

Who Decides Your Fate in FDA Enforcement Matters?



by John R. Fleder

The Food and Drug Administration (FDA) takes various types of enforcement actions, either directly or through the Department of Justice (DOJ). Most readers of this publication are quite familiar with those actions. However, what is probably less clear is what companies should do if they want to prevent an enforcement action. They have the right, and sometimes the opportunity, to seek to communicate with the government officials involved in the decisions to take such actions. This article breaks down the key enforcement mechanisms available to FDA, and provides an outline of the various offices that are involved in the decision making.

Companies will often first hear that they have a “problem” when they are inspected by FDA and receive an FDA Form 483. Companies seeking to head off potential enforcement actions should generally avoid directly contacting the FDA investigators who conducted the inspection.¹

Warning (and Untitled) Letters

In general, FDA’s Centers issue Warning Letters for alleged: labeling violations, computer application and software violations, Bioresearch Monitoring Program violations, product advertising violations and some other violations. FDA’s Districts issue Warning Letters for other types of violations.²

If a Center issues the Warning Letter (or an Untitled Letter), it is drafted by a Center Consumer Safety Officer (CSO) or a Center scientist; a “final” draft is sent to FDA’s Office of Chief Counsel (OCC) for review and concurrence. Once OCC concurs, the Warning Letter is finalized and normally signed by the Center’s Division or Office Director.³

If a District issues a Warning Letter, it is drafted by a Compliance Officer in the District where the company resides; a “final” draft is sent to OCC for review and concurrence. Once OCC concurs, the Warning Letter is finalized by the District and is typically signed by the District Director.⁴

Some Warning Letters issued by a District need Center concurrence.⁵ In those instances, the proposed Warning Letter is sent by the District to the Center CSO/scientist for review/concurrence, as well as to OCC. Once concurrence is received from both the Center and OCC, the letter is finalized by the District, and the District Director generally signs it.⁶

Seizures

FDA has the statutory authority to ask the DOJ to initiate a civil seizure action, seeking a court order to condemn adulterated and misbranded foods, drugs, devices and cosmetics.⁷ The initial recommendation for a seizure action usually comes from the District that conducts an inspection of a firm that may hold or manufacture allegedly violative products.⁸

A District Compliance Officer drafts the recommendation memo for the seizure and the supporting legal documents. After approval from the District Director, it is sent to the pertinent Center for review and approval. In some instances, the Center is bypassed and the recommendation is sent directly to FDA’s Office of Regulatory Affairs (ORA), Office of Enforcement, Division of Compliance Management and Operations (DCMO).⁹

The Center CSO/scientist will write an approval memo.¹⁰ The recommendation is sent to FDA’s ORA, which reviews the proposed action for adherence to agency policy and assures that the necessary documents (proposed letter to the Justice Department, a draft Complaint, and other necessary pleadings) are complete and address the needs of the specific jurisdiction where the seizure action will be filed.¹¹

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The completed recommendation and draft documents are sent to the OCC, where its Deputy Associate General Counsel for Litigation or his Deputy will review the documents for substance and make any necessary changes, and either approve or disapprove the proposed action. The proposed pleadings are returned to ORA for further revisions. OCC also notifies the District's Compliance Officer and Center CSO/scientist of the OCC attorney assigned to the case.

A District Compliance Officer will deliver the letter (that goes out under the name of FDA's Chief Counsel) recommending the seizure action to an Assistant United States Attorney (AUSA) located in the judicial district where the goods are located.¹² At the same time, FDA will forward a copy of that letter to the Office of Consumer Litigation (OCL) of the Civil Division of the Justice Department. However, the AUSA is permitted to file the seizure action without having received approval or concurrence from the Justice Department.

Once the seizure action is filed, litigation of the case is handled by an AUSA, a lawyer from FDA's OCC, a lawyer from OCL or any combination of the three organizations. An FDA Compliance Officer will be the primary investigative agent assigned to the case.

