

ENFORCEMENT CORNER



Search Warrants—What Happens When the FDA Storm Arrives

by John R. Fleder

Bad boys, bad boys, whatcha gonna do? Whatcha gonna do when they come for you?” Many people associate that rhythmic phrase with the television show “COPS,” and images of police officers apprehending unsavory individuals. People think that a legitimate FDA-regulated company will never be in a position where armed law enforcement officers are barking orders in a search, but that scenario is not far-fetched at all.

The most famous, or infamous, of recent such raids involving FDA is the search of the Peanut Corporation of America (“PCA”).¹ On January 30, 2009, FDA’s Office of Criminal Investigations (“OCI”) probed into PCA’s alleged distribution of salmonella-tainted peanut products, which reportedly caused severe illness and even eight deaths, in over 43 states.² A little over a week later, the FBI announced it had joined in the probe of PCA,³ and federal agents executed search warrants the next day at PCA’s Blakely, Georgia plant and Lynchburg, Virginia headquarters.⁴ A Georgia television station reported seeing a set of bolt cutters, black brief cases, a trailer, and vehicles entering the rear of the plant,⁵ and agents later leaving the facility with boxes.⁶

The public descriptions of what occurred at PCA may not seem particularly similar to an episode of “COPS,” but here is how such a scenario may transpire from the perspective of the employees in the business at the time a search warrant is being executed. It is an average Monday morning at approximately 8 a.m. The manager of a manufacturing facility for a blockbuster drug, Mr. Johnson, has just arrived at work and is getting his morning cup of coffee when he gets a call from his secretary. “Mr. Johnson, federal agents are here demanding access to the facility!” Mr. Johnson greets the agents in the lobby, where they flash a criminal search warrant and credentials. They say they need unfettered access to every inch of the facility, and that any attempt to prevent such access will result in an arrest for obstruction of justice.

The agents then disperse throughout the facility, seemingly ransacking it as they throw piles of files and other documents into numbered, but otherwise unmarked, boxes. Meanwhile, other agents carry away many of the computers (or their contents) in the facility, and interview employees who do not have legal counsel with them. Whenever Mr. Johnson attempts to ask a question or protest, he is threatened with arrest, told not to interfere with the agents and to stay in his office. After several hours of this, the agents leave as abruptly as they entered, only now the company’s most important documents and computer files are gone and that facility can no longer effectively function. How such a scenario could happen to a company and how it can be most effectively handled are among several important issues to consider *before* federal agents “knock” on a company’s doors.

Mechanisms FDA May Employ to Search a Company’s Offices and Facilities

In order to better understand what leads FDA and other agencies to obtain a criminal search warrant, we initially explore other mechanisms whereby FDA gathers information and evidence from entities. First, FDA may use the authority granted under section 704 of the Federal Food, Drug, and Cosmetic Act (“FDC Act”) to inspect a facility upon presentation of credentials and a Notice of Inspection (better known as an FDA Form 482).⁷ This power is probably the most common means by which FDA exercises its inspection authority, and the one that most readers are likely familiar with.

Second, occasionally, an FDA investigator will attempt to inspect a facility through presentation of his or her credentials, but *without* a Form 482 notice of inspection.

Mr. Fleder is a Principal in the law firm of Hyman, Phelps & McNamara, PC, in Washington DC.

In those instances the investigator is actually seeking the consent of the company being inspected. If a company “consents” to such an inspection, it generally forfeits any right it may have otherwise had to challenge the evidence FDA obtains from the inspection.

Third, FDA may obtain an administrative inspection warrant (“AIW”) from a federal Magistrate Judge.⁸ FDA does not regularly use AIWs when conducting investigations or inspections of regulated entities.⁹ An AIW is usually sought only after an inspection request has been refused outright, or if certain elements of an inspection are not “consented to” by the company.¹⁰ However, even without a refusal, FDA may preemptively seek an AIW if it has reason to anticipate a refusal of inspection based on the company’s compliance history, if there is a documented corporate policy that mandates inspection refusal in some or all circumstances, or if there is reason to believe that evidence may be destroyed.¹¹

Before attempting to obtain an AIW, FDA is supposed to verify three points: 1) that FDA is “entitled by statute or regulation to inspect the facility and to have access to the information which has been refused;” 2) “there is a compelling FDA need for that information;” and 3) “the firm/individuals have refused to allow inspection or access to that information in spite of a clear demonstration or explanation of appropriate statutory authority.”¹² Practically, this means that FDA can obtain an AIW without any specific reason to believe there has been wrongdoing by the inspected entity. Rather, FDA may seek and obtain an AIW for something as simple as verifying that a company is fully complying with federal law and regulations, without any reason to believe there has been a lack of compliance.

