Enforcement Mechanisms Available to the FDA

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Introduction

The mission of the Food and Drug Administration is to protect public health by ensuring compliance of products and goods with the Food, Drug, and Cosmetic Act. In order to do this, the FDA, through its centers, conducts post-market enforcement activities which include the removal of nonconforming products from the market and other actions to correct the violations. The type of enforcement activity is commensurate with the violations and may include a letter notifying the firm and requesting a correction to the criminal prosecution of the responsible firm or individual(s).

This whitepaper discusses the types of enforcement tools available to the FDA and what it means to the firm or the individual(s) involved.

Administrative Mechanisms Available to the FDA

There are a variety of administrative mechanisms that the FDA employs to enforce an action such as:

Warning Letters

When FDA identifies that a company has significantly violated FDA regulations, they notify the company via a letter that identifies the violation such as poor manufacturing practices, problems with claims for what a product can do, issues with regulatory clearance, or incorrect instructions for use … to name some examples that would warrant a Warning Letter. Remember a Warning Letter is leveraged to ignite voluntary compliance from the company.

In the case of a Warning Letter, time is of the essence. The company has 15 business days to respond to a Warning Letter indicating the corrective action(s) the company is going to take. If a company does not comply with responding to the Warning Letter, it could lead to seizure, injunction, or other enforcement actions.[6]

According to Levine (2012), "The basic elements of a Warning Letter are fairly straightforward. The letter summarizes the facts or circumstances found during an FDA inspection, labeling review, adverse reaction report, recall, or some other underlying event. The letter asserts that those facts or circumstances cause the recipient's products to be adulterated or misbranded, and describes the facts giving rise to a finding of noncompliance."[6]

It is important when responding to a Warning Letter that a company does not argue with the FDA, rather they should indicate what due diligence they plan on implementing to correct the non-compliant events.[1]

Inspections and 483s

The Office of Regulatory Affairs (ORA) at FDA leads inspections of companies. During these inspections, if ORA investigators observe conditions that they feel may be non-compliant, they list the observations on an FDA Form 483 and present it to company management.[2] Moreover, "FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and significant. Observations are made when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device, or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.".[2] Form 483 is an enforcement action to have a company respond and indicate in writing their corrective action plan. In many cases, an organization's response to form 483 will remedy the observations cited, resolve the non-compliance, and as a result, no further enforcement action is warranted by FDA.[6]

Adverse Publicity and Recalls

FDA first hears about a problem product in several ways; a company discovers a problem and contacts FDA, FDA inspects a manufacturing facility and determines the potential for a recall, FDA receives reports of health problems through various reporting systems such as the MedWatch, and/or the Centers for Disease Control and Prevention (CDC) contacts FDA[3] or in some cases, the FDA monitors the company's website and social media presence. It is important to note that recalls are almost always voluntary. In many cases, a company discovers a problem and recalls a product on its own. Other times, a company recalls a product after FDA raises concerns. It is rare for FDA to request a recall.[3] However, in every case, FDA's role is to oversee a company's strategy and assess the adequacy of the recall.

When the FDA feels that a harmful product has spread throughout the public, they will seek to officially announce the recall to protect the public. Often the chosen course of action to do this is the news media.[3]

Major Statutory Enforcement Authority Under the Food, Drug, and Cosmetic Act

Seizures

According to the Regulatory Procedures Manual, "The United States of America, as plaintiff, proceeds under the Supplemental Rules for Certain Admiralty and Maritime Claims (Supplemental Rules) by filing a Complaint for forfeiture and obtaining a warrant for arrest, directing the United States Marshal to seize (take possession or place in constructive custody of the court) the article." [4] It is important to remember that when a seizure occurs, the goods are

considered "arrested" as a seizure is a judicial civil action that is focused on a single offending good. As stated by FDA, "The court orders the arrest of the goods by issuing a motion and warrant to the U.S. marshal, directing seizure of the goods. The marshal seizes the goods, which then become the property of the court." [5]