Injunctions

FDA also has the authority to ask the DOJ to initiate a civil action against companies and individuals, seeking a court order to prohibit those persons from violating the Federal Food, Drug, and Cosmetic Act (FDCA).¹³ Proposed injunction actions are generally recommended by a District, normally after a series of inspections that suggest serious violations of the FDCA.¹⁴

The District Compliance Officer assigned to the matter drafts an injunction recommendation, which will include a memorandum, draft complaint, and other necessary pleadings.¹⁵ The recommendation is forwarded to the relevant Center, where a Center CSO/scientist will review the recommendation and write a memorandum approving or disapproving the recommendation for an injunction.¹⁶ The CSO/scientist can make changes to the relief sought or may decline or accept all or some of the proposed charges. Once the Center has prepared the memorandum approving the recommendation, the package is sent to OCC.¹⁷

The injunction recommendation is substantively reviewed by OCC's Deputy Associate General Counsel for Litigation and/or his Deputy, and one or more staff attorneys in OCC. If

there is sufficient evidence to support the charges, the OCC attorney writes a proposed "referral letter" to DOJ, reviews and revises the proposed complaint and other pleadings, and prepares a draft Consent Decree.¹⁸

OCC formally sends the proposed case to the Justice Department's Director of OCL. The Director then assigns the case to a staff attorney who will review the proposed case for its merits. If OCL believes the case has merit, the OCL staff attorney will customarily send a "sign-or-sue" letter to the proposed defendants (or their counsel if known). That letter will advise the defendants about the proposed case, and will offer them an opportunity to sign a proposed Consent Decree that is forwarded with the letter.

Sometimes, the proposed defendants will agree to the proposed Consent Decree, or will seek changes that may be acceptable to FDA and DOJ. In other instances, the defendants will not agree, and the Justice Department will want to file an action seeking injunctive relief when it appears the defendants are prepared to litigate the matter. Under either scenario, the Director of OCL must write a memorandum to the Deputy Assistant Attorney General who supervises OCL, and to the Assistant Attorney General (AAG) for the Civil Division of the Justice Department, recommending that the case be filed. Once the AAG approves the proposed case, an OCL attorney will forward the proposed action to the United States Attorney's Office in the judicial district where the case is to be brought. That district is generally where the company and its officers reside. Depending on the practice in the United States Attorney's Office, there may be further review of the proposed case by an AUSA.

Once the injunction action is filed, litigation of the case is handled by an AUSA, a lawyer from FDA's OCC, a lawyer from OCL or any combination of the three organizations. An FDA Compliance Officer will be the primary investigative agent assigned to the case.

Civil Money Penalties

FDA has not published procedures for handling civil money penalty (CMP) cases, except for a procedure for cases emanating from the Center for Devices and Radiological Health (CDRH). To pursue a CMP action, a District investigator usually documents a firm's repetitive or knowing violative conduct and prior warnings given by FDA to the firm. The District then recommends the CMP action to the Center.¹⁹

The Center reviews the recommendation and determines whether the evidence and supporting documentation are adequate. The Center will forward the District's recom-

mentation to DCMO, prepare a memo, and notify DCMO whether it concurs or disapproves the District's recommendation.²⁰ DCMO reviews the matter and forwards the recommendation to OCC.²¹

OCC provides final legal review of the documents and determines the legal sufficiency of the evidence. OCC designates an attorney responsible for the case.²²

In some instances, CMP cases can be initiated by FDA through its own administrative procedures that involve a hearing before an Administrative Law Judge. In other instances, FDA must ask the Justice Department to file a CMP action in court. In general, the procedure used will depend on the statutory CMP authority, which will dictate in certain circumstances that the penalty can only be sought in a court action.²³

CMP actions brought directly by FDA will generally be prosecuted by a lawyer in FDA's OCC.²⁴ Actions commenced in court will be coordinated with the DOJ.

Criminal Prosecutions

FDA also has the statutory authority to recommend to the Justice Department that it commence a criminal prosecution against individuals and corporations.²⁵ The system for initiating such prosecutions dramatically changed when FDA created its Office of Criminal Investigations (OCI) in 1992.²⁶ Before OCI was created, FDA had a formal "referral" system whereby any proposed criminal prosecution went from FDA's OCC to OCL at the Justice Department. Now few, if any, cases follow that procedure. Instead, most criminal matters go from OCI directly to a U.S. Attorney's Office. Others proceed via a "referral" from OCI to OCL. Still others proceed via a referral from other investigative agencies, such as the Federal Bureau of Investigation (FBI), to a U.S. Attorney's Office or to OCL.