While this type of warrant seems to grant FDA relatively expansive authority, it does have limitations. Most lawyers agree that FDA may not *forcibly* enter a facility even with an AIW unless a traditional law enforcement officer, such as a Deputy United States Marshal, accompanies FDA in executing the warrant. Additionally, the AIW cannot exceed the scope of the FDC Act.¹³ This means that an AIW can only permit FDA to inspect what it could have inspected under the FDC Act but for the company refusing to permit the inspection.

A company may challenge the AIW by returning to the judicial officer who originally issued the warrant, and attempt to have that officer quash it by showing that it was improperly issued, such as that the AIW exceeded the scope of inspections authorized by the FDC Act.¹⁴ However, an AIW is usually easily obtained by FDA, as there is a much lower legal

standard for issuance of an AIW than the probable cause standard associated with criminal search warrants.¹⁵

Criminal Search Warrants

Often acting in coordination with other federal agencies, FDA may execute criminal search warrants to gather the information and evidence it seeks. While FDA’s use of criminal search warrants is still somewhat uncommon, it is being increasingly used as a tool for gathering evidence quickly. At this point, a fair question to ask is, why would FDA seek a criminal search warrant when it has other tools to gather evidence? FDA generally appears to take the position that preventing the destruction of evidence is the only, or at least the primary, reason for seeking criminal search warrants. We believe that FDA may often have other reasons.

One potential reason is that FDA wants to surprise the company so that it cannot prepare for the search. For instance, a criminal search warrant effectively prevents a company from seeking advice from its attorneys prior to, or even during, the search. Often, a company would seek advice from its in-house or outside counsel after receiving notice that FDA plans to inspect the company’s facilities. Many federal agents see company attorney involvement as “obstructing” the agents’ desire to gather evidence. The agents may believe that company counsel involvement often limits the amount of evidence FDA is likely to discover during regulatory inspections. Agents do not generally welcome objections posed by company counsel while the agents are executing a court-ordered search warrant.

Second, criminal search warrants can often be executed relatively quickly compared to an AIW, even though the preparation time may be considerably longer. An AIW is typically executed by a small number of FDA investigators (along with a Deputy United States Marshal), but a criminal search warrant is often executed by a team of federal agents from OCI and other federal agencies such as the FBI and the Drug Enforcement Administration.

Third, the search warrant route can provide the agents with unfettered access to company employees. Scared to death by the presence of armed federal agents, most company employees are too intimidated to assert their Constitutional rights when a federal agent starts asking questions during the execution of a search warrant.

Finally, whether intended or not, execution of a criminal search warrant can lead to publicity about the searched entity. Execution of a warrant inside a company is a great opportunity for local television and radio stations to report

on “breaking news.” Once someone inside or outside the company “tips off” the press to a raid, the public sees the lengths to which the agency is going after the supposed “bad guys” who are allegedly threatening the safe food, drug and medical device supply.

The Constitution prohibits “unreasonable searches and seizures...and no Warrants shall issue, but upon probable cause...and particularly describing the place to be searched, and the persons or things to be seized.”¹⁶ Most searches, including those of commercial premises, conducted without a warrant are presumed to be unreasonable if the owner of the area being searched has both an objective and subjective expectation of privacy in that space.¹⁷

