Introduction

After an inspection, FDA investigators issue a form FDA-483 which lists the adverse observations made during an inspection. Following the review of the 483 and the establishment inspection report (EIR), the FDA District Office may elect to send the inspected company a Warning Letter.

A Warning Letter differs from an FDA-483 in that the Warning Letter indicates that higher level FDA officials, as opposed to an individual investigator or District Office, have reviewed the inspection findings and concluded that the findings warrant formal notification of serious violations.

The Warning Letter is not a final action. The FDA Reference Guide provides: "A Warning Letter is informal and advisory. It communicates the agency’s position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued."

Warning Letters, unlike FDA-483s, are posted publicly to the agency’s website (www.fda.gov/foi/warning.htm). Additionally, responses submitted on behalf of the company as to corrective actions are also posted on the same site.

The Federal Food, Drug, and Cosmetic Act, Code of Federal Regulations; guidances from the FDA; and a limited body of case law govern the FDA’s authority to issue Warning Letters and other communications.
Your company has received a Warning Letter addressing certain manufacturing activities that were cited in a 483 form and are now highlighted in the Warning Letter. The FDA routinely issues guidances and other instructions, formal and informal, to assist companies in maintaining good practices with respect to maintenance of their facilities. Still, the majority of companies have received and are all too familiar with what is known in the industry as a Warning Letter. This article addresses examples of underlying conduct while focusing on the following: 1) specific examples in the manufacturing area that could potentially be the subject of the Warning Letter; 2) the guidances and regulations applicable to the cited conduct; 3) steps a company should take to address and respond once it has received a letter; and 4) the potential litigation implications.

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related to manufacturing processes, the effect of such letters on a company’s continued research and development, as well as any potential legal implications.

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FDA staff on how to handle various aspects of the governing activities, including drug manufacturing inspections.1

Suggested Action for Company

Once a company has received the Warning Letter, certain steps should be followed to assess the background and circumstances of the conduct underlying the Warning Letter. These steps include:

A. Evaluate Violations and the Basis for Violations Cited in Letter

1. Statement of commitment to comply with applicable laws and regulations.

2. Statement recognizing the seriousness of the Warning Letter and the company’s commitment to addressing all issues raised.

3. An address of each item in the Warning Letter individually.

4. Scope of corrective action plan, including detailed reports on what has been done and what will be done in the future to correct the issues identified in the letter.

Corrective actions and follow up correspondence updating the agency on each step taken to address the cited conduct should be taken until the company receives a final letter from the FDA stating that “the conduct in the future; (2) meeting or teleconference with FDA to discuss conduct; (3) depending on the impact that the cited conduct has on a product, consider issuing a recall notice and/or sending a Dear Health Care Provider Letter informing the field of the cited conduct.

Potential Liability Implications

The Warning Letter could potentially impact litigation involving the manufacturing facility and its products directly. As mentioned above, the Warning Letter and the relevant responses will be publicly available and easily obtained from the agency’s website. While the Warning Letter is not an individual basis for liability, the company should expect to see it in any product liability suit, particularly in the depositions of company representatives. Arguments can be made to exclude the Warning Letter at trial, and in many instances, the company may be successful in excluding the Warning Letter depending on the jurisdiction and extent of connection between the cited conduct and the event giving rise to litigation. However, even if the cited conduct is not directly relevant to the basis for lawsuits, plaintiffs may attempt to use the Warning Letter in any claim against the company to show an alleged pattern or history of bad manufacturing practices.

In assessing liability and the potential impact of the Warning Letter, the company may want to consider taking the following precautionary measures:

1. Collect and maintain all documents pertaining to the cited conduct and the Warning Letter.

2. Collect and maintain Adverse Events Reports that stem from products connected to the facility at issue.

3. Compose a list of individuals with knowledge of the cited conduct and consider conferences between these individuals and the legal department.

4. Amended to exclude the Warning Letter letter or other informal letters, therefore, do not represent the official or final position of the agency.4 Because of this inherent lack

4. The company took actions to ensure that any product potentially affected by the cited conduct was evaluated, and proper recall notice and/or sending a Dear Health Care Provider Letter informing the field of the cited conduct.

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In assessing liability and the potential impact of the Warning Letter, the company may want to consider taking the following precautionary measures:

1. Collect and maintain all documents pertaining to the cited conduct and the Warning Letter.

2. The company took the FDA’s allegations very seriously and undertook a thorough investigation.

3. To support the argument that the company took the Warning Letter seriously and addressed the cited conduct, the company will rely upon the details of response, including date, content, and any additional follow-up conversations or correspondence.

4. The company took actions to ensure that any product potentially affected by the cited conduct was evaluated, and proper recall notice and/or sending a Dear Health Care Provider Letter informing the field of the cited conduct.

As part of its regulatory procedures, FDA employees issue untitled letters and Warning Letters to companies to afford those companies an opportunity to correct perceived violations before the FDA decides whether to file an official enforcement action against the company.5 The FDA itself makes clear that a “Warning Letter is informal and advisory” and does not constitute final agency action.6 Warning Letters and other informal FDA letters, therefore, do not meet any of the requirements for a hearsay document to be admissible under the

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The company corrected the cited conduct by undertaking specific actions to address the processes cited in the Warning Letter.

6. The FDA required no further action and found that the company’s responses were appropriate.

If the company is faced with liability and the Warning Letter is exploited, the company will have arguments to exclude the Warning Letter from being used in litigation. The following analysis is based on the Federal Rules of Evidence and will need to be modified depending on the applicable law.

1. The Warning Letter was not a blanket condemnation of the manufacturing operations at the company. The Warning Letter was a complaint directed at certain discrete events.