We will first address the rare instance where FDA's OCC refers a case to OCL. The initiator of a criminal matter will generally be a District which has observed what it believes is criminal conduct as a result of an inspection. Prior to pursuing any criminal matter, the District management must communicate with its local OCI.²⁷ The District prepares a recommendation for prosecution or for investigation.²⁸ Each recommendation must be accompanied by the written concurrence of the District Director and the Regional Food and Drug Director.²⁹ If DCMO concurs in the prosecution recommendation, it will forward all relevant materials to OCC. If OCC concurs, it prepares a referral letter and a proposed Information or Indictment.³⁰ Thereafter, FDA's

Chief Counsel will send the referral letter to the Director of OCL at the Justice Department.

The typical FDA criminal case does not follow this process. Instead, OCI obtains information from various sources suggesting that criminal violations have occurred. Sources include other FDA employees, other federal and state agencies, current and former employees of companies alleged to have violated the law, prosecutors, media reports and whistleblower lawsuits. OCI has implemented a process where it generally takes potential cases directly to an AUSA,³¹ without obtaining approval from other FDA components and offices. However, OCI frequently does consult with FDA's Centers, Districts and OCC regarding scientific and legal issues that may be presented in a particular matter. In addition, OCI will often work with other federal and state agencies to jointly investigate a case.

OCI cannot initiate a criminal case on its own. Instead, it must convince either a U.S. Attorney or OCL to bring a case. Federal regulations provide that OCL has handling or supervising authority for criminal proceedings brought under the FDCA.³² In instances where OCL is involved, it must obtain approval to initiate the prosecution from the Deputy Assistant Attorney General who supervises OCL, and ultimately from the Assistant Attorney General for the Justice Department's Civil Division. However, U.S. Attorneys' Offices commence criminal cases under the FDCA without following these approval policies.

Once a criminal case is initiated, it will be prosecuted by an Assistant U.S. Attorney, an OCL attorney, an OCC attorney or any combination thereof.

AIP Procedures

If a FDA employee suspects a wrongful act that could warrant a company being placed on FDA's Application Integrity Policy (AIP), the employee is to discuss those observations with a supervisor and forward issues requiring discussion to FDA's "Application Integrity Policy Committee" (AIP-C).³³ The AIP-C is comprised of members, one of whom is a chairperson, from each Center and ORA. OCC advises on legal matters. Each member is known as an "AIP contact person." The purpose of the AIP-C is to meet regularly to discuss the AIP, including consistent implementation of the AIP.³⁴

When a District believes that someone should be considered for inclusion on the AIP, the District must submit a recommendation to the Center's Office of Compliance.³⁵ If Compliance concurs, it will prepare a letter advising a firm

that the Center has invoked the AIP. The letter is prepared for the Center Director's signature.³⁶ The Center is also to notify FDA's OCI and OCC.³⁷

Debarment

FDA has the statutory authority to debar persons from being involved, *inter alia*, in drug applications submitted to FDA, and from being involved in food imports.³⁸ FDA notifies persons of the agency's intention to debar someone and provides that person with an opportunity to seek a hearing to contest the proposed debarment. Thereafter, notice of the debarment action is published in the *Federal Register*.

Various persons within FDA's Center for Drug Evaluation and Research, Center for Veterinary Medicine and Center for Biologics Evaluation and Research have been authorized to send out notices of an opportunity to contest a debarment action.³⁹ Normally, FDA employees in these Centers (and also the Center for Food Safety and Applied Nutrition) will learn that a person has been convicted of a crime that could support a debarment action. This information will often come from OCI. The Center will draft proposed debarment papers, submit them to OCC for review and comment, and then initiate the debarment action after OCC has provided the necessary clearance.

Detention

FDA has the statutory authority to detain medical devices and food products.⁴⁰ FDA investigators can detain food products that are found during an FDA inspection, examination or investigation when the investigator has credible evidence that the food presents a threat of a serious adverse health consequence or death to humans or animals.⁴¹ The District Director in whose district the food is located, or another senior FDA official, must approve a detention order.⁴² Persons claiming the article may appeal the detention and request a hearing.⁴³

FDA can detain devices if, during an inspection, FDA has reason to believe that a device is adulterated or misbranded. A device detention requires prior approval of the District Director and the concurrence of CDRH's Director for Compliance.⁴⁴ Persons claiming the article may appeal the detention and request a hearing.⁴⁵

In addition, a FDA District employee (usually a Compliance Officer) may detain any food, drug, device or cosmetic that is imported into the United States whenever the "article" merely "appears" to be in violation of the FDCA. The owner is thereafter entitled to request a hearing.⁴⁶ ▲

¹ Investigators generally function to gather facts, rather than make decisions on enforcement matters. See Richard M. Cooper and John R. Fleder, *Responding to a Form 483 or Warning Letter: A Practical Guide*, 60 FOOD AND DRUG L.J. 479 (2005).

