Appendix 5.5.4
Compliance Actions and Enforcement

As a result of an FDA audit, the inspector issues what is called a "483," which refers to the government form on which the audit report is provided. In this report, the company's results are classified into one of three categories:

- **NAI** – No Action Indicated
- **VAI** – Voluntary Action Indicated
- **OAI** – Official Action Indicated

Rarely is a company designated NAI. It is far more common for the report to include "findings" from the audit, which are actionable items that the company must correct (VAI). Receiving findings on a 483 does not mean that the company has serious quality problems. However, all items cited should be taken seriously and warrant correction and/or corrective action. Corrective action is taken to address the cause of the problem, thereby preventing the recurrence of the nonconformance issue.

Generally, corrections and corrective action proposals, along with the documented evidence of those efforts, should be submitted in writing to the FDA. They should contain a detailed description of the action(s) taken and to be taken, in order to bring a given process or product into compliance within a specified time frame. Bear in mind that, just because a company takes voluntary action to correct a problem, this does not preclude the FDA from initiating administrative and/or judicial action against the firm. In determining whether quality systems deviations are sufficient to warrant legal action, the FDA will consider the significance of the device, the company's quality history, and whether the problem(s) is widespread or continuing.[1]

When responding to FDA audit findings, it is important for companies to follow a number of basic guidelines:

- **Accept the findings** – Do not dispute the FDA's audit results unless they are truly egregious.
- **Fix the findings** – A company is not obligated to correct a problem in the way that the auditor suggests. However, it must make an appropriate, sincere effort to address all identified issues and become compliant.
- **Follow up and verify fixes at regular intervals** – Make sure, over time, that the problems have been addressed, as well as their causes. Confirm that all corrections have been sustained over time.
- **Complete all follow-up reports and documentation requested/required by the FDA** – Use this as an opportunity to strengthen the company's relationship with the FDA (by being responsive), not jeopardize it (through sloppy follow-up).
- **Be reasonable, responsible, and friendly to FDA** – Maintain a collaborative, cooperative tone in all interactions.

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More serious findings (those which the FDA believes could impact the health or safety of patients) result in an OAI classification. One of the most common official actions is for the FDA to issue a warning letter, which is a formal communication to the company (or individual(s) within the company that control the processes in question) indicating that the FDA considers certain products, practices, processes, or other activities to be in violation of QSR requirements. The warning also states that failure to take appropriate and prompt action to correct the violations may result in regulatory action being initiated without further alerts. Warning letters can result in more severe penalties if the same problems are discovered on a subsequent audit.

Other actions that may be taken by the FDA, including citations, injunctions, administrative detentions, seizures, prosecution, and civil penalties, are summarized below.

Table 5.5.4-1 – The FDA can take a series of different action in response to quality problems.

Action	Description
Citation	• Formal warning to a company of the FDA's intention to prosecute if violations are not corrected. • A meeting held prior to consideration of criminal proceedings that gives the parties (possible defendants) an opportunity to present their position in the matter.
Injunction	• An order issued by the court requiring a device company to do, or refrain from doing, a specific act (e.g., manufacturing a device). Usually issued if a company has a continuing pattern of significant deviations in spite of past warnings. • If a serious health/safety hazard exists, the FDA may request a temporary restraining order (TRO) to prevent the distribution of devices that have been manufactured under the violative conditions documented by the inspection report.
Administrative Detention	• Serves as a temporary "cease and desist" order. • Suspension allows the agency 20 or 30 days to determine what action to take. • Often leads to seizure of a device upon expiration of the administrative detention.
Seizure	• An action taken against a specific device. May include raw materials, labeling, packaging, or the finished device. • Intended for the FDA to take quick control over a product in violation of quality regulation and put it under the possession or custody of the court. • The owner or claimant of the seized merchandise is usually given approximately 30 days to decide on a course of action (i.e., contest the charge or request

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Action	Description
	court permission to bring the product into compliance). If no action is taken, the court recommends disposal of the goods.
Prosecution	• Criminal action directed against the company and/or responsible individuals. • A misdemeanor or felony can result in fines and/or imprisonment.
Civil Penalties	• Monetary penalties imposed on a company (or responsible individuals) after an appropriate hearing for violations of the law related to medical devices. • In determining the amount of civil penalty, the FDA takes into account the nature, circumstances, extent, and gravity of the violations, the violator's ability to pay, the effect on the violator's ability to continue to do business, and any history of prior violations.

The FDA may also make a legal agreement with a company to force it to make specific changes (or bar it from particular actions). These agreements, which are known as consent decrees, are enforced by the federal courts. They can include fines, government reimbursement for inspection costs, timelines for specific actions, and penalties for noncompliance.

