

Exhibit 8

FDA Form 483 Frequently Asked Questions

Q: When is an FDA Form 483 issued?

A: An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and significant. Observations are made when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.

Q: What is the purpose of an FDA Form 483?

A: The FDA Form 483 notifies the company's management of objectionable conditions. At the conclusion of an inspection, the FDA Form 483 is presented and discussed with the company's senior management. Companies are encouraged to respond to the FDA Form 483 in writing with their corrective action plan and then implement that corrective action plan expeditiously.

Q: Is the FDA Form 483 intended to be an all-inclusive list of every possible deviation from law and regulation?

A: No, it's not. The FDA Form 483 is a report which does not include observations of questionable or unknown significance at the time of the inspection. There may be other objectionable conditions that exist at the firm that are not cited on the FDA Form 483. FDA investigators are instructed to note only what they saw during the course of the inspection. Companies are responsible to take corrective action to address the cited objectionable conditions and any related non-cited objectionable conditions that might exist.

Q: How is the FDA Form 483 shared with the company?

A: FDA Form 483s are discussed with a company's management at the conclusion of the inspection. Each observation is read and discussed so that there is a full understanding of what the observations are and what they mean.

Q: What are the implications of the FDA Form 483 for agency enforcement and what happens next?

A: The FDA Form 483 does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any of its relevant regulations. The FDA Form 483 is considered, along with a written report called an Establishment Inspection Report, all evidence or documentation collected on-site, and any responses made by the company. The Agency considers all of this information and then determines what further action, if any, is appropriate to protect public health.

Resources For You

- [FDA-483 Inspection Observations \(/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations\)](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations)