



## FDA Inspections of Pharmacies: What Should You Do?

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*Knowing your legal rights and having a clear policy in place will help you to respond effectively when FDA inspects your pharmacy*

FDA inspections of pharmacies are not uncommon. What should you do if a representative from the Food and Drug Administration (FDA) shows up to inspect your pharmacy? First, remember that, according to the Federal Food, Drug, and Cosmetic Act (FDC Act), FDA has the right to inspect your pharmacy. Section 704(a) of the FDC Act authorizes FDA to inspect facilities where drugs are stored, including pharmacies. Section 704(a) also contemplates inspections of pharmacies. Refusing to allow FDA inspectors to enter the pharmacy during your normal business hours can violate Section 301(f) of the FDC Act as a “refusal” to allow inspection. Therefore, outright refusal during your business hours is almost never a viable option.

However, the investigator does not have free rein to go everywhere in your facility or to see everything. Although FDA has broad powers to inspect drug manufacturers, the FDC Act restricts the scope of FDA inspections of retail pharmacies. Under Section 704(a)(2)(A), FDA’s inspections are far more limited when visiting a pharmacy than when auditing a drug manufacturer.

FDA can only inspect at reasonable times, “all pertinent equipment, finished and unfinished materials, containers, and labeling therein.” Unlike with a drug manufacturer, it does not have the right to inspect the items in third sentence listed in Section 704(a): “records, files, papers, processes, controls” or other related documents of a pharmacy that meets certain criteria. For a compounding pharmacy to qualify for this exemption, it must meet the following criteria:

Pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

If a pharmacy does not compound, or compounds medication only in the normal course of pharmacy practice and meets the other criteria, FDA’s broad inspectional powers to inspect do not apply.

FDA investigators generally are not trained to inspect pharmacies, and many investigators do not know that there is this exemption for pharmacies. However, this exemption was upheld by the district court in the Medical Center Pharmacy v. Gonzalez case. The court said, “In order to conduct a third sentence inspection of a pharmacy who meets the requirements found in the exemptions the FDA must demonstrate when the pharmacy does not qualify for the exemption.” Although the court’s order applied only to the plaintiffs, the logic and analysis applies to all compounding pharmacies. A copy of the decision is available at [www.iacprx.org/MidlandDistrictDecision](http://www.iacprx.org/MidlandDistrictDecision). Therefore, if the investigator tries to insist that he or she has a right to inspect the records, you can use this decision to explain that FDA may not inspect your records.

**Dealing with an FDA Investigator**

FDA may inspect a pharmacy for a variety of reasons, such as following up on a recall or investigating a complaint by a third party, including doctors, patients, and competitors. Over the years, many inspections have been made to try to determine whether a pharmacy is a drug manufacturer. FDA may give some general information about why it is there, e.g., "We received a report of a subpotent medication." However, the investigator may give very little information about the details of the alleged event. Investigators will not tell you who filed the complaint.

Regardless of FDA's reason for inspecting, compounding pharmacies should be prepared to handle a FDA inspection. Because FDA inspections are usually unannounced, a pharmacy should establish a plan in advance to deal with these unexpected visits.

An investigator arriving at a pharmacy should show FDA credentials. The investigator will also issue a Form FD-482 Notice of Inspection, which quotes FDA's authority from the FDC Act. This form does not, however, quote Section 704(a)(2)(A), which *limits* FDA's authority to inspect pharmacies. It is your obligation to know and understand the limits of FDA's powers to inspect; the investigator will not mention them.

FDA's Compliance Policy Guides (CPGs) on human and veterinary pharmacy compounding do not confer any inspectional power on FDA. Thus, an investigator cannot accurately say that he or she has a "right" to see records because of a CPG.

Your best approach is to tell the investigator to direct all questions to a particular individual at the pharmacy and not to ask questions of technicians and other employees. This will minimize disruption of the pharmacy's operations and ensure conformity with the pharmacy's policies concerning inspections.

FDA cannot compel you to answer questions, but any questions that are answered must be answered truthfully. Oral responses may be admissible evidence in any subsequent court actions. If you are in doubt about an answer, you should politely decline to respond at that time by saying, "Let me check into that." Do not speculate or guess. Knowingly submitting false information to FDA – whether in writing or oral statements – can be a criminal violation.

You should take notes on the questions or points raised by the investigator, and try to ensure that there is always a witness to any statements. These notes may later prove helpful. If the investigator makes a copy of a document, such as product labeling, make a copy for yourself and keep it in the files. Do not initial any documents. When the investigator leaves for the day, consider discussing the progress of the inspection with your colleagues. In particular, the discussion should focus on any deficiencies or objections that might have been noted by the investigator.

If you decide to let the investigator have access to some records, never let the investigator rummage through files or records, or roam through the pharmacy unescorted. A pharmacy representative should accompany the investigator at all times.

