Chapter 10
OTHER PROCEDURES

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10-1 PRIOR NOTICE

10-1-1 Purpose

This section defines “prior notice” and establishes uniform criteria to determine if adequate prior notice has been provided.

10-1-2 Background

Except in a few specifically defined areas, the Food and Drug Administration (FDA) has no legal obligation to warn firms or individuals that they, their practices, or their products are in violation of the law prior to taking formal enforcement action. However, a basic principle of FDA’s enforcement policy is the belief that the majority of persons will voluntarily comply with the law when given information as to what is required, what violations appear to exist, and, in the case of violations of regulatory significance, that failure to comply may result in the initiation of enforcement action.

10-1-3 Policy

When it is consistent with the public protection responsibilities of the agency and if a violative situation does not present a danger to health or does not constitute intentional, gross or flagrant violations, it is FDA’s policy to afford individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action. If voluntary correction is not achieved, documentation that adequate prior notice was provided strengthens the agency's position in enforcement actions by establishing that responsible individuals continued violating the law despite having been warned by the agency.

The following factors should be considered in evaluating the adequacy of prior notice (prior warning):

1. The conduct, condition, practice, or product violates the laws enforced by FDA.
2. The notice (warning) adequately identified the violative conduct, condition, practice or product. (Note: Similar violations do not need separate prior notices, for example, separate prior notices are not necessary for each unapproved new drug shipped.)
3. Notice (warning) was provided to the firm and the most responsible individuals.
4. The firm was afforded a reasonable amount of time to implement corrections. Corrections may include halting shipments, recalling product in violation, or changing procedures and controls.
5. Consider if situations have occurred that may affect the adequacy of prior notice, such as a change in ownership or responsible management. For example, consider what is known by the new management, and if the "firm" received notice.

Note: Prior Notice may be provided orally or in writing. Where there is no dispute as to what is required to comply with the law, adequate notice may well be the Investigator's discussion of objectionable conditions with responsible management at the conclusion of the inspection. If, however, the violative conduct involves a controversial area, an area in which policy is still emerging, or one that has not been pervasively regulated in the past, written notice (usually in the form of a Warning Letter) may be required prior to the initiation of further enforcement action.

Consideration of these factors will facilitate meeting the prior notice requirements for civil and certain criminal actions.

10-1-4 Procedures

Warning Letters are the principal means by which the agency provides prior notice of violations and of achieving voluntary compliance. See RPM Chapter 4, Advisory Actions. However, Prior Notice may be provided by means of a civil suit, administrative action, or other less formal ways, including the following:

1. Enforcement action or notification by State, municipal or other Federal agencies involving the same or similar violations.
2. Issuance of the FDA-483, List of Observations, at the conclusion of an inspection. Issuance of a copy of the FDA-483 to a firm's most responsible person(s) must follow guidance in Field Management Directive 120.
3. Discussion with management by an FDA investigator, documented in the EIR.
4. Recall Classification Notification Letters.
5. Properly documented meetings or telephone conversations between agency officials and a firm's top management.
6. Properly documented advisory communications by FDA Center personnel concerning critical scientific issues.

Note: For further information related to "properly documented" telephone conversations and meetings, see Staff Manual Guide, External Relations, Guide 2126.2, Memoranda of Telephone Conversations and Meetings with Non-FDA Persons, on the OIRM Intranet site.

10-2 ESTABLISHMENT INSPECTION REPORT (EIR) CONCLUSIONS AND DECISIONS

For further information related to "EIR Conclusions and Decisions," see Field Management Directive No. 86, or refer to the web site at http://www.fda.gov/ora/inspect_ref/fmd/fmd86.htm.

10-3 INTERSTATE TRAVEL PROGRAM (ITP) CLASSIFICATIONS AND ADMINISTRATIVE ACTIONS

For further information related to ITP see Compliance Program 7318.029, "Interstate Travel Program-- Conveyances and Support Facilities" or visit the web site at http://www.cfsan.fda.gov/~comm/cp18029.html. In addition, see Field Management Directive No. 122, "Interstate Travel Sanitation: Potable Water on Interstate Carrier Conveyances and at Watering Points" or visit the web site at http://www.fda.gov/ora/inspect_ref/fmd/fmd122.htm

10-4 REPORTING AND MONITORING

The Field Accomplishments and Compliance Tracking System (FACTS) replaces this section. Please see your FACTS Lead User for further guidance

10-5 AD HOC COMMITTEE

10-5-1 Purpose

This section outlines the function, composition, and activities of agency ad hoc committees that are convened for enforcement purposes, and lists the responsibilities of the field and headquarters units in recommending and carrying out the goals of the ad hoc committee.

10-5-2 Background

In 1984, an Office of Planning and Evaluation (OPE) study of the routine and non-routine case procedure disclosed considerable support for the ad hoc committee system from agency managers and case reviewers. An updated 1986 OPE study demonstrated that the use of ad hoc committees expedited the processing of injunctions by resolving issues, planning regulatory procedures, and committing responsible units to an action plan.

10-5-3 Function

There are two principle types of ad hoc committees, "strategy" and "referral."

Strategy ad hoc committees are formed to resolve issues for which agency precedent is lacking on matters that involve complex and difficult enforcement issues, or where there is a dispute between two or more offices over strategy.

Referral ad hoc committees are formed to consider the referral of a matter to the Department of Justice for further criminal investigations or proceedings. See Chapter 6, "Judicial Actions."

Note: The Office of Criminal Investigations (OCI) is responsible for reviewing all matters within the scope of FDA for which a criminal investigation may be recommended. If the district or center office believes that there is a need for a criminal investigation, they must contact OCI immediately. If OCI concludes that they will not be participating in the matter at the time, the district office or center may then proceed as outlined below under "Procedures."

Either type of ad hoc committee may be formed at any point in the case development or review process. However, early identification of the need for an ad hoc committee expedites subsequent decision-making and enables a more prompt review of legal actions. Every effort should be made to use this procedure in the early stages of a complex or difficult investigation, before enforcement action is recommended or fully developed.

An ad hoc committee may also be convened to resolve disagreements among agency components regarding an appropriate regulatory course of action where enforcement policy is inconsistent, unclear or non-existent. Before such an ad hoc is requested, the parties in disagreement should first attempt to resolve the disputed issues between themselves.

10-5-4 Composition

The ad hoc committee will be chaired by the Director, Office of Enforcement (OE), and will consist of the Regional Food and Drug Director (RFDD), the appropriate Center Director of Compliance, the Deputy Chief Counsel for Litigation and, if appropriate, the Director, OCI. These individuals are the "principals." When the principals are unable to participate in a scheduled ad hoc meeting, they must designate a senior compliance official (or attorney for the Office of Chief Counsel (OCC)) to serve in their absence.

