FDA Adopts New Post-Inspection Procedures: "Need for Speed" to Prevent Warning Letters

On August 11, 2009, the Food and Drug Administration (FDA) announced a pilot program requiring companies to respond within 15 business days to FDA inspectional observations if the company wants FDA to consider its response before issuing a public Warning Letter. The purpose of the pilot is to "facilitat[e] the timely issuance of warning letters." The 18-month pilot, which begins on September 15, 2009, will require FDA-regulated companies to revamp their procedures and strategies for handling FDA inspections.

Background

When FDA observes regulatory violations during the course of an establishment inspection, it reports such violations to the company using FDA form "483." Although not required to do so, most companies will submit a written "483 response" to FDA. FDA historically has been willing to take such responses into consideration when determining whether to issue a Warning Letter following the close of an inspection. A Warning Letter is a tool that FDA uses to advise a company that it may be subject to formal enforcement action such as a seizure, injunction, civil money penalty, or criminal prosecution if it fails to correct the alleged violations promptly and adequately.

Until now, there has been no deadline for the submission of a 483 response. Many companies have adopted a 30-day rule of thumb for responding, but FDA has often been willing to delay its decision on whether to issue a Warning Letter for even longer periods pending receipt of a 483 response.

Changes Introduced by the Pilot

Under the pilot, FDA will no longer ordinarily delay the issuance of a Warning Letter following an inspection unless a written 483 response is received within 15 business days. FDA will review information submitted outside the 15-business-day period, but will not delay the issuance of a Warning Letter to do so.

Implications for Industry

The pilot program will result in faster issuance of FDA Warning Letters. Because such letters are public, they can have significant adverse consequences for a company. In most cases, therefore, it will be in the company's interest to submit a 483 response within 15 business days of an FDA inspection. Doing so can be a daunting challenge, particularly where the inspection resulted in a substantial number of observations. In addition, having such a short time to respond increases the risk of making inaccurate factual statements, committing to undertake actions or adhere to timelines that later prove to be unworkable, or making unnecessary admissions that can later have harmful legal consequences.

Consequently, FDA-regulated companies should evaluate and revise their procedures for responding to form 483 notices. Companies should be prepared to:

- dedicate more resources than they have in the past to responding to 483s;
- develop standard 483 response templates; and
- establish standard operating procedures for quickly assembling the team (which may include internal and external resources) needed for preparing the response; collecting information, drafting, and reviewing responses to each 483 observation as well as the more global elements of the response; preparing the final response; and submitting the response so that it is received by FDA within 15 business days.

Additionally, companies may wish to adopt a practice of beginning to prepare a 483 response before an inspection has closed. This approach will work for multi-day inspections in which the FDA investigators are willing to provide ongoing feedback regarding their findings. To this end, companies that currently do not do so should begin requesting daily debriefs from FDA investigators regarding the progress of the inspection, the estimated timing for the inspection close-out, and the inspectional observations noted to date.

Tips for Drafting Effective 483 Responses

The goal of a 483 response is to convince FDA not to issue a Warning Letter or pursue other enforcement action against a company. Strategies for drafting an effective 483 response include:

- Expressing senior management's commitment to addressing the observations in a comprehensive manner rather than responding narrowly to the specific observations. Companies must show proactive commitment to compliance. It is not FDA's job to inspect the company into compliance.
- Addressing each of the inspectional observations separately, noting whether the company disagrees with the observation, and explaining whether specific corrective and preventive actions have been accomplished or planned.
- If corrective and preventive actions have already been accomplished, submitting documentation allowing FDA to verify that the alleged deficiency has been addressed without conducting a follow-up inspection.
- If corrective or preventive actions are planned but not yet completed, (1) describing the actions in sufficient detail to enable FDA to assess their adequacy; (2) explaining how the actions address the observation; (3) including time frames for completing the actions; and (4) offering to keep FDA updated on the company's progress toward completing the actions.
- If the company disagrees with an inspectional observation, providing data to support its position (e.g., data indicating that the observed deficiency was an isolated event rather than a routine occurrence).
- Avoiding language that unnecessarily admits to a legal violation or implies that the company or its management is at fault for a violation. Focus instead on positive action to remedy the FDA's observations.

For more information regarding the pilot program, and tips for drafting effective 483 responses, please contact your Ropes & Gray attorney or any one of the attorneys from the Ropes & Gray Life Sciences practice group.