

## ALERTS

### Food, Drug & Device Law Alert - FDA Finalizes Guidance On Food Records In Light Of Food Safety Modernization Act

April 14, 2014 | [Atlanta](#) | [Chicago](#) | [Columbus](#) | [Delaware](#) | [Elkhart](#) | [Fort Wayne](#) | [Grand Rapids](#) | [Indianapolis](#) | [Los Angeles](#) | [Minneapolis](#) | [South Bend](#)

The FDA recently released two guidance documents on the new and stricter record-keeping requirements imposed by the Food Safety Modernization Act (FSMA) on companies in the food supply chain. The FSMA also expanded the FDA's authority to inspect such records any time the FDA "has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals." The two guidance documents are "Guidance for Industry: What You Need to Know About Establishment, Maintenance, and Availability of Records" and "Guidance for Industry: FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act."

Both guidance documents incorporate the "reasonable belief" standard for authorizing the FDA to demand copies of a firm's records on twenty-four hours' notice. This standard has also been incorporated into the applicable regulation at 21 C.F.R. § 1.361. The practical effect of this change is that it will be more difficult than it was under prior law to challenge successfully an FDA request for records.

These developments also provide a good opportunity to remind companies of the surprising breadth of some food record-keeping requirements. Does your company furnish bottled water, coffee, tea or other beverages to employees? If so, it is subject to regulations requiring it to maintain certain records of the source of those beverages. In fact, as far as bottled water is concerned, this example is taken directly from the Q&A guidance (Edition 5) described above. The requirement would apply equally to any type of food provided to employees. This example highlights the need for any company that operates at any point in the food supply chain (except certain expressly excluded firms, such as farms and restaurants) to become familiar, and begin complying, with the record-keeping regulations if they are not already doing so.

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 [hae.park.suk@btlaw.com](mailto:hae.park.suk@btlaw.com).

>

©2014 Barnes & Thornburg LLP. All Rights Reserved. This page, and all information on it, is proprietary and the property of Barnes & Thornburg LLP. It may not be reproduced, in any form, without the express written consent of Barnes & Thornburg LLP.

This Barnes & Thornburg LLP publication should not be construed as

## RELATED PEOPLE



**Lynn C. Tyler, M.S.**

Partner  
Indianapolis

P 317-231-7392  
F 317-231-7433  
[lynn.tyler@btlaw.com](mailto:lynn.tyler@btlaw.com)

## RELATED PRACTICE AREAS

Food, Drug and Device Law

*legal advice or legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and you are urged to consult your own lawyer on any specific legal questions you may have concerning your situation.*

Visit us online at [www.btlaw.com](http://www.btlaw.com) and follow us on Twitter [@BTLawNews](https://twitter.com/BTLawNews).