

FDA Inspection Guidelines

The following points have been compiled from authoritative sources and are suggested as a general procedure. ICMAD emphasizes that they are being disseminated as "guidelines" only and are not intended to replace competent legal assistance tailored to your specific situation.

Some points are repeated deliberately for emphasis and to make sure that the basic principles involved are understood.

How to handle an FDA Inspection

Since an FDA or state inspector can come to your place of business at any time without notice, it is highly recommended that you and your key people be aware of what you should and should not do, say or reveal during this visit. What you or your people do or say can be held against you!

1. The inspector should come to your office reception area first. If he or she seeks admittance through any other area, your employees should politely but firmly direct the inspector to the office via the exterior of the building. Do not allow the inspector to walk through the plant to get to the office. You should designate in advance one person as the individual to escort any government inspector who appears at your place of business. You should also designate one or more additional persons to perform this task if the first person is unavailable when an inspector appears. Every employee should know who the designated escorts are and should be instructed to direct the inspector to these persons upon arrival.
2. Conduct the inspector into your private office or conference room. Ask to see his/her credentials. By law the inspector must show them and present a written notice to inspect your plant. If the inspector doesn't have them, ask him/her to leave. In the meantime, while you are talking to the inspector, your plant and supervisory personnel should be notified that there is an inspector in the building so that they can prepare to receive him/her.
3. You and the persons designated to escort any inspector should be familiar with an inspector's authority. The Food, Drug and Cosmetic Act gives the FDA authority "to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle" being used to transport or hold FDA-regulated articles in interstate commerce "and all pertinent equipment, finished and unfinished materials, containers, and labeling therein." For facilities involving only cosmetics, these are the only items to which the inspector is entitled.

In facilities in which over-the-counter drugs are involved, the inspection may extend to all items bearing on whether the drugs may be adulterated or misbranded or otherwise marketed unlawfully. These items include master formula records, batch production records, results of analyses, and possibly shipping records and complaint files. They also include data as to qualifications of technical and professional personnel. The inspector is not entitled, however, to financial data, sales data other than shipment data, pricing data, personnel data, or research data.

4. Ask the inspector the purpose of the inspection. It may be that the inspector is investigating a single complaint or problem. It is possible he or she may want only one fact, one label or one product. If that should be the case, try to confine the visit to that one subject. Ask the inspector how long the inspection is likely to last. This will allow you to rearrange any scheduled appointments you may have in order to conduct the inspection.

There is no point in bringing up matters that only serve to prolong what may be a routine call. Show only the areas pertinent to the inspection. However, do not give the impression that you are reluctant to have the inspector view the entire premises.

5. The plant should be in condition to be inspected at all times. However, this may not always be possible. If you would prefer that the inspector see your plant at a more appropriate time, you can refuse him/her permission. This generally is not advisable but it is within your rights. It is likely to antagonize the inspector, cause the inspector to suspect that there is a problem, and therefore possibly provoke additional inspections. Furthermore, the inspector can and will get a warrant and return.

6. You or a designated escort should accompany the inspector for the entire time. The inspector should not be allowed to wander alone through your premises or talk to your employees. Employees should be instructed not to speak with the inspector without permission of the designated escort. Any questions from the inspector should be answered by you or the designated escort.

If the inspector does anything unusual, make a note of it. Try to keep a record of all questions asked by the inspector and the answer that was given. If the inspector requests a package or product sample, note the lot number and retain several samples of the package or a portion of the product taken. These may have to be tested at a later date.

7. It has not been settled legally whether the inspector is allowed to take photographs or make a tape if you object. Usually, the inspector will not insist upon taking pictures or making a tape if an objection is voiced. However, if the inspector is permitted to do so, any photographs or tapes may be used against you at a later date. If you do allow photographs or taping, make your own at the same time, and retain them.

8. Answer all questions truthfully, but do not volunteer information unless you are confident that the information will not raise additional issues. Do not make up an answer when you are not sure of the answer. The inspector may ask you questions which seem to be beyond the scope of the inspection. You are not required to give such information. However, if you do give such information, it may be entered into the inspector's report. If and when you decline to provide such information, do it respectfully but firmly. If not entitled to the information, the inspector will probably back off. If he or she does not and you are doubtful whether you are required to give such information, ask to call your lawyer, consultant or the ICMAD office.

9. Some materials which the inspector has a right to see in inspections of facilities involving OTC drugs may contain trade secrets. To protect against possible disclosure of trade secrets to competitors or other third parties, you should request that such information be deleted from the inspection report if

the report is subsequently sought in a Freedom of Information Act inquiry. The FDA will typically honor a request of this nature. However, it is prudent to follow up with a letter after the inspection specifying in writing the information that is to be deleted in the event of a FOIA request.

10. Do not sign any affidavit or other document presented by the inspector -- except a paper (a) acknowledging that the inspector has taken a package or product sample or (b) acknowledging that you have been given a copy of the inspector's report.

11. To prepare for an inspection, you should develop a written set of procedures to govern any inspection. You should make sure that you and any designated escorts are familiar with that document. Approximately twice a year, you should hold mock inspections to help assure that all employees, and particularly the designated escorts, know what to do during an inspection. Mock inspections are more effective than oral or written instructions.

12. Again, we stress the importance of not volunteering unnecessary information. One knowledgeable cosmetic executive has said, "I have had 25 years of experience with FDA inspections. Once the word gets beyond your teeth, there is no way to get it back in your mouth. The proverbial 'can of worms' is always lurking. Those of you whose regular business involves salesmanship and dealing with customers usually find it especially hard to hold to this rule. However, it is of supreme importance."

13. Before leaving, the inspector should hand you Form #483. These are the observations he/she chooses to cite for you. The inspector's actual report will be in much greater depth. However, the Form #483 is available to anyone who requests it under the Freedom of Information Act. It is therefore of great importance that you go over these observations very carefully. If you take issue with anything, inform the inspector on the spot. If the inspector's observations are incomplete or tend to portray an inaccurate picture of your operations or conditions that have been remedied during the actual course of the inspection, ask the inspector to so note. He or she may choose to do nothing. However, you have nothing to lose in attempting to negotiate the number of observations downward.

14. If the inspector does not give your Form #483, make sure to request the form. The observations listed on Form #483 should be answered in writing to the FDA as soon as possible. List any exceptions you may make to the observations. Explain how you intend to overcome the problems or change your procedures in the future.

Here is the full text of the provision of the Food, Drug and Cosmetics Act (21 U.S.C. §374 (a)) which governs factory inspections:

"§ 374. Inspection

(a) Right of agents to enter; scope of inspection; notice; promptness; exclusions

(1) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into

interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this chapter), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 355 (i) or (k), section 360i, or 360j(g) of this title, and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 355(j) of this title). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.”