Standard Operating Procedure:
U.S. Food and Drug Administration Inspection—Releasing a Sample to the U.S. Food and Drug Administration

Thomas C. Kupiec, PhD
Jesse Kemp, MSFS
Analytical Research Laboratories
Oklahoma City, Oklahoma

Purpose

The purpose of this standard operating procedure is to provide a plan of action for releasing a sample to a U.S. Food and Drug Administration (FDA) investigator during a pharmacy investigation.

Equipment/Materials

- Camera
- Contact information for a qualified quality control (QC) analytical laboratory
- Pharmacy internal protocol for FDA inspection
- Pharmacy Chain of Custody Form

Responsibility

The pharmacist-in-charge is responsible for this procedure.

Procedure

Questions to ask the FDA Inspector

A. Is my submission of this sample voluntary or required?

B. May I have a receipt, such as an FD-484?

C. Will you maintain a Chain of Custody Form?

D. Which tests will you perform?

E. Which methods will you use to test my preparation?
   1. Are the methods used by the United States Pharmacopeia approved for raw powders being used to test my preparation?
   2. Do you know whether there is any interference between the active ingredient and any excipient?
   3. How can you be sure that the method you are using is accurate?
   4. Is it a high-performance liquid chromatographic stability-indicating method that you are using?

Plan of Action – Part 1

A. If you are asked to provide a sample to the investigator:
   1. Ideal World – Provide a sample from a lot that has already been tested by a qualified QC analytical laboratory.
   2. Otherwise – Ensure that the sample you provide is a simple, nonaqueous, nonsustained release preparation (e.g., capsules or an ointment).

B. After the preparation has been selected, sequester the remainder of the lot.
   1. Ensure that you possess at least 2 times the amount of sample that you provided to the FDA.

C. Acquire a receipt for the sample submitted and ensure that the following information is documented:
   1. Name and description of the sample
   2. Description of the container
   3. Lot number
   4. Date on which the sample was prepared
   5. Date on which the sample was released to the FDA investigator
   6. Name of the FDA investigator
   7. Name of the individual who released the sample
   8. Photograph of the sample and the receipt

D. Issue Pharmacy Chain of Custody form. ***Note:*** *This document should contain all the information that the receipt contains.*

E. Ask the inspector which tests will be conducted on the sample and inform the inspector that you will perform the same tests (e.g., for potency, content uniformity, sterility, endotoxins, particulate matter, etc.) with an independent laboratory.

F. Submit the same amount of sample that you gave to the FDA to an independent QC analytical laboratory and request the same tests.
   1. Inform the independent laboratory staff of the reason for testing: The more they know, the more they can assist you.
   2. Ensure that you provide the laboratory with a copy of the formulation sheet.
   3. Sequester the remainder of the samples from the same lot until both sets of results have been received.

Plan of Action – Part 2 (Follow-up on FDA Investigation)

A. Ask for the results from the independent analytical laboratory and from the FDA regarding your preparation. ***Note:*** *A copy of the FDA analytical results can be acquired through the Freedom of Information Act.*

B. Examine the results for discrepancies.
   1. If the results differ, contact both the FDA and your independent laboratory to discuss the discrepancy.
   2. If a retest is needed, you will still have samples from the same lot.

Written By_____ Date_____

Authorized By _____ Date _____

Implementation Date _____

Chain of Custody Form

Chain of Custody: Persons relinquishing and receiving samples: Provide signature, organization, and date/time to document transfers. (Start with Box Number 1 below.)

Sample Name/Concentration:	Description:
Lot/Batch #:	Container:
Prepared By:	Date of Preparation:
Notes/Miscellaneous:	

Relinquished By 1.	Organization	Date/Time	Received By 2.	Organization	Date/Time
Relinquished By 3.	Organization	Date/Time	Received By 4.	Organization	Date/Time
Relinquished By 5.	Organization	Date/Time	Received By 6.	Organization	Date/Time
Relinquished By 7.	Organization	Date/Time	Received By 8.	Organization	Date/Time
Relinquished By 9.	Organization	Date/Time	Received By 10.	Organization	Date/Time
Relinquished By 11.	Organization	Date/Time	Received By 12.	Organization	Date/Time
Relinquished By 13.	Organization	Date/Time	Received By 14.	Organization	Date/Time