The compliance officer and the district managers evaluate the following factors before initiating a seizure case: prior warning, home district concurrence, voluntary hold or embargo, size of lot to be seized, violations which appear easily corrected, violations when the agency has other means of control, voluntary reconditioning, continuing violations, section 702(b) samples, preservation of shipping records, and trial venue.[4]

In regard to seizures, FDA would recommend a seizure to the U.S. Attorney in the state where the products are located.[6] Upon agreement by the U.S. Attorney to initiate the seizure action, a complaint is then filed in a federal court.6 Subsequently, "the clerk of the court issues a warrant for the "arrest" (the seizure) of the products. Usually, a Deputy U.S. Marshal will make the seizure".[6]

Injunctions

An injunction is a civil restraint issued by the court to reduce the flow of non-compliant products in interstate commerce and to correct the conditions in the company.[5] What makes an injunction different from a seizure is that injunction actions must be processed in strict time frames.[5]

According to the 2015 Regulatory Procedures Manual, "For an injunction action to be credible in the eyes of the Department of Justice (DOJ), the U.S. Attorney, and the court, the evidence must be current. Timeliness is an important factor when considering an injunction action, with or without a Motion for Preliminary Injunction, or a temporary restraining order (TRO). However, case quality and credibility must not be sacrificed to meet guideline time frames. The purpose of the guideline time frames is to limit, as much as can reasonably be expected, the need to update evidence." [4]

Once the injunction is granted, FDA has the obligation to monitor the injunction and notify the court if the defendants are in violation of their injunction.[5]

Criminal Prosecutions

The Office of Criminal Investigations (OCI) will promptly decide whether or not to pursue a criminal referral case.[5] The Office of Criminal Investigations (OCI) is the point of contact for all criminal matters and is accountable for reviewing all FDA matters that recommend a criminal investigation. According to the 2015 Regulatory Procedures Manual, "this includes criminal search warrants, misdemeanor prosecutions, felony prosecutions, referrals for criminal

investigation, and Section 305 meetings. District management must communicate with the local OCI office before pursuing any criminal matter."[5]

Also, in criminal prosecution, it is important to know what the 'park doctrine' is. This doctrine was established by Supreme Court case law and, "provides that a responsible corporate official can be held liable for a first-time misdemeanor (and possible subsequent felony) under the Federal Food, Drug, and Cosmetic Act ("the Act") without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense." [5]

Criminal Fines for Food Drug and Cosmetic Act Violations

Misdemeanor fines under the Act may reach $500,000 under some circumstances. The Criminal Fine Enforcement Act of 1994 (Public Law 98-596) provides for fines for violations of Federal law. Although it is not part of the Act, the Criminal Fine Enforcement Act of 1994 applies to all fines levied under the Act, as well as other statutes that contain provisions enforced by FDA.

The following fines are applicable for each offense:[7]

Up to $100,000 for a misdemeanor by an individual that does not result in death.
Up to $200,000 for a misdemeanor by a corporation that does not result in death.
Up to $250,000 for a misdemeanor by an individual that results in death, or a felony.
Up to $500,000 for a misdemeanor by a corporation that results in death, or a felony.
The maximum imprisonment for a misdemeanor under the Act remains a year for each offense.

Other Federal Agencies or Actors Involved in Enforcement Activities

Within FDA

Department or Non-Departmental Entity and Component	Law Enforcement Mission	Primary Authorities
Department of Health and Human Services, Food and Drug Administration, Office of Criminal Investigations (OCI)	The mission of the Office of Criminal Investigations (OCI) is to investigate suspected criminal violations of the Federal Food, Drug, and Cosmetic Act (FDCA); the Federal Anti-Tampering Act (FATA); and other statutes including applicable Title 18 violations; and to collect evidence to support successful prospective actions through the federal or state court systems as appropriate. OCI was established to provide an additional enforcement resource to augment the Food and Drug Administration's inspectional, compliance, and regulatory efforts. OCI concentrates its resources on investigations of significant violations of the FDCA and FATA which pose a danger to the public health. OCI is the entity within the Food and Drug Administration (FDA) responsible for the conduct and coordination of criminal investigations and, as such, maintains liaison and cooperative investigative efforts with other federal, state, local, and international law enforcement agencies.	21 U.S.C. 372(e) 21 C.F.R 5.31 Rule 41 of the Federal Rules of Criminal Procedures as stipulated in 60.2(b) and 60.3(a)(3) of Title 28 of the Code of Federal Regulations

