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Enforcement

Prohibited Acts and Enforcement Tools

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I. INTRODUCTION

The Food and Drug Administration's (FDA's) most significant enforcement authority is derived from 21 U.S.C. § 331, which allows FDA to exercise that authority when there has been a "prohibited act."

In order to lawfully market a medical device, a firm must comply with all applicable premarket and postmarket requirements. Failure to do so will constitute a prohibited act under the Federal Food, Drug, and Cosmetic Act (FDCA),¹ thus triggering possible agency enforcement action.

II. PROHIBITED ACTS

Some of the prohibited acts under the FDCA involve "adulterated"² or "misbranded"³ devices. In very general terms, a device is "adulterated" if there is or may be something wrong with it that makes or could make it unsafe and/or ineffective, e.g., the device was made without complying with the Quality System Regulation (QSR), the device was made under unsanitary conditions, or the device's quality falls below that represented. Another action that can render a device "adulterated" includes failure to obtain a required premarket approval (PMA).⁴

In general, a device is "misbranded" if there is or may be something wrong with its labeling that renders it false or misleading or could lead to the device's unsafe or ineffective use because the instructions for use are inadequate. Another action that can render a device "misbranded" includes failure to obtain a required 510(k) clearance.⁵

The FDCA sets out numerous prohibited acts,⁶ including, but not limited to:

- Interstate shipment⁷ of adulterated and/or misbranded medical devices, e.g., selling devices not made in conformance with FDA's QSR requirements.⁸
- Giving a false guaranty that a medical device complies with the FDCA.⁹
- Failure to register as a device establishment and/or to list a medical device with FDA.¹⁰

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¹ Pub. L. No. 75-717, 53 Stat. 1040 (1938).

² FDCA § 501, 21 U.S.C.A. § 351 (West 1999 & Supp. 2009).

³ FDCA § 502, 21 U.S.C.A. § 352 (West 1999 & Supp. 2009).

⁴ See FDCA § 501, 21 U.S.C.A. § 351 (listing all of the ways in which a device can be adulterated).

⁵ See FDCA § 502, 21 U.S.C.A. § 352 (listing all of the ways in which a device can be misbranded).

⁶ See FDCA § 301, 21 U.S.C. § 331 (West 1999 & Supp. 2009) (listing all of the FDCA's prohibited acts).

⁷ For purposes of enforcing the FDCA, there is a presumption that "interstate commerce" has occurred. FDCA § 709, 21 U.S.C.A. § 379a (West 1999).

⁸ FDCA § 301(a), 21 U.S.C.A. § 331(a) (West 1999).

⁹ FDCA § 301(h), 21 U.S.C.A. § 331(h) (West 1999).

¹⁰ FDCA § 301(p), 21 U.S.C.A. § 331(p) (West 1999).

- Failure to comply with Medical Device Reporting (MDR) obligations.¹¹
- Failure to comply with Investigational Device Exemption (IDE) requirements.¹²
- Failure to file a 510(k) submission before marketing a new medical device or a modified version requiring an additional clearance.¹³
- Submission of a false or misleading required report to FDA.¹⁴

III. ENFORCEMENT TOOLS

FDA has three types of enforcement tools at its disposal—advisory actions, administrative actions, and judicial actions—some established by statute and regulations, while others are a matter of policy.¹⁵ Advisory actions include Warning Letters and untitled letters. Administrative actions include administrative detention, recalls and civil penalties. Judicial actions include seizures, injunctions and criminal prosecutions.

A. *Advisory Actions*

1. *Warning Letters*

Noncompliances with FDCA requirements are frequently identified during the course of an FDA inspection. Upon completing an inspection, the FDA inspector may provide the firm with a written report—known as a Form FDA-483—identifying the conditions or practices that, in the inspector's judgment, may be violative of the FDCA.¹⁶ If FDA finds the firm's response to the Form FDA-483 observations inadequate, a common initial enforcement step is for the agency to issue a Warning Letter. However, not all Warning Letters are the result of a bad inspection and therefore many are not preceded by a Form FDA-483. FDA may issue a Warning Letter that deals with any alleged significant violations the agency believes the firm is responsible for. For example, a Warning Letter may be issued regarding violative advertising and promotional practices.