The principals or their designated representatives should be prepared to make agency decisions on the issues based upon the evidence presented prior to and during the ad hoc meeting. The principals are also responsible for identifying and arranging for the participation of any appropriate resource persons they feel are necessary. Resource persons should be limited to those individuals who have knowledge of the events at issue or who can significantly help in the decision making process.

10-5-5 Procedures

Requests for forming an ad hoc committee may originate from an RFDD, a District Director (with RFDD concurrence), a Center Director of Compliance or its equivalent, the Director, Office of Regional Operations (ORO), the Director, OE, or the Deputy Chief Counsel for Litigation.

The requesting office must submit an **original and three copies** of the ad hoc request and supporting material to OE, Division of Compliance Management and Operations (DCMO), HFC-210. Except in case of an immediate emergency, the committee must be given at least ten working days to review the ad hoc request and the accompanying material.

The ad hoc request (consisting of an executive summary no greater than five pages in length) must provide the following information:

1. A brief factual background of the case or enforcement matter.

2. A description of the evidence that FDA has in hand, including pertinent exhibits (exhibits should be limited to the matter at issue).
3. For a strategy ad hoc, the requesting office's recommended outcome of the ad hoc meeting.
4. For a referral ad hoc, a description of the evidence expected to be gained through the grand jury and the reasons it is necessary to refer the matter to the grand jury instead of continuing with an FDA investigation.
5. A description of options previously considered, and the reasons those options were rejected.
6. Any other reasons for submitting the ad hoc request.

The meeting will be chaired by the Director, Office of Enforcement. The principal committee member requesting the ad hoc meeting will briefly summarize the reason for the request, the recommended outcome of the meeting, describe any foreseeable problems, and provide whatever additional information that may be useful in reaching a decision.

All decisions made by the ad hoc committee, including necessary follow-up and strategy, will be recorded and disseminated by the DCMO Compliance Officer assigned to the matter. The ad hoc committee may reconvene in cases of significant changes/revisions to the original ad hoc supporting material, the discovery of new information or evidence, or when other issues arise that could impact the original decision of the committee. If it is necessary to reconvene the ad hoc committee, the ad hoc principals attending the original meeting should make every effort to attend any follow-up ad hoc meeting.

In most instances, the committee will reach a decision through consensus of the members. When consensus is not possible, the Director, OE, will refer the matter to the Associate Commissioner for Regulatory Affairs (ACRA) with a recommendation for making a final decision. All committee decisions are subject to review by the ACRA and OCC, and the final decision will not be subject to appeal.

10-5-6 Responsibilities

OE/DCMO receives the request for convening an ad hoc committee, reviews and assesses the submission to determine if there is a clear indication of a dispute or other issue in need of resolution, determines that the supporting information is complete, establishes the time and place for the meeting, and disseminates supporting material to the principal members of the ad hoc committee.

The Director, OE, chairs the ad hoc committee and issues the final decision based upon the ad hoc committee's discussion. If the ad hoc committee cannot reach a decision, the Director, OE, refers the matter to the ACRA for a final decision.

The Director, ORO, may recommend convening an ad hoc committee based on issues that rise from ORO headquarters based program activities.

The RFDDs make a final decision on all recommendations for an ad hoc committee from the field. The Regional Director serves as a principal on the ad hoc committee.

The District Director may recommend the convening of an ad hoc committee and forward the

recommendation with appropriate background information to OE through the RFDD.

The Center Director of Compliance or equivalent approves or disapproves all recommendations for an ad hoc committee from the center and will serve as a principal on the ad hoc committee.

The Deputy Chief Counsel for Litigation, OCC, will serve as a principal on the ad hoc committee to provide legal counsel.

Principals who are unable to participate in a scheduled ad hoc meeting are responsible for designating a senior official to serve in their absence. The principals are also responsible for identifying and arranging for the participation of any appropriate resource persons they feel are necessary, and for providing necessary background information to those persons.

10-6 APPEAL PROCESS

10-6-1 Purpose

This section sets forth a procedure for the appeal of decisions regarding recommendations for legal or administrative actions.

10-6-2 Who May Appeal

Appeals may be originated by the RFDDs or the Center Directors for Compliance (or equivalent).

10-6-3 What May Be Appealed

Appropriate officials may appeal any decision disapproving a proposed action, administrative or legal, which is allegedly inconsistent, or where there is nonexistent enforcement policy. The directors of the involved offices must have attempted to resolve the disagreement prior to submitting an appeal.

10-6-4 When An Appeal Is Not Appropriate

An appeal is not appropriate when additional information that overcomes the basis for the original denial becomes available. In such cases, the recommendation should be updated to include the new or additional information and resubmitted to the reviewing office with an explanation for the resubmission and a request for reconsideration.

10-6-5 Requests For Appeal

District offices should submit appeals over the signature of the RFDD. Centers should submit appeals over the signature of the Center Director for Compliance. The appeal memorandum and two copies of relevant supporting material must be identified, indexed, and submitted to the Director, OE (HFC-200).

The appeal memorandum must identify the issues on which the appeal is based, and the reasons for disagreeing with the decision of the declining unit. Recommendations must include a summary of communications regarding attempts to resolve differences of opinion.

10-6-6 Review Of Appeals

OE/DCMO will review the appeal package to assure that it is complete, determine that an appeal is appropriate, and will determine whether the appeal deals with policy, regulations, or a statute. DCMO will initially attempt to gain a resolution of the disagreement by the parties to the appeal.

10-6-7 Decision On Appeals

If DCMO cannot get the parties to agree, an ad hoc committee meeting to be chaired by the Director, OE, will be scheduled, following the procedures outlined in section 10-50, Ad hoc Committee.

The meeting will include the RFDD, the Center Director for Compliance, and the Deputy Chief Counsel for Litigation, if appropriate. If the principals are unable to attend, they will designate a senior compliance official to serve in their absence. Usually only one resource person must accompany the senior compliance official.

Resolution of appeals is by consensus of the ad hoc committee members. If the ad hoc committee can not reach a consensus, the matter will be forwarded to the ACRA for a final decision.

Decisions made by the ad hoc committee will be recorded and distributed to meeting participants. The decision may be limited to a decision on the merits of the case or it may include instructions to develop policy in a particular program area. The ACRA or OCC may review all committee decisions.

