FDA Issues Notice of Secure Supply Chain Pilot Program

January 21, 2009

On January 15, 2009, the FDA issued a proposal for a secure supply chain pilot program. The FDA is seeking written comments no later than March 16, 2009. The secure supply chain pilot program provides for up to 100 applicants to participate in a streamlined importation process for holders of new drug applications ("NDAs"), abbreviated new drug applications ("ANDA") or foreign manufacturers of imported active pharmaceutical ingredients ("API"). The applicant must either have a pending application or be certified with the U.S. Customs and Border Protection's Customs – Trade Partnership Against Terrorism ("CTPAT") Tier II certified secure supply chain. The application must have a sufficient plan for recalling finished products or APIs that do not meet requirements of the FDA or other applicable law. The pilot program has certain recordkeeping requirements.

For Further Information

If you would like more information concerning this secure supply chain pilot program, please contact Frederick R. Ball, any of the other health law lawyers in the Pharmaceutical & Biotechnology industry group or the attorney in the firm with whom you are regularly in contact.