The government obtains criminal search warrants pursuant to Rule 41 of the Federal Rules of Criminal Procedure. It is generally thought that even strict liability misdemeanor violations of the FDC Act may constitute the basis for a search warrant, although it is not often that FDA would obtain a search warrant for such an offense.¹⁸ Probable cause for issuance of a warrant is enough particularized facts to lead a person of common sense and reasonable caution to believe there is a fair probability of finding evidence of criminal activity in the area to be searched. The facts that a federal Magistrate Judge considers are usually found in a supporting affidavit submitted by a government agent, summarizing information the agent obtains from a variety of sources including, but not limited to, company employees and even anonymous informants.¹⁹ A search warrant must particularly describe the places to be searched and the items to be seized.²⁰ However, particularity can be a subjective term and descriptions in search warrants are often less restrictive than a company would want to see.²¹

Unlike an AIW, a criminal search warrant may authorize the search and seizure of evidence outside the scope of the FDC Act. For example, manufacturing and financial records and formulae for foods or other products may be seized pursuant to a search warrant even though they would be unavailable under an AIW or through a compelled Form 482 inspection.

OCI is generally the entity within FDA that coordinates all activities related to criminal search warrants. In order to execute a warrant,²² a team of OCI special agents, as well as agents from other relevant agencies, arrive at the site and disperse throughout the area to be searched. After hours of searching, agents will seize the items described in the warrant, often leaving the company management with an

uninformative list of what has been taken.²³ The description of the items to be seized in the search warrant is often somewhat general, potentially allowing the agents to seize massive amounts of documents and computer equipment.

Preparing for a Criminal Search by FDA

What should a company do when faced with the possibility that federal agents could, without notice, “knock” at its door? Most companies regulated by FDA assume that this will not happen to them. However, it is better to be prepared than caught unaware. The time to prepare for a search warrant is well *before* its execution. Once the search has commenced, the damage to a company is already done and there will be little that a company can do. Thus, every company should have a written response plan in place in case it is subject to a criminal search.

When developing such a plan, a company must consider a multitude of issues. A simple, yet often overlooked, issue to initially consider is developing procedures for employees to review the search warrant for potential defects. Also, because federal agents will often seek to interview employees during a search, a plan should include instructions for employees regarding such interviews, including what their rights are in such a situation. Some companies may determine that it is better to send all employees home in the event of a search, while others may feel it is more important to attempt to continue with business as usual.

It is also a good idea to keep privileged documents, such as attorney-client privileged materials, separate from non-privileged ones. Agents executing a search warrant are not supposed to read privileged documents. However, they often do seize and remove privileged documents, particularly if a company does not flag to the agents which documents are privileged. Theoretically, privileged documents may be retrieved from the government if they are wrongfully taken, but it is a time-intensive and issue-driven process to do so. Therefore, it is preferable, as part of a response plan, to regularly segregate privileged documents in preparation for a potential search, and immediately advise agents, should the search occur, that documents in certain locations or drawers are privileged.

Another issue a response plan should address is whether one or more employees should be instructed to follow agents as they conduct the search. It may be a good idea to have a handful of employees observe the agents’ activities and take copious notes of what is searched, reviewed, and seized, since it is unlikely the inventory produced by the agents will be

very useful. However, it is also important to carefully instruct employees how to observe the agents without interfering. Any interference with the search can be considered obstruction and lead to an arrest. Further, a company does not want to put employees in a situation where they are asked to consent to parts of the search that may exceed the scope of the warrant. If the warrant is not clear as to whether a particular area can be searched or an item may be seized, an agent may decide to ask for “permission” of a nearby employee. Giving such consent may permit evidence to be gathered that would not have been otherwise permitted by the warrant. Obviously, many uncounseled employees are likely to be too scared to say no to any request or demand.

In addition to legal and regulatory issues, an effective plan should also include provisions dealing with non-legal, but important concerns, such as coping with the media attention that often follows a raid by federal agents. As the scenario described at the beginning of this article indicates, a search by federal agents can be intrusive, unnerving and even frightening to the company and the employees involved, particularly when television cameras arrive at the scene. A well-thought-out plan can mitigate the damage, stress and subsequent legal fallout. ▲

1 FBI Raids Peanut Butter Plant Suspected in Outbreak, Feb. 10, 2009, *available at*: <http://edition.cnn.com/2009/CRIME/02/10/peanut.butter.raid/index.html>.