10-7 EXPERT SUPPORT FOR CASES

10-7-1 Purpose

This section sets out a procedure for assuring that medical, scientific, or technical (collectively "expert") support is available for a case. For purposes of this section, the term "case" refers to a matter that is or may become a court case or hearing. The term "experts" is used to describe individuals from within or outside of FDA, who may serve as consultants and/or as expert witnesses in a case. FDA may seek expert support whether or not a case is contested or litigated.

10-7-2 Responsibility

The Centers have the primary responsibility for assuring that FDA has appropriate expert support for a case, if needed. The Center Compliance Office, in consultation with OCC, should determine whether or not FDA needs expert support for a case. If the Center determines that expert support is needed, it should consult with its medical or scientific review staffs to ensure that the Center position on the subject represents the consensus of current informed medical or scientific opinion. If necessary, the Center should also consult the Office of Regulatory Affairs (ORA) district offices to make this determination (see also FDA Staff Manual Guide 2610.2, Obtaining Services of Expert or Fact Witnesses (7/2/98)).

The Center should also determine whether FDA will be able to obtain expert support for a case, when it is necessary to do so. The Center should not send a case forward to institute actual legal proceedings until it makes these determinations about expert support.

10-7-3 Criteria For Determining The Level Of Expert Support

FDA requires outside expert support in precedent-setting cases when FDA does not have sufficient in-house expertise. If in-house experts are available, the Center should contact them to determine whether it should also contact individuals from outside FDA to assess the consensus of current medical, scientific, or technical opinion

The Center generally should review complex cases involving state-of-the-art and/or current good manufacturing practice to determine whether it should obtain concurrence by the experts.

The Center generally needs only limited additional expert support for cases that are sufficiently similar to previous cases, except where a new court decision, regulation, or policy has sufficiently changed the factors to consider.

The Center generally needs to refer only to recent cases when determining the need for expert support in a current case that is identical to a recent case.

10-7-4 Documentation

The Center's approval memorandum for a case should include a section regarding expert support, under a separate heading. This section should summarize the Center's effort to provide assurance of expert support and describe significant issues or concerns related to the expert support. It should also include relevant information about prior or pending court cases, testimony or affidavits developed during a recent court case or hearing, information derived during recent processes to propose or finalize rules, advisory committee meetings, literature searches that support the consensus of current opinion, memoranda of conversations with experts, etc.

10-7-5 List Of Individuals For Expert Support

The Center should develop and maintain a list of experts. The Center might develop this information from a variety of sources, but it is responsible for assuring the adequacy of the expert support for a case. For example, when the Center contacts an expert, it should consider asking that expert to identify other individuals with similar expertise. This may be useful in the case at hand (e.g., if a corroborating witness is needed) as well as in future cases.

10-7-6 Obtaining And Paying For Expert Support

The Center might determine that FDA needs expert support from outside FDA to review a case and/or to serve as an expert witness. In that event, the Center should consult with other FDA components, e.g., Office of Chief Counsel and ORA district offices, to identify the most suitable witness, obtain the services of that individual, and pay for fees. Further background about obtaining the services of experts and paying for expert support is set out in an August 25, 2003, memorandum from Donald Vasbinder, Acting Director, Office of Enforcement, to FDA Center and ORA managers. A copy of the memorandum can be found on the Office of Enforcement's intranet web site.

As explained in that memorandum, it is important to keep in mind the overall principle that each case is brought on behalf of the FDA, not any particular part of the organization. It is the responsibility of all involved elements of the FDA to cooperate and work together to provide the best possible support for all cases, regardless of which particular office may be the lead. Thus, it is the joint responsibility of the Center and field offices to identify and obtain the best witnesses and other case support, with the Office of Chief Counsel responsible for the final determination of use of witnesses if we anticipate a contest or litigating a case. Although the Centers have primary responsibility for assuring the availability of expert support as noted in section 10-7-2, field offices should work closely with the Centers and provide any possible assistance in the process, such as identifying and suggesting to the Center possible good local experts. Field/Center consultation and cooperation on considering the possible need for and the obtaining of expert support should start as soon as necessary and feasible in the case development process and continue throughout each stage.

The following procedures are to be followed for obtaining and paying for the services of experts when needed for support of court cases or hearings:

A. Decisions are to be made jointly by the responsible Center and field offices on the type and scope of expert support needed for support of cases and hearings. It is also important that, if the Agency anticipates that a case will be contested, the Office of Chief Counsel be consulted as to the use of expert witnesses. The office that first identifies the need to obtain expert support is responsible for contacting and consulting with the other offices responsible for the case.

B. For outside (non-FDA) consultants and expert witnesses agreed upon as necessary by all parties to support cases or hearings at any stage (including support for a recommendation, review and approval, and litigation), all costs associated with such services will be shared equally among each major office (other than OCC) having responsibility for the case (e.g., each Center and District involved). This includes all necessary expenses for such expert services, such as contracting for and consulting with experts, travel and per diem, and other associated expenses necessary for this purpose.

    1) For outside experts, the responsible Center and field offices involved shall also consult and agree with one another on which office will be designated to take the lead role in actually contacting the expert, negotiating a contract for services, and making sure the necessary paperwork is completed.

    2) Normally, unless mutually agreed otherwise, the designated lead office for these

administrative purposes will be the one having primary responsibility for the aspect of the case that requires the expert support. For example:

(a) The District would normally be the administrative lead for expert support (such as declarations) required for its regulatory action recommendations, or for expert witnesses needed for testimony for a trial or hearing under the District's purview.

(b) The Center would normally be the administrative lead if either the Center or OCC concluded in reviewing a recommended case that outside expert review is required to ensure adequate scientific support is available before proceeding with the case, or for expert witnesses needed for testimony at a hearing under the Center's purview.

3) The designated lead office that prepares the necessary paperwork to procure the services for outside expert support is also responsible for ensuring timely payment of all invoices related to the services provided. In order to accommodate the shared-funding arrangement, the following accounting procedures should be employed:

(a) <u>When an ORA field office is designated as the lead for an outside expert</u>:

The total expense should be charged to the applicable ORA field central funding CAN using category E. Accounting technicians should code field "N" of the DHR as follows:

"E (Last name of witness)"

Copies of each obligating document, including information concerning the Center with which the cost will be shared, should be faxed to ORA's Office of Resource Management, Division of Management Operations (DMO) at (301) 827-1679. DMO will provide the respective Center a copy of the obligating document for tracking purposes. Each quarter, DMO will contact the budget personnel in the applicable Center to request a transfer of funds to recover half of the total cost.