A Warning Letter is an FDA communication notifying an individual or firm that the agency considers one or more of its products, practices, processes or other activities to be in violation of the FDCA, and that failure of the responsible party to take appropriate action may result in administrative and/or regulatory enforcement action without further notice.¹⁷ Warning Letters are typically issued by the appropriate District Office and should be only issued for violations of regulatory significance. A Warning Letter is FDA's principal means of achieving prompt, voluntary compliance with the FDCA.

¹¹ FDCA § 301(q)(1), 21 U.S.C.A. § 331(q)(1) (West 1999).

¹² *Id.*

¹³ FDCA § 301(p), 21 U.S.C.A. § 331(p).

¹⁴ FDCA § 301(q)(2), 21 U.S.C.A. § 331(q)(2) (West 1999).

¹⁵ FDA Office of Regulatory Affairs, Regulatory Procedures Manual, Chapters 4, 5, and 6 (March 2010) available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm> (last visited Mar. 8, 2010).

¹⁶ FDCA § 704(b), 21 U.S.C.A. § 374(b) (West 1999).

¹⁷ FDA Office of Regulatory Affairs, Regulatory Procedures Manual, § 4-1 (March 2010), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf> (last visited Mar. 8, 2010).

Elements common to Warning Letters include:

- The title “WARNING LETTER”;
- Addressed to the highest known company official;
- The dates of inspection (if applicable) and a description of the violative condition, practice or product, including the section of law and/or regulation violated;
- Acknowledgement of any corrections promised during an inspection;
- A request for correction and a written response within a specific period of time after the date of the receipt of the letter (usually 15 working days);
- A warning statement that failure to correct the violative condition(s) may result in enforcement action without further notice;
- The following statement(s): “Federal Agencies are advised of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.”; For Warning Letters that include current Good Manufacturing Practices (cGMP) violations: “Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.”
- Instructions that the response include (as appropriate):
 - Each step that has been or will be taken to correct/prevent the violations;
 - Time of completion;
 - The reason(s) the corrective action has not been completed within the response time; and
 - Any documentation necessary to support that the violation has been corrected.
- A designated contact person.¹⁸

The appropriate District Office is required to follow up on any violations associated with a Warning Letter.

2. *Untitled Letters*

Another initial enforcement step that FDA sometimes takes is to issue an Untitled Letter. An Untitled Letter is a way for the agency to communicate with a firm about alleged violations that do not reach the same threshold of regulatory significance as alleged violations that result in a Warning Letter.¹⁹ The letter:

- Is not titled;
- Does not include a statement that FDA will advise other federal agencies of the issuance of the letter;
- Does not include a warning statement that failure to take prompt corrective action may result in an enforcement action;
- Does not evoke a mandated district follow-up; and
- Requests, rather than requires, a written response from the firm within a reasonable amount of time.

¹⁸ *Id.* at § 4-1-10.

¹⁹ *Id.* at § 4-2.

These letters are generally issued for alleged violations that are not associated with inspectional QSR violations.

B. *Administrative Actions*

1. *Administrative Detention*

If FDA determines that there is reason to believe that a device is adulterated or misbranded, FDA can order the device to be detained for up to 30 days.²⁰ A detention order may lead to a product seizure (which is discussed in more detail below). The main purpose of bringing an administrative detention action is to protect the public by preventing distribution or use of violative devices until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action.²¹

2. *Recalls*

FDA-requested recalls are ordinarily reserved for urgent situations. The request is made when the responsible firm does not undertake a product recall on its own initiative or when FDA believes that a recall action should be taken quickly and has not been informed by the firm that it has decided to undertake a recall. FDA-requested recalls are most often classified as Class I. Generally, before FDA formally requests a firm to conduct a recall action, the agency will have evidence capable of supporting legal action, i.e., seizure. Exceptions include situations where there exists a real or potential danger to health, or in emergency circumstances such as outbreak of disease involving epidemiological findings. The completion of either a firm-initiated or FDA-requested recall does not preclude FDA from taking further regulatory action against a responsible firm.²²

3. *Civil Penalties*

In an administrative proceeding, FDA can impose civil monetary penalties for FDCA violations related to medical devices. Civil penalties may be imposed against responsible individuals, as well as corporations. The maximum civil penalty for an individual or corporation is \$15,000 per violation, not to exceed \$1 million for all violations in a single proceeding.²³

In determining the amount of the penalty, FDA must take into account the nature, circumstances, extent and gravity of the violation(s) and the violators:

- Ability to pay;
- Ability to do business after imposition of the penalty;
- History of prior violations; and
- Degree of culpability.