2. The company took the FDA’s allegations very seriously and undertook a thorough investigation.

3. To support the argument that the company took the Warning Letter seriously and addressed the cited conduct, the company will rely upon the details of response, including date, content, and any additional follow-up conversations or correspondence.

4. The company took actions to ensure that any product potentially affected by the cited conduct was evaluated, and proper recall notice and/or sending a Dear Health Care Provider Letter informing the field of the cited conduct.

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Suggested Action for Company

Once a company has received the Warning Letter, certain steps should be followed to assess the background and circumstances of the conduct underlying the Warning Letter. These steps include:

A. Evaluate Violations and the Basis for Violations Cited in Letter

The company should start by analyzing what the basis was for the Warning Letter and determine whether the inspection giving rise to the Warning Letter was a routine inspection, the result of MedWatch reports, or the result of other specific complaints. The company should assess the status of the inspection and look back at the FDA-483 to analyze observations noted in the FDA-483. The company will most likely have already prepared a response to the 483, initially in an exit interview, followed by a formal written response. Additionally, the company should look back to the EIR and analyze inspection observations and links to evidence supporting observations.

B. Preparing the Response and Other Actions to Consider

A formal response to the Warning Letter will need to be submitted to the FDA. Below is a sample outline for what should be included in the response.

1. Statement of commitment to comply with applicable laws and regulations.

2. Statement recognizing the seriousness of the Warning Letter and the company's commitment to addressing all issues raised.

3. An address of each item in the Warning Letter individually.

4. Scope of corrective action plan, including detailed reports on what has been done and what will be done in the future to correct the issues identified in the letter.

Corrective actions and follow up correspondence updating the agency on each step taken to address the cited conduct should be taken until the company receives a final letter from the FDA stating that “the conduct in the future; (2) meeting or teleconference with FDA to discuss conduct; (3) depending on the impact that the cited conduct has on a product, consider issuing a recall notice and/or sending a Dear Healthcare Provider Letter informing the field of the cited conduct.

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2. Collect and maintain Adverse Event Reports that stem from products connected to the facility at issue.

3. Compose a list of individuals with knowledge of the cited conduct and consider conferences between these individuals and the legal department.

4. The company will have arguments to exclude the Warning Letter from being used in litigation.

5. The company corrected the cited conduct by undertaking specific actions to address the processes cited in the Warning Letter.

6. The company has a pattern or practice of unlawful manufacturing.

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3. To support the argument that the company took the Warning Letter seriously and addressed the cited conduct, the company will rely upon the details of response, including date, content, and any additional follow-up communications or correspondence.

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Given the punch of video on the perspective of jurors, part of the law
yer’s job is to prepare the company witness to be a master of the video
medium so as to convey credibility. Here are a few practical tips:
- When you are giving a videotaped deposition, think of it as your
real-life television show where the camera is always on you, even when
you are not speaking.
- Be aware of your non-verbal communication. I saw a deponent once
so flustered that he put the wrong hand on the Bible, shifted his eyes
under his brow, and mumbled to the camera. The entire ex-
session took less than fifteen seconds, but it would be quite damaging
to the deponent’s credibility if played to a jury. Be ready calm and
avoid distracting facial gestures, hand movements, and paper
shuffling are crucial to building credibility. Be prepared to get into
the substance and to get out the company’s side of the story when
the appropriate questions are asked.
- Be aware of time when answering questions. larg pauses are not
recorded in the written transcript but on video may look evasive, un-
certain, or nervous.
- Make sure that the camera is in front of you and not cocked at an
angle. Watching a person speak in profile diminishes the impact of the
words.

- Wear conservative clothing. solids work well.

Practice. Practice. Practice.

Videotaped deposition present a wonderful opportunity to relate
to a jury and communicate your side of the story.

1 Campbell, Karen Martin. “Tell Tape — The Admissibility of Videotaped
2 Tuchler, Gerald R. & Neuman, F. O’Neill, “Videotapes on Trial: A View from the
Jury Box,” 58 (1994).
3 Baron, Stanley J. The Jenner’s Television Book: A Personal Guide to Understanding
5 Id. at §30(a) (5).
6 Id. at §30(a)(5).

A POORLY PERFORMED DEPOSITION of a company representative
on videotape can haunt litigation for years to come in the mass tort
context. It may be something as inconsequential as a sweaty brow or
twittor’s or a smile at a certain, or nervous.

The deposition may also be used by any party for purposes of con-
trading or impeaching the testimony of a defendant as a witness or
when the witness is unavailable because of events such as death, age,
illness, illness, imprisonment, or lives more than 100 miles from the
place of trial or hearing.

The videotaped deposition is not the final and official position of the
FDA. The jury may not understand the important difference between
the position of an employee of the FDA and a final and official determi-
nation of the FDA. The jury should obtain all relevant information and
statutes and regulations. These programs are
applicable to records of “the internal function of a
particular agency” and not “observations of […] condi-
tions external to the office”).

Conclusion

In order to address a Warning Letter re-
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1 See Chapter 4: Advisory Actions,” Regulatory Procedures
Manual, Section 10.1-5 (March 2007), available at
2 See Chapter 4, supra, Section 4-1-1, “Who was responsible?
How will you prevent reoccurrence? […]”
3 See Chapter 4, supra, Section 4-1-1 (“FDA is under no legal
obligation to warn individuals or firms that their
produces in violation of the law before taking enforcement
action”).
852 F.2d 136, 139 (4th Cir. 1988) (holding inadmissi-
ble “communications that do not constitute final action”).
5 See Chapter 4, supra, Section 4-1-1 (“FDAs Compliance Programs provide guidance and
for FDA personnel but are made available
electronically to the public as they become available."