Published on *The National Law Review* https://natlawreview.com

An Update on FDA Records Access Powers

Article By:

Food Regulation at Varnum Law

Earlier this month, FDA issued an interim final rule (and request for comments) regarding record availability requirements, new draft guidance for industry on its authority to access records, and updated Q&A guidance. All of these have been issued as part of the implementation of the new and expanded authority given to the **FDA under the Food Safety Modernization Act.** The new authority granted to the FDA allows it to access and copy records from domestic and foreign facilities that manufacture, process, pack, transport, distribute, receive, hold or import food if FDA has a reasonable belief that the food, and any other food FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

These newly issued documents, although non-binding on the FDA, help shed light on the following: (1) when is the FDA likely to exercise its authority to inspect and copy your records?; (2) what records can the FDA inspect and which records do they not have the authority to inspect?; (3) who do these rules apply to?; (4) what are the potential consequences from refusing to the let the FDA copy certain records?; (5) how can you protect your trade secrets from being made public? In light of these new materials, you will want to revisit your records retention program to ensure you're capable of complying with any FDA requests, as well as review your inspection policy to specifically address any issues in advance of an inspection or request for records

National Law Review, Volume II, Number 57

Source URL:https://natlawreview.com/article/update-fda-records-access-powers