

ALERTS

Food, Drug & Device Law Alert - FDA Agrees To New Deadlines For Rules Implementing FSMA

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In the ongoing saga of the much-delayed rules to implement the Food Safety Modernization Act (FSMA), the FDA recently agreed to a new set of deadlines to submit final rules for publication in the Federal Register.

President Obama signed FSMA into law in January 2011, and it originally established an 18 month deadline for the FDA to adopt implementing regulations. Congress did not give the FDA additional money to perform the additional duties imposed by FSMA, however, and the new rules languished. Eventually, two public interest groups sued FDA and asked the Court to order FDA to complete the rules. The Court sided with the public interest groups and, in June of last year, ordered FDA to complete all of the rules by June 30, 2015.

Most recently, however, the FDA and the public interest groups agreed to a Consent Decree that includes a new schedule for FDA to complete the rules. The new schedule is as follows:

- Preventive Controls for Human Food (FSMA Section 103(a) and 103(c)) - Final rule: Aug. 30, 2015
- Preventive Controls for Animal Food (FSMA Section 103(a) and 103(c)) - Final rule: Aug. 30, 2015
- Foreign Supplier Verification Program (FSMA Section 301(a)) - Final rule: Oct. 31, 2015
- Produce Safety Standards (FSMA Section 105(a)) - Final rule: Oct. 31, 2015
- Accreditation of Third Party Auditors (FSMA Section 307) - Final rule: Oct. 31, 2015
- Sanitary Transport of Food and Feed (FSMA Section 111) - Final rule: March 31, 2016
- Intentional Contamination (FSMA Section 106(b)) - Final rule: May 31, 2016

FDA agreed to try in good faith to meet these deadlines. The Consent Decree does contain provisions allowing FDA to seek further extensions to complete the rules by filing a motion showing "good cause and/or exceptional circumstances." One reason the rules have been delayed in the past is because they had to be reviewed by the White House's Office of Management and Budget. If OMB causes delay in the future, it will be interesting to see if the Court accepts such delay as "good cause and/or exceptional circumstances."

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A copy of the Consent Decree can be [found here](#).

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