²⁰ 21 U.S.C.A. § 334(g)(1).

²¹ FDA Office of Regulatory Affairs, Regulatory Procedures Manual, § 5-5-2 (March 2010), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074324.pdf> (last visited Mar. 8, 2010).

²² FDA Office of Regulatory Affairs, Regulatory Procedures Manual, § 7-5-2 (March 2010), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074312.pdf> (last visited Mar. 8, 2010).

²³ FDCA § 303(g), 21 U.S.C.A. § 333(g) (West Supp. 2009); see, also 21 C.F.R. Part 17 (2009).

FDA is given subpoena authority to require attendance of witnesses and production of evidence that relates to the matter under investigation.

In order to impose civil penalties, FDA must provide written notice to the individual or corporation and provide the opportunity for a full adjudicatory hearing in accordance with the Administrative Procedure Act.²⁴ Issuance of an order for civil penalties is reviewable by petition in the U.S. Court of Appeals for the District of Columbia or the circuit court where the business was transacted. The Secretary of Health and Human Services may compromise, modify or remit any civil penalty order.²⁵

Civil penalties may not be imposed for: i) MDR or QSR violations, unless the violations constitute a significant or knowing departure from MDR/QSR requirements, or present a risk to public health; ii) minor violations of device tracking requirements; iii) minor violations of the requirement to report a correction or removal, if substantial compliance with such requirements has been demonstrated; or iv) preparing, packing or holding medical devices under unsanitary conditions if the devices are not defective.²⁶

4. *Other Administrative Enforcement Tools*

FDA has a number of other administrative enforcement tools at its disposal:

- **PMA Suspension and Withdrawal**—FDA may withdraw or suspend the approval of a PMA if there is evidence that:
 - The device is unsafe or ineffective under the conditions of use prescribed, recommended or suggested in the labeling;
 - There is a lack of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended or suggested;
 - There is an untrue statement of a material fact;
 - The applicant has failed to maintain records or submit required reports;
 - The methods used in, or the facilities and controls used for, the manufacture, processing, packing or installation of the device do not conform with the requirements of GMP regulations;
 - The device labeling is false or misleading; or
 - The device does not conform to a performance standard.²⁷

- **Application Integrity Policy (FDA Fraud Policy)**²⁸—FDA's investigations regarding fraudulent data began as inquiries into illegal gratuities and questionable data in abbreviated new drug applications. The discovery of an extensive pattern of fraudulent data submissions prompted FDA to develop a program 1) to ensure validity of data submissions called into question by the agency's discovery of wrongful acts such as fraud, untrue statements of material fact, bribery, and illegal gratuities and 2) to withdraw approval of, or refuse to approve, applications containing fraudulent data.

²⁴ Pub. L. No. 79-404, 60 Stat. 237 (1946).

²⁵ FDCA § 303(g)(2)(C), 21 U.S.C.A. § 333(g)(A)(B) (West Supp. 2009).

²⁶ FDCA § 303(g), 21 U.S.C.A. § 333(g); *see, also* 21 C.F.R. Part 17.

²⁷ FDCA § 515(e), 21 U.S.C.A. § 360e(e) (West 1999).

²⁸ Application Integrity Policy Procedures (1998), *available at* <http://www.fda.gov/downloads/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm072631.pdf> (last visited Mar. 8, 2010).

An investigation may be conducted if there is evidence that a submission may contain a misstatement of material fact (false, misleading or unreliable information). When FDA finds that data in an application are unreliable, the agency will refuse to approve the application (in the case of a pending application) or proceed to withdraw approval (in the case of an approved application), regardless of whether the applicant attempts to replace the unreliable data with a new submission in the form of an amendment or supplement. The truthfulness and accuracy of the new application should be certified by the president, chief executive officer or other official most responsible for the applicant's operations.

