Responding to FDA 483s

Strategies for Successfully Obtaining Closeout

From the Editors of

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FDANEWS

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Introduction

The FDA's inspection process and the receipt of a Form 483 or warning letter has always been a serious matter. And the importance of sending an appropriate response is essential. A company must show the FDA that an effective corrective action plan has been established, and adequately spell out the plan in a response to the agency.

The response has always been critical, but the timeliness of that response has not been as critical. In the past, some companies have submitted multiple written responses to Form 483 observations, sometimes over many months. The FDA would review these responses as they came in before deciding on whether to issue a warning letter. Thus, the entire process of writing responses and reviewing them delayed enforcement and compliance.

That sometimes-lengthy process of sending responses has come to an end, however. The FDA has begun to enforce a program that calls for a more timely review of its Form 483 inspection observations. As of Sept. 15, 2009, six new policies became effective, including one that states a company has 15 days to respond to a Form 483 before the FDA decides whether to issue an official warning letter.

The FDA's new strategy was described by FDA Commissioner Margaret Hamburg as "swift, aggressive and effective" enforcement of the FDA's laws and regulations. The FDA is also continuing to beef up its heretofore slim resources, hiring more inspectors and establishing more international bases.

And, while the FDA is planning to be tougher, there is an upside for companies within this new strategy. Companies that fix problems cited by the FDA in a 483 and/or warning letter could receive a "closeout letter," which is something like being issued a clean bill of health. This can be a positive sign to investors looking for reassurance.

With these new policies, the FDA hopes to make the best use of its resources and to encourage companies to correct violations in a timely manner. The agency has stated that the ultimate goal is not to necessarily look for more violations, but to emphasize the protection of the public's health and safety.

This management report is based in part on an FDAnews audioconference conducted by Frederick H. Branding, partner in the health law group of McGuireWoods LLP in Chicago, Illinois, and Cathy L. Burgess, senior counsel for regulatory law at the American Red Cross.

This is a sample.

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