If you are the only pharmacist who knows the operations of the pharmacy and you are away, your substitute – or you, if you can be reached – should tell the investigator that you are unavailable and that an inspection would not be very productive. Since a pharmacy inspection may be a waste of time if you're not there, the investigator may agree to a delay.

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### Recommended Policies

Pharmacies should have policies in place for handling FDA inspections and inspection-related issues. These policies should never be shown to the FDA investigator. When discussing a request that is contrary to policy, tell the investigator politely but firmly that complying with the request is against your policy.

A crucial decision for a compounding pharmacy is whether to assert that it complies with Section 704(a)(2)(A) and therefore is not subject to FDA's full powers of inspection. Relying on your company's status as a licensed pharmacy, you could elect to decline the investigator's request to see "manufacturing" records, such as formulas, batch records, and standard operating procedures for compounding. If you assert you are in compliance with the exemption in Section 704(a)(2)(A), be prepared for the investigator to disagree and say that you are a

manufacturer. If the inspector does disagree and says that you are a manufacturer, you should ask the investigator to explain the reasons in detail.

The investigator may say that he or she needs to see your records in order to find out whether you qualify for the pharmacy exemption for compounding. This is a classic Catch-22. The investigator is, in effect, saying that the exemption from records inspection needs to be ignored in order to prove that you're entitled to it. This approach was rejected by the court in Medical Center Pharmacy. You may also want to consult your state board or an attorney during the inspection if the investigator continues to insist that you are a manufacturer.

The investigator may assert that you are "refusing" an inspection, or ask you if you are "refusing" an inspection. You can respond that you are not refusing, but just asking FDA to follow the limits on inspection in the FDC Act and the Medical Center Pharmacy opinion. You should make it clear that the investigator is still free to look at equipment, materials, containers, and labeling, which are the objects covered by the first sentence of § 704(a).

FDA believes that the Western States decision means that § 503A is no longer valid. (The court in Medical Center Pharmacy did say that § 503A is in effect; FDA has disagreed with that statement.) Although it is very unlikely an investigator would cite §503A, if that happens you can say that FDA has no additional inspection rights under §503A.

It is up to each individual pharmacy to decide how to handle an FDA inspection and set its own procedures. The following is a summary of some inspection issues and suggested approaches.

▪ **Documents**

Whatever documents you furnish, do not give the investigator free access to your copy machine. A pharmacy employee should do all copying for the investigator. Provide only those documents that are specifically requested; never give the investigator unrestricted access to your files. Sometimes, the investigator will be accompanied by a state inspector, or will bring in a state inspector if you do not turn over the requested documents. If the state inspector insists that you provide him or her with records, and that request is consistent with state law, you should comply. However, you may be able to dissuade the state inspector from requesting the documents. Sometimes state inspectors will not ask for documents when it is pointed out that they are simply doing FDA's bidding.

▪ **Samples**

FDA is entitled to samples of products and their accompanying labels. If the inspector asks for these, take at least one duplicate sample (and preferably more) from the same batch or lot for outside testing, particularly if the sample has been compounded. Ask the investigator what tests are going to be performed – such as potency and sterility tests – so that a laboratory can do duplicate tests for the pharmacy. A copy of FDA's analytical results can later be obtained through the Freedom of Information Act. Even if you do not know what tests will be done, you may want to have a laboratory run a battery of tests. The investigator should issue a Form FD-484 when taking a sample. This form documents that a sample was obtained. FDA may ask you to sign the FD-484. It is better to decline. You may charge FDA for the cost of the product samples.

▪ **Photographs**

FDA investigators have sometimes taken photographs during pharmacy inspections. The best policy your pharmacy can set is "No cameras are allowed in the facility." This policy, applied uniformly, will protect patient privacy and pharmacy procedures. The investigator may retort that FDA has the statutory right to take photographs as a result of a U.S. Supreme Court decision. The case relied on by the FDA involved the Environmental Protection Agency's right to photograph a facility from an airplane and is, therefore, largely irrelevant. There are no direct precedents that say you must allow FDA to take photographs.

▪ **Patient confidentiality**

The investigator may want to copy records that include patient names. You may ask that this information be deleted from the copy given to the investigator. Generally, investigators have concurred with this type of request and accepted copies that omit patient names.

- **Unusual inspections**

Occasionally, the FDA investigator may not be doing a routine inspection. For example, the investigator may be there to serve a subpoena, or be accompanied by a U.S. Marshall or an FDA Office of Criminal Investigations agent. Under these circumstances, you should not answer any questions. You should call your attorney immediately.

- **Signing official documents**

At the conclusion of the inspection, the investigator may ask you to sign an affidavit. This document, which is drafted by the investigator, will include information that the investigator believes could help support an enforcement case. FDA has no authority to force pharmacists or other pharmacy employees to sign anything. You should establish in advance a policy about signing such forms or statements. The best policy is simple: sign nothing. Signing an affidavit does not benefit the pharmacy in any way; you will receive no credit for being "cooperative." If you decline to sign the affidavit, the investigator may ask you to read it and say whether you agree with its language. The best policy is not to do this. An oral acknowledgment of the accuracy of the affidavit could be used against you. You may, however, agree to have a copy of the affidavit left behind for you to review later, once the investigator has left. If you do this, do not later tell FDA that you agree with the affidavit.