(b) <u>When a Center is designated as the lead for an outside expert</u>:

The total expense should be charged to the applicable Center's accounting point. Copies of each obligating document, including information concerning the field location with which the cost will be shared, should be faxed to ORA's Office or Resource Management, Division of Management Operations (DMO) at (301) 827-1679. Each quarter, the applicable Center will contact the budget personnel in DMO (301-443-3350) to request a transfer of funds to recover its half of the total cost.

C. For expert support provided by FDA employees, all such expenses (including travel and per diem) will be borne by the office of the employee involved. Expenses should be paid by the employee's office in accordance with its normal procedures. (NOTE: For expert support by FDA employees, this changes some provisions in sections 5.b. and 7.b.iii. of Staff Manual Guide 2610.2, which are somewhat in conflict.)

10-8 TESTIMONY; PRODUCTION OF RECORDS; CERTIFICATION OF RECORDS

10-8-1 Purpose

The purpose of this section is to provide information about responding to **requests (from a "requester") including verbal requests, or subpoenas (from a "submitter")** for the testimony of Food and Drug Administration (FDA) personnel, in their official capacity, in non-FDA proceedings, including judicial, administrative, and legislative proceedings. Any FDA employee must obtain authorization to testify before any tribunal pertaining to any function of FDA or any information acquired in the discharge of official duties (21 C.F.R. § 20.1(a)) (see Exhibit 10-1). FDA may authorize the giving of testimony if testimony will be in the public interest and promote FDA's objectives (§ 20.1(a)).

In addition to a request or subpoena for testimony, this section also describes the procedures for handling: (A) a request or subpoena, including a Subpoena Duces Tecum (21 C.F.R. § 20.2) for the production of records, or (B) a request or subpoena for certification of FDA records (21 C.F.R. § 20.3).

The procedures set forth below represent the typical steps that FDA follows when responding to a request or subpoena covered by this section. However, the facts in a particular case, or advice from the Office of the Chief Counsel (OCC), might require variations from these procedures that are justified as long as FDA complies with the applicable regulations. FDA handles each request or subpoena for testimony or production of records on a case-by-case basis.

10-8-2 Limitations

The procedures in this section do not apply to the situations set forth below. However, except for item A, contact DCP immediately regarding any request or subpoena for testimony of an FDA employee.

A. a proceeding in which FDA is a party either directly or, because the Department of Health and Human Services (DHHS) is a party, indirectly. Contact OCC and, for testimony, the supervisor of the employee whose testimony is requested;

B. a request from Congress for testimony. Contact FDA's Office of Legislation;

C. employee personnel records related to litigation. Contact FDA's Employee and Labor Relations Branch (HFA-430);

D. a request from the DHHS Inspector General or from the DHHS Office of Equal Employment Opportunity for affidavits or other statements. The DHHS Standards of Conduct require all employees to "assist the [DHHS] Inspector General and other investigative officials in the performance of their duties or functions. This requirement includes the giving of statements or evidence to investigators of the Inspector General's office or other DHHS investigators authorized to conduct investigations into potential violations." (45 C.F.R. § 73.735-302(d)). Regarding requests from the DHHS Inspector General that relate to investigations of FDA employees, contact FDA's Office of Internal

Affairs (HF-9). Regarding requests from the DHHS Office of Equal Employment Opportunity, contact FDA's Office of Equal Opportunity, Office of the Commissioner (HF-15);

E. testimony as a private citizen. Some testimony as a "private citizen" (i.e., not in one's official FDA capacity) may raise special concerns such as possible conflict of interest or may require approval as an outside activity. NOTE: If the individual's planned testimony is based on information derived during FDA employment, the employee must contact the Office of Regulatory Affairs (ORA), Office of Enforcement (OE), Division of Compliance Policy (DCP) (HFC-230) for clearance of this testimony under 21 C.F.R. § 20.1. For testimony as a private citizen, employees also should refer to the Standards of Ethical Conduct for Employees of the Executive Branch, 5 C.F.R. § 2635.805, and the HHS Supplemental Standards of Ethical Conduct, 5 C.F.R. § 5501.106. Contact FDA's Ethics and Integrity Staff for further information regarding approval of the testimony as an outside activity; or

F. testimony by former FDA employees. Requests for the testimony of former FDA employees are not covered specifically by 21 C.F.R. § 20.1. Encourage former employees to contact the Office of Regulatory Affairs (ORA), Office of Enforcement (OE), Division of Compliance Policy (DCP) (HFC-230) if they receive a request or subpoena to provide testimony regarding FDA-related matters, because FDA may assist that individual. Advise former employees that there may be other restrictions on their ability to provide the requested testimony, including possible conflict of interest concerns and statutory and regulatory restrictions on the release of trade secrets and other kinds of confidential information.

10-8-3 Authorities

In addition to the Commissioner of Food and Drugs and other senior-level officials whose titles are listed in 21 C.F.R. § 5.20(b), FDA's regulation at 21 C.F.R. § 5.23(a)(2) lists the titles of FDA officials who may authorize the giving of testimony when FDA is requested or subpoenaed to provide testimony. The titles, as they appear in the regulations, for these officials are listed below. These officials may not further redelegate this authority:

A. The Deputy Associate Commissioner for Regulatory Affairs (Deputy ACRA), ORA;
B. The Director and Deputy Director, OE; and
C. The Director, DCP (see item 7.A.).

10-8-4 References

"Enforcement Notes," Issue No. 85 (Testimony), available on ORA's Intranet.
Staff Manual Guide 1410.23 (General Redelegations of Authority, Certification of True Copies and Use of Department Seal) (Many Staff Manual Guides are available on FDA's Intranet.)
Staff Manual Guide 1410.24 (General Redelegations of Authority, Disclosure of Official Records and Authorization of Testimony)
Staff Manual Guide 2127.1 (Attendance by FDA Employees at Congressional Hearings)
Staff Manual Guide 2127.2 (Requests for Testimony of FDA Personnel in Non-FDA Proceedings)
Staff Manual Guide 2460.7 (Procedures for Implementing the Freedom of Information Act) (Not

on Intranet)
5 U.S.C. § 552a (Privacy Act); 21 C.F.R. Part 21(Privacy Act regulations)
5 U.S.C. § 552(b) Freedom of Information Act (FOIA); 21 CFR Part 20 (FOIA regulations), particularly 21 C.F.R. §§ 5.20, 5.23, 20.1, 20.2, and 20.3
5 CFR § 2635.805 (Standards of Ethical Conduct for Employees of the Executive Branch)
5 CFR § 5501.106 (HHS Supplemental Standards of Ethical Conduct)
Information Disclosure Manual on ORA's Intranet Information Disclosure Main Page
FDA's FOIA Page on FDA's Intranet

10-8-5 Definitions

The following list contains definitions of commonly used terms in the context of testimony, subpoenas, or production of records.