The chart above depicts the authority (actor) within FDA that helps enforce FDA compliance.[8]

Other Agencies

In its enforcement efforts, FDA relies upon partnerships with local, state, federal and international agencies to help with enforcement activities. Some of the agencies the FDA interacts/partners with are the following:

- Federal Trade Commission (FTC)
- Department of Health & Human Services (HHS)

- Department of Homeland Security
- Department of Justice
- Department of Labor: Occupational Safety and Health Administration
- Treasury Department

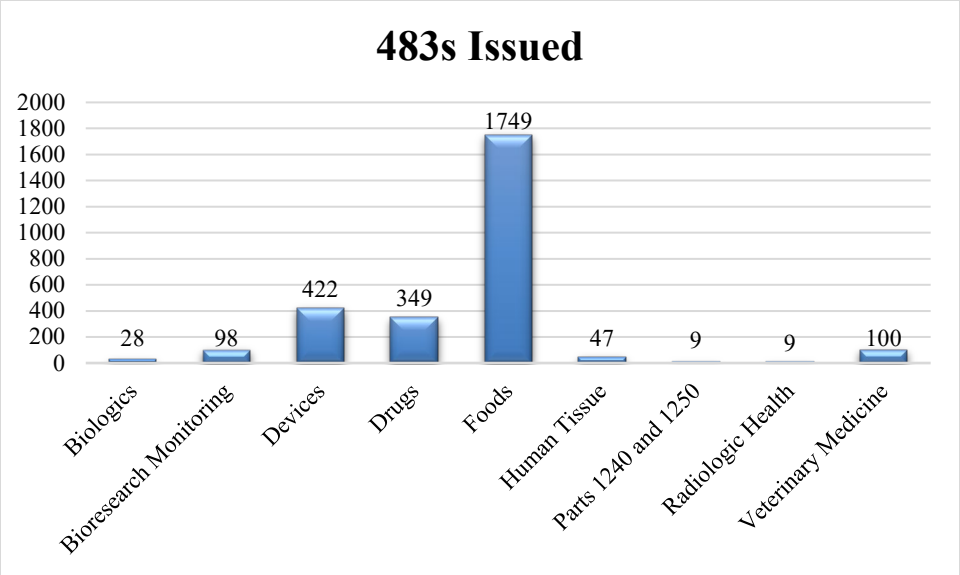
Form 483s and Warning Letters Issued in FY 2020

The pandemic has definitely impacted the enforcements from the FDA. A total of 2811 Form 483s[9] and 5508 warning letters[10] were issued in FY 2020, which is a massive decline from 4849 Form 483s[9] and 15,098 warning letters[10] in 2019. The graphs below show the number of 483s and warning letters issued as a result of inspection, investigation, or surveillance activity for FY 2020 by each product area. There were no injunctions or seizures reported in FY 2020.

Most of the 483s that were issued in FY 2020 were for the food, medical devices, and the drug industries, respectively. The most cited observation for the three respective industries is tabulated below:

Reference Number	Description	Product Area
21 CFR 1.502(a)	Firms failed to develop a Foreign Supplier Verification Program	Food
21 CFR 820.100(a)	Inadequacy or lack of firms to establish a robust CAPA Program	Medical Devices
21 CFR 211.22(d)	Firms failed to establish or follow quality control practices	Drugs

Data source:[9]



Data source:[9]

