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ALERTS

Food, Drug & Device Law Alert - Conflicting Developments On Timing Of New Food Safety Rules

April 30, 2013 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

In January 2011, President Obama signed the Food Safety Modernization Act (FSMA) which included, among many other provisions, a requirement for the FDA to issue within 18 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. The 18 months came and went with no proposed regulations and instead a statement that the FDA would exercise enforcement discretion until the rules were promulgated. In January of this year, the agency released proposed produce safety and GMP rules, but no others.

On April 24, the FDA announced that it was extending the comment period for the two proposed rules by 120 days from May 16 to Sept. 16 of this year. This action was taken in part in response to comments from various stakeholders that they needed more time to comment on the two proposed rules, which combined exceed 1,200 pages in length, and because stakeholders hoped to be able to consider all five sets of proposed rules together.

Two days earlier, however, the U.S. District Court for the Northern District of California had entered an Order finding that the FDA has already violated FSMA by not having promulgated the regulations within the statutory deadline. The court held that the FDA's failure to promulgate the regulations amounted to action "unlawfully withheld" under the Administrative Procedures Act and ordered the parties, which include 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.

Presumably, to the extent of any conflict, the court's Order will trump the FDA's decision to extend the comment period for the two proposed rules. The court may face a practical problem, however, in implementing any proposed relief. Pursuant to a long-standing Executive Order, the White House's Office of Management and Budget (OMB) must review and approve the proposed regulations. Indeed, the two proposed regulations underwent a lengthy OMB review and extensive OMB revision, and some of the other proposed rules are currently undergoing OMB review (and potential revision). OMB is not a party to the case, however, so it will be difficult for FDA to commit to any future deadlines given its lack of control over the length of the OMB review process. Only time will tell how these matters will get resolved.

A copy of the District Court's Order can be found here.

For more information, please contact the Barnes & Thornburg LLP

RELATED PEOPLE

Lynn C. Tyler, M.S.
Partner
Indianapolis

P 317-231-7392
F 317-231-7433
lynn.tyler@btlaw.com

William W. Wales
Retired Partner
Indianapolis

P 317-231-7493
F 317-231-7433
william.wales@btlaw.com

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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; and Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com. You can also contact the following attorney in the firm's Agriculture and Food Processing Practice Group: William Wales at (317) 231-7493 or william.wales@btlaw.com.