Affidavit. An affidavit is a written or printed statement of facts signed by the individual affiant in the presence of a notary public who notarizes the individual's signature. FDA considers an affidavit to be testimony covered by 21 C.F.R. § 20.1.

Certification (also known as "certificate"). A certification is a written assurance, or official representation, that some act has or has not been done, or some event occurred, or some legal formality has been complied with. Typically, a requester will ask that FDA certify as to the authenticity of an FDA record as a true copy. FDA processes requests or subpoenas for certification under 21 C.F.R. § 20.3.

Courts. The distinction between a subpoena from a federal court and one from a state court is important. Typically, a subpoena from a federal court has a caption at the top of the form that indicates the United States and the U.S. district in which the court resides, e.g., "United States District Court, [for the District of ____]." (See Exhibit 10-2.) A subpoena from a state court has a caption at the top of the form that indicates the level of the state court, sometimes the county, and the state, e.g., "In the Circuit Court of [County], [State]." (See Exhibit 10-3.) Both types of subpoenas show the names of the parties litigating (plaintiff and defendant).

Declaration. A "declaration" is a statement made out of court under the penalty of perjury under 28 U.S.C. § 1746. The statute at 28 U.S.C. § 1746 is a law that permits a statement, for FDA matters, to be made under penalty of perjury as a substitute for notarization. An affidavit and a declaration are indistinguishable as written testimony for federal court proceedings. However, a declaration would not serve as an affidavit for state court proceedings. FDA considers a declaration to be testimony covered by 21 CFR § 20.1.

Deposition. A deposition refers to the testimony of a witness taken upon questions, not in open court, but as a result of an order of the court. The testimony is reduced to writing, duly authenticated (authentication is often handled like a certification) and intended to be used in a trial or an action in court. The deposed individual gives his or her answers under oath. FDA considers the employee's response in a deposition to be testimony covered by 21 C.F.R. § 20.1.

Interrogatories. Interrogatories are a series or set of written questions used in the judicial examination of a party or witness. FDA considers the employee's response to an interrogatory to be testimony covered by 21 C.F.R. § 20.1.

Notary Public. A notary public is an officer of the court who has the authority to administer an

oath to the individual attesting to the truthfulness of that individual's written or printed statement.

Subpoena. A subpoena reflects a process to cause a witness to give testimony or otherwise provide testimony. For purposes of this section, a "subpoena" means a subpoena for verbal or written testimony (e.g., an affidavit). A federal or state (including local) court, or a federal agency judicial body (Administrative Law Judge), issues a subpoena. A subpoena for testimony also might include a request for records. In that case, FDA would process the subpoena under 21 C.F.R. §§ 20.1 and 20.2.

Subpoena Duces Tecum. A Subpoena Duces Tecum reflects a process by which the court commands a witness who has in his or her possession or controls a record, to produce that record for use at trial. A Subpoena Duces Tecum might request records without the appearance of the individual. FDA processes these subpoenas, which are intended for the production of records, under 21 C.F.R. § 20.2.

Rogatory Letter. A commission from one judge to another requesting the latter to examine a witness. FDA considers the employee's response to a rogatory letter to be testimony covered by 21 C.F.R. § 20.1.

Testimony. Testimony is an individual's statement, made under penalty of perjury, in writing (such as an affidavit or declaration) or by appearance at a proceeding. The individual's statement might be in response to a deposition or interrogatories. Testimony is covered by 21 C.F.R. § 20.1.

10-8-6 Originators of Requests or Subpoenas

A requestor's request or a submitter's subpoena for testimony, production of records, or certification of records may originate from a:

A. member of the public, or a representative of a member of the public;

B. for a subpoena, a federal (U. S. District) or state (including local) court; or a federal agency judicial body (Administrative Law Judge) (see Exhibit 10-2 for an example of a subpoena from the U.S. District court and Exhibit 10-3 for an example of a subpoena from a state court); or

C. federal, state (including local), or foreign government agency official. For purposes of this section, the term "government agency" includes a legislative body, such as a state legislature.

10-8-7 Informal Meetings

A person (individual, company, corporation, etc.) might request an informal meeting with an FDA employee to discuss information the employee obtained during the course of his or her employment.

A. If the requester is <u>not</u> an official from another government agency, and if private civil litigation is involved, decline the request and suggest that the requester submit a request for testimony under 21 C.F.R. § 20.1. Also, advise the requester that FDA has a long-

standing policy against granting one-sided interviews or informal testimony to avoid creating the impression that FDA is biased toward a party.

B. If the requester is not an official from another government agency, if the request relates to a matter other than private civil litigation (e.g., the requester seeks general information about FDA's activities), advise the requester to submit a written request to the employee's office, to be handled as general correspondence under routine office procedures.

C. If the requester is an official from another government agency, advise the requester to submit a written request to the employee's office to be handled under appropriate agency procedures for the sharing of publicly releasable or non-public information. Contact OCI's information disclosure senior investigator if the request is from a law enforcement agency and the request is for non-public information.

D. Consult with DCP if needed.

10-8-8 Responsibilities

A. Division of Compliance Policy (HFC-230).

(1) **Introduction**.

(a) The Director, DCP, is the Agency lead for authorizing testimony (by request or subpoena) and disclosure of records in response to a subpoena for production of records. DCP will forward the request for certification of records to the appropriate component for direct response.

(b) DCP conducts the initial review of a request or subpoena for testimony, or production of records**, unless the request or subpoena is sent by or on behalf of a state government agency. In the latter case, ORA's Division of Federal-State Relations (DFSR) (HFC 150) conducts the initial review and contacts the requester or submitter (see item 8.B.).**

(2) **DCP: Testimony.**

a. (Subpoena from a federal court for testimony.) For a subpoena issued by a federal (U.S. District) court for testimony, DCP contacts the submitter to discuss the subpoena. DCP asks if the submitter would agree to accept publicly releasable records, in lieu of testimony, if records are available and address the information the submitter seeks.

(i) If the submitter of the subpoena that was issued by a U.S. District Court agrees to accept publicly releasable records, DCP determines if those records are available. If the records are available, DCP notifies FDA's DFOI and provides an explanatory note, and a copy of the subpoena for that office to log in and assign administrative controls.

(ii) If the submitter of the subpoena that was issued by a U.S. District Court

does not agree to accept publicly releasable records, in lieu of testimony, DCP consults with OCC and processes the subpoena under 21 C.F.R. § 20.1.

(iii) If FDA does not have publicly releasable records, DCP consults with OCC and processes the subpoena under 21 C.F.R. § 20.1.

