U.S. FOOD & DRUG ADMINISTRATION

Center of Excellence Understanding the Form FDA 483 Process and Timeline

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Inspection Observations

- FDA's Office of Regulatory Affairs (ORA) is the lead office for all field activities, including inspections and enforcement.

- During an inspection, ORA investigators may observe conditions they deem to be objectionable. These observations, are listed on Form FDA 483.

When is a Form FDA 483 issued?

- A Form FDA 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed conditions that in their judgment may constitute violations of the Food, Drug, and Cosmetic (FD&C) Act and other Acts or regulations.

- FDA investigators are trained to ensure that each observation noted on the Form FDA 483 is clear, specific and significant.

What is the purpose of a Form FDA 483?

- The Form FDA 483 notifies the company's management of observed objectionable conditions. At the conclusion of an inspection, the Form FDA 483 is presented and discussed with the company's senior management.

Is the Form FDA 483 intended to be an all-inclusive list ?

- There may be other objectionable conditions that exist at the firm that are not cited on the Form FDA 483.

- FDA investigators are instructed to note only what they observed during the course of the inspection.

How is the Form FDA 483 shared with the company?

- Form FDA 483s are discussed with a company's management at the conclusion of the inspection. Each observation is read and discussed to encourage a full understanding of what the observations are and what they mean.

What are the implications of the Form FDA 483 for agency enforcement?

- The Form FDA 483 does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or relevant regulations.

- The Form FDA 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.

Top Five 483 Citations

1. 21 CFR 211.42(c)(10)(iv)-Environmental Monitoring System
2. 21 CFR 211.113(b)-Procedures for sterile drug products
3. 21 CFR 211.192- Investigations of discrepancies, failures
4. 21 CFR 211.42(c)(10)(v)-Cleaning System
5. 21 CFR 211.113(b)-Validation lacking for sterile drug products

Posted 483s

- Compounding: Inspections, Recalls, and other Actions | FDA


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Breakout Session

- Question 1: If your company disagrees with a 483 observation what are your options?

Breakout Session

- Question 2: Are labeling deficiencies cited on a 483 for an Outsourcing Facility (OF)?

Breakout Session

- Question 3: What type of information should be included within the 483 response?