² Food and Drug Administration's Regulatory Procedures Manual, March 2006 (RPM), Chapter 4, Section 4-1-4.

³ RPM, Exhibit 4-1, Sections 6.2.2, 6.2.4, 6.2.5.

⁴ RPM, Exhibit 4-1, Section 6.2.1. If OCC does not provide a response to the entity asking for the Warning Letter within fifteen business days, that entity can issue the Warning Letter. RPM, Chapter 4, Section 6.2. However, if OCC provides comments on the proposed Warning Letter, rejects it, or seeks more time to comment, the entity cannot send out the proposed Warning Letter.

⁵ RPM, Chapter 4, Section 4-1-4.

⁶ RPM, Exhibit 4-1, Section 6.2.3.

⁷ 21 U.S.C. § 334. Once a person files a Statement of Interest (Claim) to the seized products, FDA often will try to seek injunctive relief against the manufacturer of the products as part of the seizure case.

⁸ RPM, Chapter 6, Section 6-1-4.

⁹ RPM, Chapter 6, Section 6-1-4.

¹⁰ RPM, Chapter 6, Section 6-1-9.

¹¹ RPM, Chapter 6, Section 6-1-9.

¹² RPM, Chapter 6, Section 6-1-4.

¹³ 21 U.S.C. § 332.

¹⁴ RPM, Chapter 6, Section 6-2-8.

¹⁵ RPM, Chapter 6, Section 6-2-8.

¹⁶ RPM, Chapter 6, Section 6-2-8.

¹⁷ RPM, Chapter 6, Section 6-2-8.

¹⁸ RPM, Chapter 6, Section 6-2-8.

¹⁹ RPM, Chapter 6, Section 6-6-6.

²⁰ RPM, Chapter 6, Section 6-6-7.

²¹ RPM, Chapter 6, Section 6-6-8.

²² RPM, Chapter 6, Section 6-6-9.

²³ See 21 C.F.R. § 17.1 for the statutory citations to CMP actions that FDA can commence without going to court.

²⁴ 21 C.F.R. §§ 17.5-17.51 set forth the procedures for FDA's assessment of a CMP.

²⁵ 21 U.S.C. § 333.

²⁶ For a general overview of OCI, see James A. Dahl and Stephen J. Haynes, FDA's Office of Criminal Investigations, FDLI Update 7-9, 40 (July/Aug. 2001).

²⁷ RPM, Section 6-5-2.

²⁸ RPM, Section 6-5-3.

²⁹ Id. FDA's manual also outlines the procedures for holding so-called "305 Hearings," which refer to hearings held pursuant to 21 U.S.C. § 335, whereby the target of a proposed case is provided an opportunity to argue why FDA should not commence a criminal prosecution. RPM, Section 6-5-4. However, those hearings have been quite rare over the past fifteen years.

³⁰ RPM, Sections 6-5-4 and 6-5-5.

³¹ See FDLI Update 8 (July/Aug. 2001).

³² 28 C.F.R. § 0.45(j).

³³ FDA's AIP Procedures—Responsibilities of Agency Personnel and Organization Policy (AIP Procedures), Section 1-1-5, available at http://www.fda.gov/ora/compliance_ref/aip-procedures/resp.html.

³⁴ AIP Procedures, Section 1-1-3.

³⁵ AIP Procedures, Section 1-1-5.

³⁶ *Id.*

³⁷ *Id.*

³⁸ 21 U.S.C. § 335a.

³⁹ See FDA Staff Manual Guide § 1410.35.

⁴⁰ 21 U.S.C. §§ 334(g) and (h).

⁴¹ See 21 C.F.R. § Part 1, Subpart K. FDA also can detain meat, poultry and egg products under statutory provisions besides the FDCA. RPM, Chapter 5, Section 5-4.

⁴² RPM, Chapter 5, Section 5-3-3.

⁴³ RPM, Chapter 5, Section 5-3-4.

⁴⁴ RPM, Chapter 5, Section 5-5-2.

⁴⁵ RPM, Chapter 5, Section 5-5-3.

⁴⁶ 21 U.S.C. § 381(a); RPM Chapter 9.