

## ALERTS

### Court Orders FDA To Complete FSMA Rules By June 30, 2015

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In April, one of our Alerts noted that the Food Safety Modernization Act (FSMA) contained a requirement for the FDA to issue within eighteen months regulations in several areas related to food safety, including produce safety, good manufacturing practices (GMPs), foreign supplier verification programs, preventive controls for animal food, and accreditation of third party auditors and that the FDA has missed this statutory deadline. In January of this year (two years after FSMA's enactment), the agency released proposed produce safety and GMP rules, but no others.

We further noted that on April 22, the U.S. District Court for the Northern District of California had entered an Order finding that the FDA had violated FSMA by not having promulgated the regulations within the statutory deadline. The court ordered the parties, which include FDA and two public interest groups, the Center for Food Safety and the Center for Environmental Health, to meet and confer on a proposed schedule for the regulations and to submit the proposed schedule to the court on or before May 20.

The parties were unable to reach an agreement on new deadlines by May 20, but did first agree to a 30 day extension of time to submit a joint response to the Court's Order. When the 30 day extension expired, however, the parties were still unable to submit a joint response with agreed deadlines. Instead, the parties submitted competing proposals. The public interest groups submitted a proposal for all but one of the rules to be completed by the end of this year. The FDA's proposal, on the other hand, contained "target timeframes" to complete the final regulations, rather than specific deadlines. The earliest of FDA's target timeframes would have ended in April, 2015, and the latest could have extended into 2016 (over three years after the statutory deadline).

It did not take the Court long to reject both proposals. Instead, the Court ordered the FDA to complete the rules by June 30, 2015, over two years from now and nearly three years beyond the statutory deadline. The Court indicated that it intended to include the new deadline in an injunction, so that FDA would risk contempt if it does not comply. The rules are subject to review by the White House Office of Management and Budget, however, so compliance with the deadline is not completely within FDA's control. One would hope that the additional two year period will be more than sufficient for FDA and OMB to complete this work.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device group: Lynn Tyler at (317) 231-7392 or [lynn.tyler@btlaw.com](mailto:lynn.tyler@btlaw.com); and Hae Park-Suk at (202) 408-6919 or

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