(iv) DCP consults with OCC as needed.

b. (Subpoena from state court for testimony.) For a subpoena issued by a state court for testimony, DCP contacts the submitter to discuss the subpoena. DCP requests that the submitter accept publicly releasable records, in lieu of testimony, if records are available and address the information the submitter seeks.

(i) If the submitter of the subpoena that was issued by the state court agrees to accept publicly releasable records, in lieu of testimony, DCP determines if those records are available. If the records are available, DCP notifies FDA's DFOI and provides an explanatory note, and a copy of the subpoena for that office to log in and assign administrative controls.

(ii) If the submitter of the subpoena that was issued by the state court does not agree to accept publicly releasable records, in lieu of testimony, DCP processes the subpoena under 21 C.F.R. § 20.1.

(iii) If FDA does not have publicly releasable records, DCP processes the subpoena under 21 C.F.R. § 20.1.

(iv) DCP consults with OCC as needed.

(v) Generally, when a subpoena from a state court is involved, federal Supremacy Clause considerations prohibit a state court from compelling a federal agency employee who is the subject of a subpoena to testify in response to that subpoena.

c. (Subpoena submitted on behalf of federal or foreign government agency for testimony.) See item 8.B.(1)(d) for a state government agency.

(i) (Federal government agency.) If the subpoena is submitted on behalf of a federal government agency, DCP contacts the submitter to discuss the subpoena. DCP asks if the submitter would accept publicly releasable records, in lieu of testimony, if records are available and address the information the submitter seeks. If the submitter agrees to accept publicly releasable records, DCP determines if those records are available. If those records are available, DCP notifies the appropriate FDA component that is responsible for reviewing and redacting the record, and provides an explanatory note, and a copy of the subpoena for that office's records. If FDA has no publicly releasable records, and the submitter agrees to accept non-public records, in lieu of testimony, DCP may process the subpoena as a request under § 20.85 or under other law, if authorized. If the submitter

does not agree to accept publicly releasable or non-public records, in lieu of testimony, or no records are available, DCP consults with OCC and processes the subpoena under 21 C.F.R. § 20.1.

(ii) (Foreign government agency.) If the subpoena is submitted on behalf of a foreign government agency, DCP contacts the submitter to discuss the subpoena. DCP asks if the submitter would accept publicly releasable records, in lieu of testimony, if records are available and address the information the submitter seeks. If the submitter agrees to accept publicly releasable records, DCP determines if those records are available. If those records are available, DCP notifies the appropriate FDA component that is responsible for reviewing and redacting the record, and provides an explanatory note, and a copy of the subpoena for that office's records. If FDA has no publicly releasable records, and the submitter agrees to accept non-public records, in lieu of testimony, DCP may process the subpoena as a request under § 20.89 or under other law, if authorized. If the submitter does not agree to accept publicly releasable or non-public records, in lieu of testimony, or no records are available, DCP consults with OCC and processes the subpoena under 21 C.F.R. § 20.1.

d. (Request from a person other than a state government agency for testimony.) See item 8.B.(1)(d) for a state government agency. For requests from persons other than a state government agency, DCP contacts the requester to discuss the request for testimony. DCP asks if the requester would accept publicly releasable records, in lieu of testimony, if records are available and address the information the requester seeks.

(i) (Federal government agency.) DCP follows the procedures in item 8.A.(2)(c)(i).

(ii) (Foreign government agency.) DCP follows the procedures in item 8.A.(2)(c)(ii).

(iii) (Member of the public.) If the requester agrees to accept publicly releasable records, in lieu of testimony, DCP determines if those records are available. If those records are available, DCP notifies FDA's DFOI and provides an explanatory note, and a copy of the subpoena for that office to log in and assign administrative controls. If the requester does not agree to accept publicly releasable records, in lieu of testimony, or no publicly releasable records are available, DCP processes the request under 21 C.F.R. § 20.1.

e. If the Director, DCP, authorizes an FDA employee to provide testimony, DCP:

(i) if needed, contacts OCC or the Office of the United States Attorney to determine if the scope of the testimony should be limited in the description in the authorization memorandum;

(ii) may request that an Assistant United States Attorney (AUSA) be

present at the trial or deposition to protect FDA's interest;

(iii) requests that OCC assign an attorney to attend the event or assist the employee;

(iv) sends a memorandum to the employee, along with a copy of the letter to the requester or submitter signed by the Director, DCP, authorizing the giving of testimony by the employee;

(v) sends a letter signed by the Director, DCP, to the requester or submitter;

(vi) distributes copies of the letter and memorandum to OCC and any other involved FDA components; and

(vii) reviews the summary memorandum from the employee who testified, and distributes copies within FDA, as appropriate.

f. If the Director, DCP, does not authorize the giving of testimony, DCP:

(i) if needed, consults with OCC to determine if a motion to quash or other legal step is appropriate. If appropriate, OCC and/or DCP works with the AUSA in the jurisdiction of the court.

(ii) sends a letter signed by the Director, DCP, to the requester or submitter; and,

(iii) distributes copies of the letter to OCC and any other involved FDA components.

(3) **DCP: Production of records**. FDA's regulations at 21 C.F.R. § 20.2 permit FDA to process a subpoena (Subpoena Duces Tecum) or request for records according to the FOIA provisions of 21 C.F.R. Part 20.

a. (Subpoena from a federal court for records.) For a subpoena issued by a federal (U.S. District) court for records, DCP contacts the submitter to discuss the subpoena. DCP asks if the submitter would agree to accept publicly releasable records, if records are available and address the information the submitter seeks.

(i) If the submitter of the subpoena that was issued by a U.S. District Court agrees to accept publicly releasable records, DCP determines if those records are available. If the records are available, DCP notifies FDA's DFOI and provides an explanatory note, and a copy of the subpoena for that office to log in and assign administrative controls.

(ii) If the submitter of the subpoena that was issued by a U.S. District Court, does not agree to accept those publicly releasable records, DCP consults with OCC to determine how to process the subpoena and whether a motion to quash or other legal step is appropriate.

(iii) If FDA does not have publicly releasable records, DCP notifies the submitter of that fact and consults with OCC as needed.

b. (Subpoena from a state court for records.) For a subpoena for records, issued by a state court, DCP contacts the submitter to discuss the subpoena and request that it accept publicly releasable records, if records are available and address the information the submitter seeks.

(i) If the submitter of the subpoena that was issued by the state court agrees to accept publicly releasable records, DCP determines if those records are available. If those records are available, DCP notifies FDA's DFOI and provides an explanatory note, and a copy of the subpoena for that office to log in and assign administrative controls.

