Act

October 11, 2011

> **The new guidance covers commonly asked questions related to the implementation of these fees under the FSMA and also provides information on the process for requesting a reduction of fees assessed in fiscal year 2012.**

On October 6, 2011, the U.S. Food and Drug Administration (FDA) announced in the *Federal Register* its issuance of a question-and-answer guidance document related to the implementation of the fee provisions of the Food Safety Modernization Act of 2011 (FSMA). This follows up on the August 1, 2011, publication of the fee rates for fiscal year 2012 for domestic and foreign facility reinspections, recall orders and import reinspections under the FSMA.

For background, the FSMA provides the FDA with the authority to assess and collect fees from, among others:

- The responsible party for a domestic or foreign facility subject to reinspection;
- The responsible party for a domestic facility or importer who fails to comply with the recall order; and
- An importer subject to a reinspection to cover reinspection-related costs.

The new guidance covers commonly asked questions related to the implementation of these fees under the FSMA. For example, the guidance provides information related to what would trigger the facility reinspection fee—*i.e.*, a reinspection to determine corrective actions following an FDA inspection that was classified by FDA as "Official Action Indicated" and FDA determined the noncompliance was materially related to food safety. In addition, it provides examples of what the FDA would consider "noncompliance materially related to food safety" (*e.g.*, food-borne pathogens in ready-to-eat products, pesticide residues on food or feed product above tolerance levels, failure to declare a major allergen in labeling, or the lack of adequate hazard controls for seafood or juice). In addition, the guidance also provides information on the process for requesting a reduction of fees assessed in fiscal year 2012.[1]

For Further Information

If you have any questions concerning this *Alert*, please contact Frederick R. Ball, any other lawyer in the Pharmaceutical, Pharmacy & Food industry group or the Duane Morris attorney with whom you are regularly in contact.

Note

1. We note that fiscal year 2012 begins on October 1, 2011, and while the FDA will begin to assess fees at that point, it will not invoice for such fees until January 1, 2012.