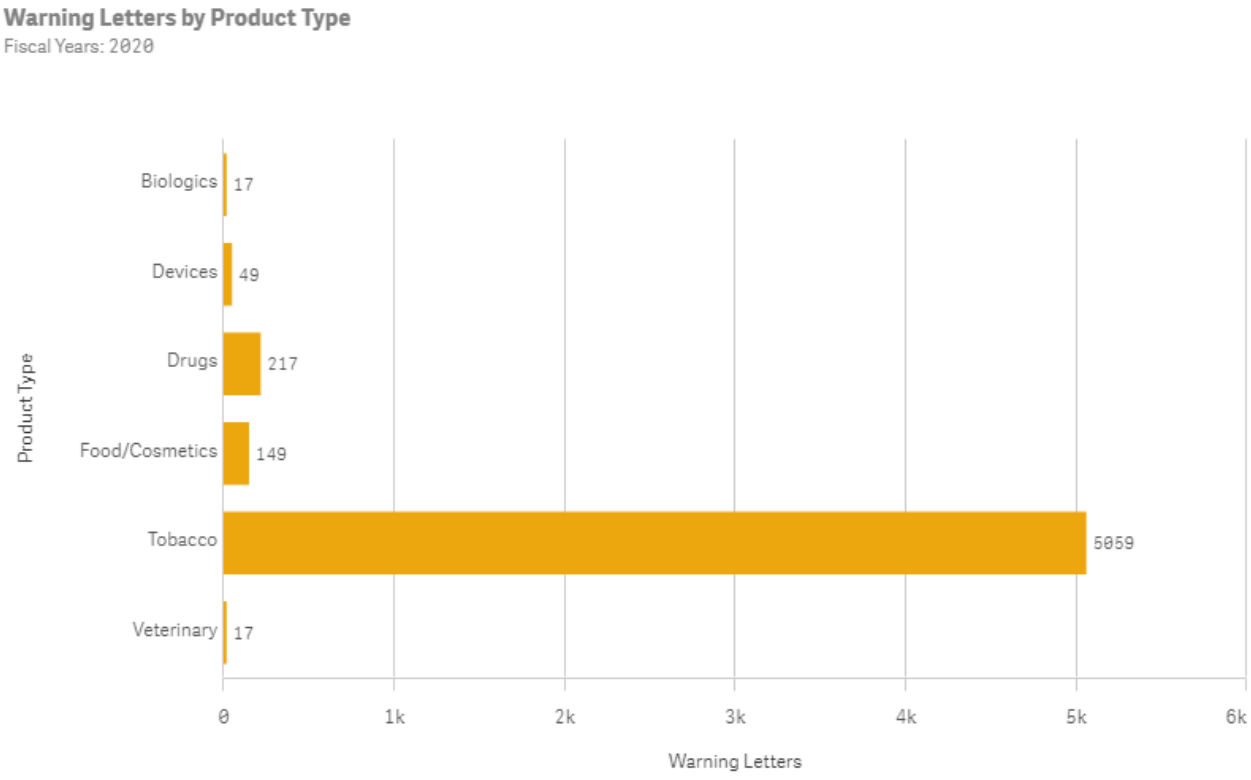


Image source:[10]

The graph below illustrates the number of foreign and domestic inspections conducted in FY 2020. The steep decline in the number of inspections in the April-July timeframe is attributable to the period when FDA halted all of their foreign inspections due to the public health emergency declaration and were only performing for cause inspections on a case-by-case basis.

