Response to FDA Inspections

Updated December 10, 2013

The following guidance is recommended when determining the best means of communication with the FDA Seattle District Office to resolve any compliance issues identified during regulatory inspections and reported on the Form FDA 483, Inspectional Observations (henceforth “FDA 483”), and upon receipt of a Warning Letter.

Form FDA 483, Inspectional Observations

An FDA 483 is issued to a processor at the conclusion of an inspection when an FDA Investigator has observed conditions that in their judgement may constitute violations of the Food, Drug and Cosmetic Act.

At one time, FDA Investigators could annotate the FDA 483 to indicate the processor’s immediate or planned corrective actions for the conditions observed and cited on the FDA 483. The annotated FDA 483 was included in the investigator’s narrative establishment inspection report and considered during the review by the District Office Compliance Officer. As a result of a policy change in 2009, investigators no longer annotate the FDA 483 for food inspections. Therefore, a prudent processor should prepare a written response to the agency addressing all observations cited on the FDA 483, although there is no regulatory requirement to respond.

Processor Response to FDA 483 Observations

We continue to recommend an immediate response, in writing, that addresses all observations cited on the FDA 483. Even if corrective actions are verbally discussed and/or verified by the investigator during the course of the inspection, a written response is recommended for all FDA 483s.

The processor’s written response may mitigate an FDA compliance decision to pursue regulatory action (see below), demonstrates to the FDA an understanding and acknowledgement of the observations, demonstrates to the FDA a commitment to correct the observations by voluntary compliance, and establishes credibility with the FDA.

An effective response should be specific (e.g., observation-by-observation), be complete, be realistic, be able to deliver what is promised, address affected products, provide time frames for correction, provide method of verification and/or monitoring of corrections, include supporting documentation (e.g., records, photographs, purchase orders) and be submitted in a timely manner.
The written response should be sent by e-mail to expedite submission and then mailed, or just mailed; the response should be addressed to the District Director. Another option is to request an in-person meeting with the District Director to present and discuss the response. The meeting option also provides an opportunity to obtain clarification of any issues, disagree with the FDA 483 observation(s), or discuss other questions.

A processor may provide a response at any time. However, it is recommended the response be submitted within 15 business days. If significant observations were reported on the FDA 483, the agency may issue a Warning Letter (see below). If a response is received within 15 business days, it will be reviewed by the District Office Compliance Officer and considered in evaluating whether to issue a Warning Letter. If a Warning Letter is issued despite the response, the letter will acknowledge the processor's response and comment on the corrective action(s) deemed inadequate. If a response is received more than 15 business days after issuance of the FDA 483 and a Warning Letter is issued, the letter will not acknowledge receipt of the response or address the inadequacy of the corrective action(s).

Acknowledgement of FDA 483 Response

FDA makes every effort to acknowledge receipt of written responses to FDA 483s. The correspondence acknowledges receipt of the response but does not comment on the adequacy of the corrective actions. In some cases, if the FDA does not plan to pursue regulatory action, the correspondence may contain comments deemed beneficial to the processor.

Untitled Letters

Untitled Letters were used by the FDA for many years for minor inspectional observations or after the initial inspection of a processor under Title 21 Code of Federal Regulations Part 123 – Fish and Fishery Products and identified significant observations that required correction. Untitled Letters were not classified as “regulatory actions.” Untitled Letters are no longer issued by FDA.

Warning Letters

Warning Letters are issued to achieve voluntary compliance and to establish prior notice. Warning Letters are issued only for violations of regulatory significance. Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected. A Warning Letter is the agency's principal means of achieving prompt voluntary compliance with the Food, Drug, and Cosmetic Act. Warning Letters may contain references to the processor’s written response as previously noted. We have encouraged the FDA to include these references to assist the processor in developing an adequate corrective action.
The Warning Letter includes language requesting a response within 15 days of receipt. A processor should respond within this time frame. However, if the response can not be made within the time frame, telephone the District Office Compliance Branch and request an extension. The guidance for responding to a FDA 483 should be considered for the Warning Letter response.

Additionally, Section 743 of the Act (21 U.S.C. § 379j-31) authorizes FDA to assess and collect fees to cover FDA’s costs for certain activities, including re-inspection-related costs. A re-inspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Re-inspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA’s arranging, conducting, and evaluating the results of the re-inspection and assessing and collecting the re-inspection fees (21 U.S.C. § 379j-31(a)(2)(B)).

It should be noted that Warning Letters are considered a “regulatory action” and are publicly accessible through FDA’s website.

Follow-Up Communication Recommended

It is strongly recommended that processors follow-up by telephone or request an in-person meeting to ensure their response was received by the FDA and adequately addresses all of the FDA’s concerns noted on the FDA 483 or Warning Letter. This follow-up communication should be emphasized and it is now more critical to ensure the processor’s response adequately addresses all issues raised on the FDA 483 or Warning Letter to preclude any further regulatory action by the FDA.

State Contract Inspections

The same procedures are recommended for inspections conducted by State regulatory agencies under contract with FDA. Although the State agencies do not use the FDA 483 document, they do itemize their observations on the State inspection forms. The response should be provided to the State regulatory agency and FDA District Office.

Further Assistance from SPA

Please do not hesitate to contact the SPA staff below if you have any questions or require further assistance with regulatory inspection issues.

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