Alerts and Updates

FDA Issues Draft Guidance for Notification of Issues That May Result in Prescription Drug Shortage

March 1, 2012

FDA identified potential issues that may lead to a shortage of prescription drug and biologic products or a disruption in the supply, and is seeking comment on its draft guidance by May 29, 2012.

On February 27, 2012, the U.S. Food and Drug Administration (FDA) issued a draft guidance encouraging manufacturers of prescription drug and biologic products to voluntary notify FDA of issues that may result in a shortage of the product in the U.S. market or potential disruption in the supply. The FDA identified potential issues that may lead to a shortage or disruption, including:

- Product quality problems;
- Interruptions or adjustments in manufacturing;
- Delays in acquiring critical raw materials or components;
- Transfer of manufacturing to an alternative facility;
- Loss of production line or production capacity;
- Production problems that occur during or after manufacturing that can result in supply disruptions;
- Import delays;
- Unexpected increases in demand; and
- Product discontinuances.

FDA is seeking comment on the draft guidance by May 29, 2012.

For Further Information

If you have any questions concerning this *Alert*, please contact Frederick R. Ball, any other attorney in the Pharmaceutical, Pharmacy and Food industry group or the attorney in the firm with whom you regularly work.