

E-ALERT | Food & Drug

June 25, 2013

COURT ESTABLISHES DEADLINES FOR FDA TO COMPLETE RULEMAKING REQUIRED BY THE FSMA

On June 21, 2013, the U.S. District Court for the Northern District of California issued an [order](#) establishing deadlines for FDA to complete the rulemaking required by the FDA Food Safety Modernization Act (“FSMA”). This order stems from the suit filed against FDA by the Center for Food Safety and the Center for Environmental Health in August of 2012 in an attempt to force the agency to implement long-delayed provisions of the FSMA. In April of 2013, the court agreed that the agency violated the law by failing to meet the deadlines set forth by Congress and instructed the parties to work together and create a satisfactory timetable. The parties failed to reach consensus on new deadlines and submitted competing proposals.

The court rejected FDA’s proposal of “target timeframes” with submission of final rules ranging from 15 to 21 months after close of the respective comment periods as “inadequate.” The court also rejected the Center for Food Safety’s proposal, with May 1, 2014 as the latest date for submission of the final rules, as “overly restrictive in light of the FDA’s showing of the complexity of the task.”

The court order establishes the following deadlines:

- FDA must publish all outstanding proposed regulations by **November 30, 2013**. These include the proposals for the Foreign Supplier Verification Program, Accreditation of Third Party Auditors, Preventive Controls for Animal Foods, Intentional Contamination, and Sanitary Transport of Food and Feed.
- For each proposal, the close of the comment period must be no later than **March 31, 2014**.
- All final regulations must be published in the Federal Register no later than **June 30, 2015**.

The court noted that, other than these deadlines, FDA has the discretion to prioritize other matters relating to the rulemaking process.

Covington & Burling LLP continues to monitor FDA’s implementation of the FSMA and will keep its clients updated regarding developments and next steps.

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