(ii) If the submitter of the subpoena that was issued by the state court does not agree to accept public releasable records, DCP notifies FDA's DFOI and provides an explanatory note, and a copy of the subpoena for that office to log in and assign administrative controls.

(iii) If FDA does not have publicly releasable records, DCP notifies the submitter of that fact and consults with OCC as needed.

(iv) Generally, when a subpoena from a state court is involved, federal Supremacy Clause considerations prohibit a state court from compelling a federal agency to produce records in response to that subpoena.

c. (Subpoena submitted on behalf of a federal or foreign government agency for records.) See item 8.B.(2)(a) for a state government agency. If the subpoena is submitted on behalf of a federal or foreign government agency, DCP asks the submitter if they would accept publicly releasable records, if records are available and address the information the submitter seeks. If the submitter agrees to accept publicly releasable records, DCP determines if those records are available. If the records are available, DCP notifies the appropriate FDA component that is responsible for reviewing and redacting the record, and provides an explanatory note, and a copy of the subpoena for that office's records. If FDA has no publicly releasable records, and the submitter agrees to accept non-public records, DCP may process the subpoena as a request under § 20.85 (federal) or § 20.89 (foreign) or under other law, if authorized. If the submitter does not agree to accept publicly releasable or non-public records, DCP consults with OCC. If FDA has no publicly releasable or non-public records, DCP notifies the submitter of that fact and consults with OCC as needed.

d. (Request from a person other than a state government agency for records.) See item 8.B.(2)(a) for a state government agency. For requests from a federal or foreign government agency, DCP contacts the requester to discuss the request for records.

(i) (Federal government agency.) DCP follows the procedures in item

8.A.(3)(c).

(ii)(Foreign government agency.) DCP follows the procedures in item 8.A.(3)(c).

(iii) (Member of the public). DCP notifies FDA's DFOI and provides an explanatory note, and a copy of the request for that office to log in as a FOIA request and assign administrative controls.

(4) **DCP: Certification of records**. For requests from ORA headquarters components for certification of records, DCP forwards the request to the appropriate FDA component for handling.

B. Division of Federal-State Relations (HFC-150).

(1) **DFSR: Testimony**.

a. A subpoena from a state court could mean that a state government agency is a party in the litigation. In this case, the subpoena may, for example, refer to "State of Wisconsin v. John Doe." When the state government agency is a party in the litigation and the subpoena is submitted on behalf of the state government agency, then DFSR reviews the request and prepares the authorization recommendation package to the Director, DCP, through the Director, ORO

b. A subpoena from a state court could also pertain to private litigation in which the state government agency is not a party in the litigation. That is, the state court issued the subpoena to FDA on behalf of one of the private litigants to request testimony from an FDA employee. In this case, DCP rather than DFSR reviews the subpoena and prepares the documents for the Director, DCP's signature.

c. In addition to subpoenas submitted on behalf of a state government agency, DFSR handles all requests from a state government agency for testimony. Affidavits and other testimony in written form should be reviewed by OCC. Affidavits attesting only to the absence of records or that identify documents for the purpose of certifying records for a FOIA request do not require OCC review.

d. (Subpoena submitted on behalf of a state government agency for testimony; request from state government agency for testimony.) DFSR contacts the submitter or requester to discuss the subpoena or request.

(i) (Subpoena submitted on behalf of state government agency for testimony.) If the subpoena is submitted on behalf of a state government agency, DFSR contacts the submitter to discuss the subpoena. DFSR asks if the submitter would accept publicly releasable records, in lieu of testimony, if records are available and address the information the submitter seeks. If the submitter agrees to accept publicly releasable records, DFSR determines if those records are available. DFSR notifies the appropriate FDA component that is responsible for reviewing and redacting the record, and provides an explanatory note, and a copy of the subpoena for that

office's records. If FDA has no publicly releasable records, and the submitter agrees to accept non-public records, DCP may process the subpoena as a request under § 20.88 or under other law, if authorized (e.g., share with a commissioned official or under contract or agreement containing confidentiality provisions). If the submitter does not agree to accept publicly releasable or non-public records, or no records are available, DFSR consults with OCC, as needed, and prepares documentation for DCP under 21 C.F.R. § 20.1.

(ii) Generally, when a subpoena from a state court is involved, federal Supremacy Clause considerations prohibit a state court from compelling a federal agency employee who is the subject of the subpoena to testify in response to that subpoena.

(iii) (Request from a state government agency for testimony.) DFSR follows the procedures in item 8.B.(1)(d)(i).

(2) **DFSR: Production of records**.

a. (Subpoena submitted on behalf of a state government agency for records; request from state government agency for records.) DFSR contacts the submitter or requester to discuss the subpoena or request.

(i) (Subpoena submitted on behalf of state government agency for records.) DFSR determines if publicly releasable records are available that address the information the submitter seeks. If records are available, DFSR notifies the appropriate FDA component that is responsible for reviewing and redacting the record, and provides an explanatory note, and a copy of the subpoena for that office's records. If FDA has no publicly releasable records, and the submitter agrees to accept non-public records, DFSR may process the subpoena as a request under § 20.88 or under other law, if authorized. If the submitter does not agree to accept publicly releasable or non-public records, DFSR consults with OCC, if needed. If FDA has no publicly releasable or non-public records, DFSR notifies the submitter of that fact and consults with OCC as needed.

(ii) Generally, when a subpoena from a state court is involved, there are federal Supremacy Clause considerations present that prohibit a state court from compelling a federal agency to produce records in response to that subpoena.

(iii) (Request from a state government agency for records.) DFSR follows the procedures in item 8.B.(2)(a)(i).

(3) DFSR: Certification of records. DFSR seeks DCP's advice when it wishes to have its records certified.

C. DFOI (HFI-35) logs in a request or a subpoena for testimony or records, including a Subpoena Duces Tecum, only after DCP (or DFSR when dealing with a state government

agency) has provided DFOI with an explanatory note and a copy of the subpoena or request. DFOI logs in the request or subpoena and assigns administrative controls.

D. OCC (GCF-1) counsels DCP, DFSR, and other FDA components regarding the legal aspects of requests and subpoenas for testimony, subpoenas for records, and providing testimony, including review of written testimony, e.g., affidavits, and preparing witnesses to testify.

