

## ALERTS

### Food, Drug & Device Law Alert - Media Reporting Impostors Posing As FDA Inspectors

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As happens from time to time, recently various news media have reported that companies claim to have been visited by fraudulent FDA inspectors, i.e., people impersonating FDA inspectors to gain access to company facilities and records for illegitimate purposes. The impostors' motives are not always known, although theft of trade secrets and other crimes are likely candidates.

Any company subject to regulation by FDA should have a written policy for handling an FDA inspection. Among other things, the policy should always include requiring the inspector to produce identification, including a badge, at the very beginning. In light of the reports of impostors, companies may want to consider additional safeguards. In particular, the person responsible for interacting with the inspector should consider contacting the relevant FDA District Office to confirm that it employs an inspector by the name given and that the inspector is supposed to be inspecting the company on that day. It is not adequate simply to confirm that the FDA has an inspector by a particular name, because an impostor can also learn the name of a real inspector to give and enhance his or her apparent bona fides.

Companies in the food and medical device industries should be particularly cautious if an alleged FDA inspector shows up unannounced for a surprise inspection. In those industries, the FDA typically schedules inspections in advance, so a surprise inspection is a red flag for potential fraud. Another red flag for fraud is if the inspector asks for commercially-sensitive information, such as sales or profit figures or prices, that even a legitimate FDA inspector is not entitled to see. It has been reported that impostors have stated that an inspection otherwise went well and will be closed if they are given access to such information.

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).

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