2 *Id.*

3 Press Release, FBI Atlanta Field Office, (Feb. 9, 2009), *available at*: <http://atlanta.fbi.gov/pressrel/2009/at020909.htm>.

4 FBI Raids Peanut Corp. of America Headquarters in Lynchburg, Feb. 10, 2009, *available at*: <http://www.wdbj7.com/Global/story.asp?S=9816471>.

5 FBI Issues Search Warrants in Peanut Case, Feb. 10, 2009, *available at*: http://www.11alive.com/rss/rss_story.aspx?storyid=126689.

6 FBI Raids Peanut Corp. of America Headquarters in Lynchburg, *supra* note 4. Other recent instances of FDA utilizing criminal search warrants include the April 2007 search of ChemNutra. *See* FDA Investigators Serve Warrant on ChemNutra, Apr. 28, 2007, *available at*: <http://www.lvrj.com/business/7235816.html> (five FDA officials, with badges and two armed, searched the company’s offices for about five hours and took documents and imaged hard drives in connection with

alleged melamine tainted pet food); the September 2008 raid on Spectranetics Corp. *See* ICE, FDA Serve Warrant to Spectranetics, Sept. 5, 2008, *available at*: <http://www.manufacturing.net/News-ICE-FDA-Serve-Warrant-To-Spectranetics.aspx?menuid=> (warrant was served by FDA and other federal agents in an attempt to gather information concerning the promotion, use, testing, marketing, sales and payments to doctors of a medical device); and the December 2008 search of the Miami Maternity Center. *See* Florida Department of Health Joint Investigation Leads to Federal Search Warrant in Miami, Dec. 21, 2008, *available at*: <http://www.wctv.tv/home/headlines/36945319.html> (Miami Maternity Center was suspected of providing unapproved placental pills to clients in an attempt to mitigate the effects of post partum depression. Twelve FDA agents, six Miami Dade police, two Florida Department of Health and two Medicaid Fraud Control Unit investigators conducted the search).

7 *See* 21 U.S.C. § 374(a); *see also* 42 U.S.C. §§ 262-264.

8 FDC Act § 704 is silent on the issuance of AIWs.

9 *See* FDA, Office of Regulatory Affairs, Regulatory Procedures Manual 2009, Inspection Warrants, Ch. 6, 6-3, *available at*: http://www.fda.gov/ora/compliance_ref/rpm/chapter6/ch6-3.html.

10 An example of this would be if photography or sample collection in particular is refused. *See id.*

11 *See id.*

12 *Id.*

13 On April 8, 2009, FDA and U.S. Marshals executed an AIW on Westco Fruit and Nuts Inc. (“Westco”) in order to gain access to distribution documents after Westco declined to provide the records or recall products made from PCA peanuts. Press Release, FDA, FDA Serves Warrant for Inspection of Westco Fruit and Nuts Inc. (Apr. 8, 2009), *available at* <http://www.fda.gov/bbs/topics/news/2009/New01988.html>.

14 *See In re Medtronic, Inc.*, 500 F. Supp. 536 (D. Minn. 1980).

15 *See U.S. v. Jamieson-McKames Pharmaceuticals*, 651 F.2d 532, 541 (8th Cir. 1981).

16 U.S. Const., amend. IV.

17 *See Katz v. U.S.*, 389 U.S. 347, 361 (1967). (Justice Harlan’s concurrence).

18 In early April 2009, FDA executed a criminal search warrant which indicated that the government had demonstrated probable cause that an entity had possession of evidence relating to a misdemeanor violation of the FDC Act.

19 *See Massachusetts v. Upton*, 466 U.S. 727, 734 (1984).

20 U.S. Const., amend. IV.

21 *See Moore v. U.S.*, 461 F.2d 1236, 1237 (D.C. Cir. 1972).

22 Federal agents must usually “knock and announce” their presence before they can begin their search. *See Wilson v. Arkansas*, 514 U.S. 927, 934 (1995), and warrants must be executed within ten days of issuance. Fed. R. Crim. P. 41(e).

23 Fed. R. Crim. P. 41(f).

William T. Koustas, who is an Associate with the law firm of Hyman, Phelps & McNamara, P.C., Washington, DC, assisted in writing this article.