- **Responding to a FD-483 Notice of Observations**

At the inspection's end, the investigator may have an exit interview with you to detail the inspection's findings. At that time, the investigator may issue an FD-483 Notice of Observations, which lists the deficiencies observed. If an FD-483 is issued, the investigator is likely to request an immediate oral response. The investigator will write down any comments you make, so be careful what you say. After the exit interview, write a memorandum summarizing the discussion.

Sometimes, investigators may make useful suggestions. You can tell the investigator that you will implement that suggestion; if you believe the suggestion appropriate, however, do not "admit" that you violated the law. If violations of Good Manufacturing Practices are cited, this means that the investigator thinks that the pharmacy is a drug manufacturer, or at least wants to apply the GMP regulations. In this case, try to find out why the investigator considers the pharmacy to be a drug manufacturer. In preparing a written response to a FD-483, be timely and accurate. Make sure you do not set deadlines or make promises you cannot keep. There may be a follow-up inspection to ensure you have done everything you said you would.

- **Establishing an inspections file**

After the inspection, the pharmacy should create an inspections file. This file should include notes taken by employees during the inspection, duplicates of any records photocopied by the investigator, the FD-482 Notice of Inspection, the FD-483 Notice of Observations, all FD-484 Receipt of Samples, the analytical results of samples you had tested, and any subsequent correspondence with the agency.

## **Conclusion**

FDA is permitted by law to inspect pharmacies. However, pharmacists may protect themselves by knowing their legal rights and establishing policies to respond effectively to FDA. A clear policy for handling inspections should be developed in advance. This standing policy will improve your chances for a successful and minimally disruptive inspection.

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*The International Academy of Compounding Pharmacists (IACP) is a non-profit association of compounding pharmacists that serves to protect, promote and advance compounding pharmacy practice. Together more than 1,800 pharmacists, technicians, physicians, professors, and patients form a unified voice for compounding pharmacy. If you would like more information about IACP, call 281.933.8400 or visit [www.iacprx.org](http://www.iacprx.org)*

## Tips to Reduce the Chances of a FDA Inspection

FDA has recently issued a number of warning letters to compounding pharmacies, including five warning letters regarding the compounding of topical anesthetic creams and other preparations.

This action is another example of FDA overstepping the bounds of its authority and attempting to restrict patient and physician choice. It is deeply disturbing that the FDA continues to make the same old arguments that compounding is illegal even after the U.S. District Court ruled so clearly in August that the opposite is true. We are also concerned that the FDA is not just overstepping its authority in the usual way, but appears to be doing so even more aggressively this time.

Regardless of FDA's overreach, these five warning letters raise points of best practices for pharmacy compounding that, if followed, will not only help to ensure the safety of your patients but may also significantly reduce the risk that FDA will take enforcement action against your pharmacy.

1. Ensure that any pharmacy-branded compounded preparations are labeled appropriately, listing each active ingredient and strength.
2. Ensure that your compounded preparations are significantly different than commercially available drug products as determined by the prescriber. There must be a documented prescription calling for the specific compounded preparation dispensed.
3. Ensure that you offer appropriate counseling especially with potent preparations such as topical anesthetics with a low therapeutic index. If such preparations are used by a prescriber for office-use, take steps to ensure the prescriber and his/her staff know how to use the medication.
4. Obtain the name of the patient who receives a compounded medication administered by the prescriber in the prescriber's office whenever possible. Avoid supplying physicians with compounded medications that are being resold to patients outside of the physician's office.
5. Refrain from giving unsolicited samples to a physician. Always obtain a written order or prescription before dispensing any compounded medication, including a sample.
6. Avoid making claims of safety or effectiveness especially in all written materials, patient leaflets, print ads, brochures, websites, etc.
7. Know your rights if inspected by the FDA. If your pharmacy is compliant with state law and operating in the regular course of your business of dispensing or selling these preparations at retail, you do not have to provide the FDA papers and records. For more information, see the attached document.
8. Compound using active ingredients that are components of FDA-approved medications or that have USP monographs. Filling prescriptions such as domperidone or polidoconol greatly increase the risk of an FDA enforcement action.
9. Establish a standard procedure to have samples of your compounded medications analyzed for proper potency/strength (even non-sterile topical preparations, and capsules). This quality assurance is especially important on preparations with a low or narrow therapeutic index.

In addition, we strongly encourage you to adopt IACP's labeling guidelines. For more information, visit [www.iacprx.org/Labeling](http://www.iacprx.org/Labeling).

If you have any additional questions, please call Jennifer Goodrum at [REDACTED] or L.D. King at [REDACTED]