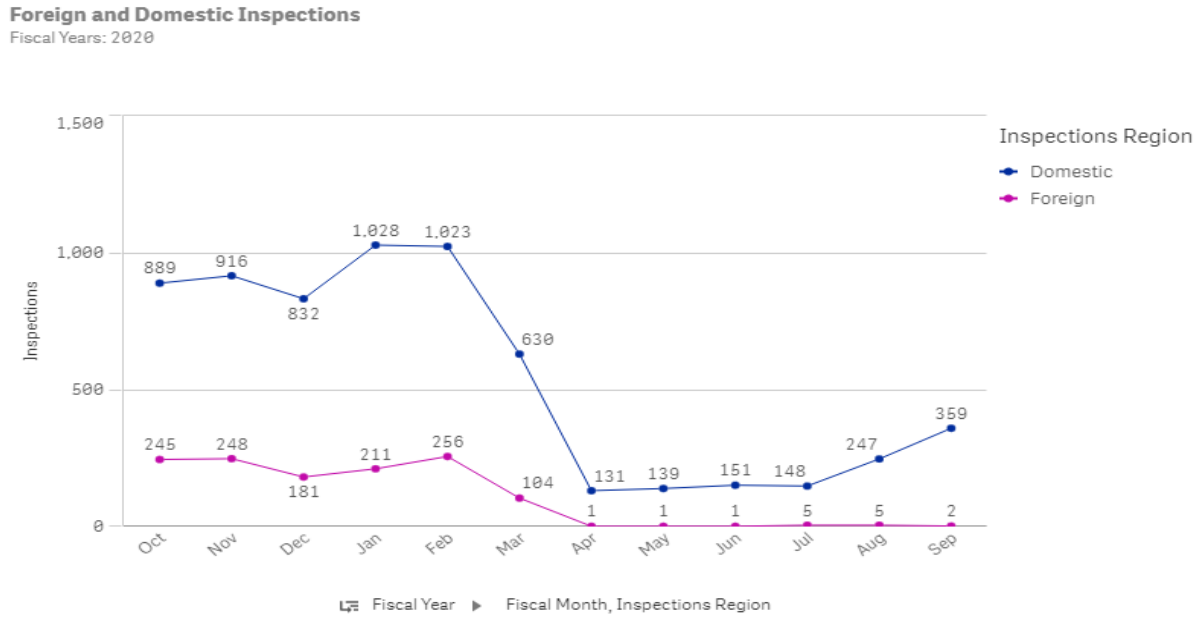


Image source[11]

Conclusion

An enforcement action is definitely not something any firm wants to deal with. However, the repercussions can be serious if any type of enforcement action is ignored. While the pandemic surely has derailed the FDA in its enforcement activities, the agency plans to pick back up on its list of priorities to recoup for the lost time. While COVID related products will continue to be the target of strict compliance scrutiny, staff members at the agency are working diligently to bring business back to normal for other industries and products as well. Seek expert advice today if you have received any type of enforcement action from the FDA, or if you are unsure whether your current practices are in compliance with the regulations by calling EMMA International at 248-987-4497 or send an email to info@emmainternational.com.

References

[1] FDA (2015). Procedures for Clearing FDA Warning Letters and Untitled Letters. Retrieved from: http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM176965.pdf

[2] FDA (2015). FDA Form 483 Frequently Asked Questions. Retrieved from: http://www.fda.gov/ICECI/Inspections/ucm256377.htm

[3] FDA (2015). FDA 101: Product Recalls. Retrieved from: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm

[4] FDA (2015). Regulatory Procedures Manual. Retrieved from: http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074317.pdf

[5] FDA (2015). Inspections, Compliance, Enforcement, and Criminal Investigations. Retrieved from: http://www.fda.gov/ICECI/Inspections/IOM/ucm122510.htm

[6] Levine, A. N. (2012). FDA Enforcement: How It Works. In K. R. Piña, & W. L. Pines, A Practical Guide to FDA's Food and Drug Law and Regulation (pp. 1-509). Washington, D.C.: FDLI.

[7] FDA (2017) Types of FDA Enforcement Actions. Retrieved from https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions

[8] Government Accountability Office (GAO) (2006). Number of LEOs, Federal Job Series Classifications, and Sources of Primary Authorities, as Reported by the 104 Federal Components. Numbers of LEOs are as of June 30, 2006. Retrieved from: http://www.gao.gov/special.pubs/gao-07-223sp/law_enforcement_survey_table.html

[9] FDA (2020) Inspection Observations retrieved from https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations

[10] FDA- Compliance Actions retrieved from https://datadashboard.fda.gov/ora/cd/complianceactions.htm

[11] FDA- Inspections retrieved from https://datadashboard.fda.gov/ora/cd/inspections.htm