FDA also may seek other enforcement actions, such as recalls, seizure, injunction, civil penalties and criminal prosecution, under the FDCA or other applicable laws, as necessary and appropriate.

The corrective actions an applicant will be expected to take will depend upon the facts and circumstances of each case, the nature of the wrongful acts, the nature of the data under consideration and the requirements of the particular review process.

Required corrective actions will normally include:

- (1) Full cooperation with FDA and other federal investigations to determine the cause and scope of any wrongful acts and to assess the effects of the acts on the safety, effectiveness or quality of products;
 - (2) Identification of all individuals who were or may have been associated with or involved in the wrongful acts and ensuring that they are removed from any substantive authority on matters under the jurisdiction of FDA;
 - (3) A credible internal review conducted by an outside consultant or team of consultants designed to identify all instances of wrongful acts associated with applications submitted to FDA;
 - (4) A written commitment to developing and implementing a corrective action operating plan to assure the safety, effectiveness and quality of their products. This commitment ordinarily will be in the form of a consent decree or agreement, signed by the president, chief executive officer or other official most responsible for the applicant's operations, and submitted to FDA.²⁹
- **Banning a Device**—In general, if FDA finds that a device presents substantial deception or an unreasonable risk of illness or injury, it may initiate proceedings to ban the device by promulgating a regulation.³⁰
 - **Notification Orders**—Where FDA determines that i) a device presents an unreasonable risk of substantial harm; ii) notification is necessary to eliminate the risk; and iii) no more practical means exist to eliminate such risk, FDA may order that a party provide adequate notification of the risk to all healthcare professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers and device users) who should properly receive such notification in order to eliminate such risk.³¹

²⁹ Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy; FDA Compliance Policy Guide 7150.09, 56 Fed. Reg. 46,191 (Sept. 10, 1991); Compliance Policy Guide available at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073837.htm> (last visited Mar. 8, 2010).

³⁰ FDCA § 516, 21 U.S.C.A. § 360f (West 1999); 21 C.F.R. Part 895 (2009).

³¹ FDCA § 518(a), 21 U.S.C.A. § 360h(a) (West 1999).

- **Safety Alerts**—If a firm chooses not to issue a notification, FDA may issue its own alert or warning. FDA will issue a Safety Alert in cases where users—either health professionals or the general public—do not understand or follow proper use instructions regarding a device. The alert will explain why problems may be occurring and clarify proper procedures to ensure safe and effective use of devices.³²

Tip: A Safety Alert issued by a firm may be considered a recall (i.e., a correction). Firms need to justify why a Safety Alert does not rise to the level of a recall.

- **Public Health Notifications**—FDA may also issue a Public Health Notification. A Public Health Notification is an important message from the Center for Devices and Radiological Health to the healthcare community describing a risk associated with the use of a medical device and providing recommendations to avoid or reduce the risk.³³
- **Repair, Replacement, or Refund Orders**—FDA may order manufacturers, importers or distributors (or any combination thereof) to submit a plan for device repair, replacement or refund where the agency determines that i) the device presents an unreasonable risk of substantial harm; ii) there are reasonable grounds to believe the device was not properly designed or manufactured under “state-of-the-art” conditions as they existed at the time of its design or manufacture; iii) there are reasonable grounds to believe that the risk is not due to improper installation, maintenance, repair or use on the part of someone other than the manufacturer, importer, distributor or retailer; iv) notification under 21 U.S.C. § 360h(a)³⁴ will not eliminate the risk; and v) repair, replacement or refund is necessary to eliminate the risk.³⁵ As part of a “repair, replacement, or refund” order, FDA can require a manufacturer, importer, distributor or retailer to reimburse another manufacturer, importer, distributor or retailer for expenses incurred in connection with carrying out the order if FDA determines such reimbursement is necessary to protect the public health.³⁶
- **IDE Withdrawal**—After an opportunity for an informal hearing, FDA may order the withdrawal of an IDE approval on various grounds. The order can issue without a prior informal hearing if FDA determines that continued testing under the IDE approval will result in an unreasonable risk to the public health.³⁷
- **Import Detentions and Refusals of Admission**—FDA can detain and refuse admission to devices for import which *appear* to violate the FDCA.³⁸

Tip: While it may be cheaper to manufacture medical devices overseas, FDA’s ability and willingness to issue import detentions and refusals of admission to stop the sale of allegedly violative devices makes it easier to do this to foreign manufactured devices than those manufactured in the U.S.

