IACP™
INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS

What should you do if a representative from the Food and Drug Administration (FDA) requests a sample of your Active Pharmaceutical Ingredient (API)?

The FDA **does** have the right to take a sample of your API for testing. The FDA also has to compensate you for the sample so be sure to prepare an invoice for your API. In a number of instances they have declined to collect API if "finished product" isn't available.
If the FDA proceeds with taking a sample of your API, this is what you need to do:

1. In the agent's presence, measure out FOUR samples from the same bulk bottle. Label each one with the usual information (e.g., name, lot, quantity, date, etc.) FDA gets one. You may give them the Certificate of Analysis (CofA) if they request it.*
2. Seal one vial with tape, sign it, have him/her sign and date it, put that on the shelf next to the bulk bottle. That will serve as an untouched, undisturbed control kept in the same environment as the bulk API. Remember... you have no idea what and how the FDA sample will be handled, transported, stored, etc. once it leaves your presence. The control is a back-up.
3. Send the other two vials to two different independent labs for S&P testing. Right away.
4. Call the supplier from whom you bought the API and alert them that a sample has been collected, and provide them with the following information – Lot # API was taken from, amount provided and date provided to FDA.

*Under no circumstances should you give them a formula, invoice or any other piece of paper. Ask specifically if this is a formal FDA inspection. They will reply that it is not. Regardless of the answer, tell them you are claiming your **exemption** as a compliant, licensed pharmacy. Look at the back of their forms (depending on which one they present), there is a place for you to claim that. Be prepared, they probably won't know what to do if you refuse to give out paperwork.

What to do When an FDA Representative Shows Up to Inspect Your Pharmacy

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 provides some specific limitations on what the FDA may inspect in a licensed and compliant pharmacy.

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.