

Working with the FDA

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If you follow industry developments closely, you probably noticed that U.S. Food and Drug Administration (FDA) warning letters seem to occur as often as product recalls. In fact, the agency sent a staggering 1,720 warning letters in 2011, up from just 673 in 2010. But the trouble is that the process can prove to be an enigma. What triggers a warning letter to be sent? When do you need to respond? When will the letters be made public? And what will cause the media to pay attention?

In this first in a series of articles, we will discuss the general ins and outs of the warning letter process. In subsequent articles, we will discuss best practices for working with FDA inspectors, the most common reasons that companies receive warning letters, how to respond, and what subsequent action can be expected.

According to FDA, warning letters are sent as a way of encouraging companies to voluntarily comply with industry standards and regulatory guidelines. In that regard, they are a way of establishing a public record of the agency's conversations with members of the industries it regulates.

Generally warning letters are sent following a routine or complaint-triggered inspection. Upon completion of an inspection, investigators may issue Form FDA-483 which documents any deficiencies found at a facility. Company officials will then be able to initially respond either through an exit discussion and/or a formal written response. Agency inspectors will also draft an Establishment Inspection Report (EIR), providing more detail on inspection observations and linking them to

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any evidence collected from the affected firm's facility. Once the EIR and Form 483 are reviewed by senior FDA officials, a warning letter may follow.

The FDA Office of Prescription Drug Promotion (formerly the Division of Drug Marketing Advertising and Communications) and the Center for Drug Evaluation and Research (CDER) are the entities that are primarily responsible for issuing such notices. Should they have concerns about whether the company's facility complies with regulations and industry standards, it has 15 days from the issue of the EIR to send a warning letter.

As a matter of procedure, this type of issuance is addressed and delivered to the highest known individual at the organization being targeted.

Firms then have 15 days to respond and to begin taking action to resolve any issues outlined in the warning letter. Otherwise, the company may face regulatory actions including seizure, injunction, and civil money penalties.

It is important to note that a warning letter is in no way a prerequisite for enforcement action. While companies, the media and even the general public typically view warning letters as just that — a letter warning of possible future enforcement — the agency can take immediate action against companies if it decides the punishment fits the crime. According to FDA, these instances include:

1. When the violation reflects a history of repeated or continual conduct.
2. When the violation is intentional or flagrant.
3. When the violations are intentional and willful acts with outcomes that cannot be reversed.
4. When the violation presents a reasonable possibility of injury or death.
5. When violations have not been corrected, or are continuing.

It is imperative that all businesses are well-versed in FDA regulations and the steps that can be taken by the agency to enforce compliance with such laws.

Understanding these types of processes will only prove beneficial to companies should a warning letter, or other enforcement papers, appear in the mail. Our next article will delve into what firms can expect from FDA inspections and how to effectively prepare for such occurrences. After all, it is this type of on-site visit that will lead FDA to decide on what future actions, if any, need to be taken to ensure regulatory compliance by a firm.

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