³² See Food and Drug Administration, Alerts and Notices (Medical Devices), available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm> (last visited Mar. 9, 2010).

³³ See Food and Drug Administration, Public Health Notifications, available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/default.htm> (last visited Mar. 9, 2010).

³⁴ See discussion on notification orders *supra*.

³⁵ FDCA § 518(b), 21 U.S.C.A. § 360h(b) (West 1999).

³⁶ FDCA § 518(c), 21 U.S.C.A. § 360h(c) (West 1999).

³⁷ FDCA § 520(g)(5), 21 U.S.C.A. § 360j(g)(5) (West 1999); 21 C.F.R. § 812.30 (2009).

³⁸ FDCA § 801, 21 U.S.C.A. § 381 (West 1999 & Supp. 2008).

- **Voluntary Recalls**—FDA can attempt, through publicity or otherwise, to pressure a firm to conduct a voluntary recall where it views a device as violative under the FDCA.³⁹

C. *Judicial Actions*

- FDA is authorized to take a number of actions in response to the actual or alleged commission of a prohibited act. Before resorting to more significant enforcement action, FDA typically takes one or more of the initial enforcement steps outlined above, e.g., issuance of an Untitled Letter or Warning Letter. If the firm fails to correct its violative activities, however, or if the violations in question are particularly serious, or repetitive, FDA may utilize one or more of its main enforcement tools: seizure, injunction, or criminal prosecution.

1. *Seizure*

A seizure is otherwise known as a “Complaint for Forfeiture.” The United States of America, as plaintiff, proceeds under the Supplemental Rules for Certain Admiralty and Maritime Claims by filing a Complaint for Forfeiture. A seizure is an *in rem* (“against the thing”) proceeding initiated by the U.S. Attorney on behalf of FDA by filing a complaint in federal court against the violative product.⁴⁰ A judicial warrant will be issued by the court directing the U.S. Marshal to take custody of the product. No formal notice is required prior to seizure of allegedly adulterated or misbranded product.

Any interested party, owner or agent may appear to claim the article by filing a verified claim stating the nature of his or her interest in the article. Seized product is subject to condemnation, forfeiture or destruction, if it cannot be reconditioned.

There are four types of seizures—single, mass, open-ended and multiple. A single seizure is against a single product or lot of product. A mass seizure is the seizure of all FDA-regulated products at an establishment/facility. Mass seizures might be conducted when all of the products are held in the same environment (e.g., a filthy warehouse) or are produced under the same conditions (e.g., non-conformance with QSR). An open-ended seizure is the seizure of all units of a specific product or products, regardless of lot or batch number, when the violation is expected to be continuous. The term “multiple seizures” is used to describe the seizure of the same product in more than one district court. Multiple seizures may be initiated to prevent the continued distribution or use of violative product at more than one location, particularly product that is dangerous.

Tip: Device seizures are not that common because of the time and expense to bring such an action compared to the benefit of such an action to the public health. FDA will usually look to a voluntary or mandatory recall instead of a seizure.

³⁹ See 21 C.F.R. Part 7 (2009) for guidelines on voluntary recalls; *see also* discussion of voluntary recalls in Chapter 6.

⁴⁰ FDCA § 304, 21 U.S.C.A. § 334 (West 1999 & Supp. 2008).

2. Injunction

An injunction is a civil process initiated to stop or prevent violation of the law, such as to halt the flow of violative products in interstate commerce, and to correct the conditions that caused the violation to occur.⁴¹ FDA, through the U.S. Attorney, can initiate a legal action in federal district court to enjoin a device firm and its officers from violating the FDCA, e.g., promoting and distributing allegedly violative medical devices. FDA is not required to demonstrate that the law has been broken in order to seek an injunction. It is only necessary to show that there is a likelihood that the law may be violated if an injunction is not entered. According to FDA, an injunction should be considered for any significant “out of compliance” circumstance, but particularly when a health hazard related to the violation has been identified.⁴² FDA may consider an injunction to be appropriate when violations are pervasive and affect many different products (e.g., significant QSR violations) or when the agency has previously warned the firm about its violative practices.