A Note About Recalls

A product recall is another enforcement action at the FDA's disposal. Recalls can be triggered from internal discoveries, field failures, or audit actions. They also can be voluntary (initiated by the company) or imposed (mandated by the FDA). If a company voluntarily recalls a product to reduce a health or safety risk or to remedy a violation of an FDA regulation, the company is obligated to report this to the FDA.[2] Recalls that are imposed by FDA are almost always more serious in nature and are usually the result of negligence on the part of the manufacturer. A company that finds itself in this position may experience damage to its reputation, financial hardship, and strain on its relationship with the FDA.

There are multiple ways that a company can remove a product from market. The appropriate approach depends on the relative severity of the health hazard presented. Different ways for removing a product from the market include:[3]

- **Recall** – Refers to a method of removing or correcting products that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action (e.g., seizure). A recall does not include a **market withdrawal** or any form of standard stock recovery.
- **Market Withdrawal** – Involves a minor violation that would not be subject to legal action by the FDA or which involves no violation (e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.).

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- **Correction** – Refers to the repair, modification, adjustment, relabeling, destruction, or inspection of a distributed product while it is still under the control of the manufacturer and does not need to be physically removed to some other location.

Recalls are classified by the manufacturer according to the relative severity of the health hazard presented by the product through a Health Hazard Evaluation. The issues considered include whether any disease or injuries have already occurred from the use of the product, degree of seriousness of the health hazard to which individuals would be exposed, likelihood of occurrence, and consequences (immediate or long-range) of the health hazard. The three classifications are:[4]

- **Class I** – Reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- **Class II** – Use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences, although the probability of serious adverse health consequences is remote.
- **Class III** – Use of, or exposure to, a violative product is not likely to cause adverse health consequences.

It is important to note that the classification of recalls is the *inverse* of the FDA's device classification in terms of severity—the higher the recall level, the lower the risk.

The steps for initiating and implementing a recall are fairly prescriptive. Notification to product users is always required. Such notification must include brief reasons for the recall, as well as instructions for returning or disposing of the violative device. A number of notifications and procedures must be followed in collaboration with an FDA district recall coordinator, with the extent of the required effort dependent on the class and scope of the recall.

If a company is faced with a recall, its quality system procedures can play an essential role in helping it effectively and efficiently respond. For example, hazard analysis processes can help in quick and accurate failure analysis of the problem. Similarly, traceability requirements (e.g., material controls) can help a manufacturer identify the lot(s) of product involved in a recall to limit the scope of the recall as much as possible. If appropriate procedures are not in place, a company could be faced with a system-wide recall of product which could leave nothing in the supply pipeline and be devastating to a manufacturer. A sound quality system provides a company with a backbone and an organized approach for handling these kinds of challenges.

Guidant Corporation, which recalled thousands of its implantable cardioverter defibrillators (ICDs) in June 2005, is one example of a company that faced sizable recall challenges. The Guidant recall was caused by a manufacturing defect that could cause several of its ICDs to short-circuit or malfunction. Thousands of plaintiffs in more than 100 class action and individual lawsuits claimed that Guidant knew of the problems with the ICDs and failed to publicly disclose the life-threatening defects until the FDA

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intervened. In total, Guidant recalled or issued warnings for more than 80,000 ICDs, which severely damaged the company financially, competitively, and in terms of its reputation.[5]

On the other hand, many companies experiencing a recall emerge without any major impact to the customer. In some cases, the company may even emerge stronger after the exercise. For example, a small biopsy company initiated two recalls in 2003 (class II) for design-related issues that could have resulted in a threat to patient safety. These issues were discovered before the device was used in a patient, and a recall was initiated. An internal investigation was taken to identify and isolate suspect products and determine whether replacement products could be provided. The suspect products were recalled and examined. In the end, the recall resulted in minimal disruption to the customer, a product improvement that was driven directly by the findings of the failure analysis, and a general improvement in both compliance and the level of attention paid to the quality system, which could help preempt such actions in the future.

Note that a quality system cannot entirely eliminate the chance of a recall, but it can minimize the chance that one will occur, while also enabling a company to more quickly and nimbly recover when problems arise to protect business value.

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[1] "Inspection of Medical Device Manufacturers," U.S. Food and Drug Administration, June 15, 2006, http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm072753.htm (February 3, 2014).
[2] "Recalls, Corrections and Removals (Devices)," U.S. Food and Drug Administration, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/ (March 21, 2014).
[3] Ibid.
[4] Ibid.
[5] "Guidant Cardiac Defibrillator Recall and Lawsuit," www.lawyersandsettlements.com, http://www.lawyersandsettlements.com/case/guidant_defective_defibrillator_class_action (March 21, 2014).

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