ALERTS AND UPDATES

FDA Issues Proposed Rule Regarding Citizen Petitions and PSAs Related to Section 505(b)(2) Applications or ANDAs

January 4, 2012

As part of the Food and Drug Administration Amendments Act of 2007 (FDAAA) enacted on September 27, 2007, Congress added Section 505(q) to the federal Food, Drug and Cosmetic Act (FDCA) (21 U.S.C. § 355(q)). Section 505(q) applied to certain citizen petitions and petitions for stay of action (PSAs) related to applications submitted under Section 505(b)(2) of the FDCA or an application submitted under Section 505(j) of the FDCA for a generic drug product. Congress enacted Section 505(q) because it believed that the citizen petition process and PSAs were being used to delay approval of generic products. The FDA has now promulgated a proposed rule clarifying how it will implement the Section 505(q) requirements. Highlights of this proposed rule include:

- FDA will calculate the data on which a citizen petitioner or PSA is submitted to FDA as the date that the Division of Dockets Management receives either the citizen petition or the PSA. That is the date on which the 180-day requirement for final action by FDA will begin to run; and

- Rules covering implementation of the certification requirements contained in Section 505(q). In essence, FDA is requiring that persons who submit citizen petitions or PSAs use the exact language contained in the proposed new rule for the required certification and include specific dates for when that person gathered the information explaining its position within the citizen petition or PSA. The FDA is also requiring that PSAs include similar certifications.

The provisions in the proposed rule should be positive developments for the generic drug industry, which has seen innovators attempt to use the citizen petition and PSA process to delay generic entry into the marketplace.

Comments are due to the FDA within 90 days of the date of publication in the *Federal Register*.

For Further Information

If you have any questions or comments, 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.