An injunction action begins with the filing of a Complaint for Injunction by an Assistant United States Attorney. The complaint is filed against one or more individuals and/or corporations and asks the court to restrain and enjoin the defendants from continuing to violate the law (e.g., to halt the flow of violative products in interstate commerce) and to correct the conditions that caused the violation to occur.⁴³

The complaint is then personally served on the corporation and each individual. Under certain circumstances, a Temporary Restraining Order (TRO)⁴⁴ may be issued without prior notice.

The firm may contest the injunction in court or settle the case according to an FDA consent decree of permanent injunction. If the court enters the injunction, the firm must comply immediately, unless it obtains a stay of the court order, pending an appeal.

3. Criminal Prosecution

The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters. If OCI chooses not to pursue a criminal matter, the District Office is at liberty to proceed with the case in accordance with the FDA administrative procedures.⁴⁵ FDA, through the U.S. Attorney, can initiate criminal proceedings in federal district court against a device firm and/or its officers for violating the FDCA. Before initiating criminal proceedings, FDA is required by section 305 of the FDCA to give the targeted entity an opportunity for hearing, in which the entity can present its views (orally or in writing) with regard to the contemplated proceeding,⁴⁶ but this is not always done and some courts have determined that it is not legally required.

⁴¹ *Id.*

⁴² FDA Office of Regulatory Affairs, Regulatory Procedures Manual, § 6-2 (2006), available at http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch6.pdf (last visited Mar. 9, 2010).

⁴³ See FDCA § 302, 21 U.S.C.A. § 332 (West 1999); see also Fed. R. Civ. P. 65.

⁴⁴ A temporary restraining order is a court enforced cease and desist order that is brought to control an emergency situation. A TRO seeks immediate, temporary relief (for a period of 10 days, which may be extended for 10 additional days) prior to a hearing for a preliminary injunction.

⁴⁵ FDCA §§ 301, 303, 21 U.S.C.A. §§ 331, 333 (West 1999 & Supp. 2009).

⁴⁶ FDCA § 305, 21 U.S.C.A. § 335 (West 1999).

a. *Misdemeanor Violations*

For misdemeanor violations, criminal intent is not required. A single FDCA misdemeanor violation is punishable by a maximum of one year incarceration, and a fine of \$100,000 for an individual and \$200,000 for a corporation.

b. *Felony Violations*

Felony prosecution under the FDCA involves violations where there was “intent to defraud or mislead” or where the violation represents a repeat offense. A single FDCA felony violation is punishable by a maximum of three years incarceration, and a fine of \$250,000 for an individual and \$500,000 for a corporation. In addition, a defendant may be required to pay twice the monetary gain derived from or loss caused by the violative conduct.⁴⁷

c. *Park Doctrine*

Under what has come to be known as the “*Park Doctrine*,” company officers can be held personally responsible for FDCA violations in misdemeanor criminal prosecutions and for violations even where the statute is devoid of language requiring proof of specific intent. Courts have found that persons in management have an affirmative duty to ensure that FDA-regulated products are safe and effective. Executives of a company that violates the FDCA can be criminally prosecuted in federal court, even if they did not personally engage in, or ever know about, the activity. Courts have viewed such executives as being obligated to prevent and correct violative acts, and will hold them responsible.⁴⁸

III. CONCLUSION

FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. It enforces the FDCA through the use of advisory, administrative and judicial actions and may take such actions against products, companies and/or individuals. FDA enforcement actions serve as punishment for those who have violated the FDCA and as a deterrent to prevent others from committing the same or similar violations. Individuals and firms need to be aware of the potential consequences of violating the FDCA and take steps to prevent such violations.

⁴⁷ FDCA § 303(a), 21 U.S.C. § 333(a) (West 1999 & Supp. 2009); 18 U.S.C. § 3571 (West 2009).

⁴⁸ See, e.g., *United States v. Park*, 421 U.S. 658 (1975).