E. Other FDA employees (testimony). Personnel who receive a request or a subpoena for testimony:

(1) advise the requester or submitter of the requirements of 21 CFR § 20.1 and FDA's procedures for processing those requests or subpoenas. Also advise that FDA does not process verbal requests for testimony. For a written request from, or a subpoena submitted on behalf of, a person other than a state government agency, the person should send the request or subpoena to DCP at its office. For a written request from, or a subpoena submitted on behalf of, a state government agency, the person should send the request or subpoena to DFSR at its office:

U.S. Food and Drug Administration
Office of Enforcement
Division of Compliance Policy (HFC-230)
5600 Fishers Lane
Rockville, MD 20857
Phone: (301) 827-0420
Facsimile: (301) 827-0482

U.S. Food and Drug Administration
Office of Regional Operations
Division of Federal-State Relations (HFC-150)
5600 Fishers Lane
Rockville, MD 20857
Phone: (301) 827-2898
Facsimile: (301) 443-2143

(2) recommend that the requester or submitter:

a. submit their request or subpoena well in advance of their desired due date to allow time for evaluating and processing the requests; and

b. include information about the hearing body, date, location, and purpose of the proceeding; the nature and scope of the testimony FDA is being asked to provide and the use to which it will be put; the name(s) of the FDA employees, if known, being asked to testify; the requester's interest in the matter sought to be disclosed; the requester's rationale for considering that the testimony is in the public interest and will promote the objectives of FDA and the laws it enforces; and any other relevant background;

(3) do not indicate any commitment regarding availability or willingness to testify in any particular case;

(4) forward written requests or subpoenas to DCP and/or DFSR and a memorandum about the conversation with the requester or submitter by email or facsimile at the telephone numbers in item 7.F.(1), and contact those offices to confirm receipt;

(5) alternatively, refer the requester or submitter to DCP or, as appropriate, DFSR;

(6) assist DCP and DFSR in responding to a request or subpoena for testimony, and when appropriate, identify suitable individual(s) to testify and draft authorized testimony, or indicate if and where records (instead of testimony) are available that will be responsive,

(7) before presenting testimony, contact the assigned OCC attorney to obtain legal advice; and the appropriate FDA component, to obtain technical advice and, if any, information about funding travel;

(8) after presenting testimony, submit a summary or copy of the testimony or a transcript of the testimony to DCP, OCC, and, if involved, DFSR. If the Director, DCP, authorizes the testimony for a hearing in a state court, the summary memorandum should address not only the individual's testimony, but also any other portions of the hearing that the individual attended.

F. Other FDA employees (records). Personnel who receive a request or a subpoena, including a Subpoena Duces Tecum, for production of records or certification of records:

(1) advise the requester or submitter of the requirements of 21 CFR § 20.2 and FDA's procedures for processing those requests or subpoenas as described in this section. Also advise that FDA does not process verbal requests for records;

(2) recommend that the requester or submitter:

a. submit their request or subpoena to the address(es) shown in item 7.E.(1) well in advance of their desired due to allow time for evaluating and processing the requests; and
b. include specific information about the records requested, the requested due date, and any other relevant background;

(3) do not indicate any commitment regarding availability of the records; and

(4) follow procedures in items 8.E.4. and 5, and indicate to DCP and/or DFSR if and where responsive records are available.

10-8-9 Publicly Releasable Information

FDA generally discloses information pursuant to a request or subpoena if that information is neither exempt from disclosure under FOIA nor prohibited from disclosure by other law. In certain circumstances, however, the law allows FDA to share certain non-public information that is otherwise exempt or prohibited from disclosure, e.g., 21 C.F.R. §§ 20.85 (disclosure to other federal agencies), 20.88 (disclosure to state and local agencies), or 20.89 (disclosure to foreign agencies). Other examples of instances in which FDA may share non-public information are set

forth below.

A. FDA may share certain non-public information with federal or state officials commissioned by FDA under law.

B. FDA may share certain non-public information with other government officials under agreements or contracts that contain appropriate confidentiality provisions.

C. FDA may share personal privacy information that a state or federal prosecuting attorney seeks without redaction for use as evidence at trial, if the release is allowed under the Privacy Act (5 U.S.C. § 552a). Contact OCC and FDA's Privacy Act Officer in DFOI before sharing this non-public information.

D. In limited circumstances, FDA may share grand jury information obtained during a criminal investigation, pursuant to Fed. R. Crim. P. 6(E). Contact OCC before sharing this non-public information.

E. 21 U.S.C. § 331(j) authorizes disclosure of trade secret information to the courts only in judicial proceedings under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Contact OCC before sharing this non-public information.

F. If OCI is involved in joint investigations with other law enforcement agencies for violations of the FD&C Act, contact OCI before sharing non-public information related to the investigation. Applicable regulations in 21 C.F.R. Part 20, the law enforcement exemption of the Privacy Act, and 21 U.S.C. § 331(j) govern disclosures of certain non-public information during the course of open multi-agency investigations. In all multi-agency investigations, OCI has obtained or, prior to the sharing, will obtain confidentiality assurances that the non-public information disclosed by FDA will be used for law enforcement purposes only, and in accordance with the provisions of the applicable statutes.

10-8-10 Tables To Illustrate Procedures

The following tables set forth abbreviated versions of the main points of the procedures in this section. One table is entitled, "Processing a Subpoena for the Testimony of an FDA employee and/or Subpoena Duces Tecum for FDA records." The other table is entitled, "Processing a Written Request for the Testimony of an FDA employee and/or a Written Request for FDA Records."

Processing a Subpoena for the Testimony of an FDA employee And/or Subpoena Duces Tecum for FDA records.	
NOTE: 1. DCP initially reviews subpoena if submitted on behalf of person other than state government agency. 2. DFSR initially reviews subpoena if submitted on behalf of state government agency. DFSR then prepares 21 CFR § 20.1 package for Director, DCP, review and signature. If OCC consult needed, DFSR notifies DCP. 3. FDA's regulations permit FDA to share non-public records with federal (21 CFR § 20.85), state (21 CFR § 20.88), or foreign (21 CFR § 20.89) government agencies.	
Subpoena Issued by a U.S. District Court For Testimony	Contact submitter to discuss and for consent to provide publicly releasable records. ▪ If consent given, determine if responsive records are available. If records are available, contact DFOI and forward subpoena. ▪ If no consent given, contact OCC and process under § 20.1. ▪ If no publicly releasable records available, contact OCC and process under § 20.1. ▪ Another government agency involved? If consent given, and records are available, contact appropriate FDA component and forward request. If no consent to publicly releasable records, but consented to accepting non-public records, may process under §§ 20.85 (federal), 20.88 (state), or 20.89 (foreign) or other law. If no consent to publicly releasable or non-public records, or no records are available, contact OCC and process under § 20.1.
Subpoena Issued by a U.S. District Court For Testimony and Records, or Subpoena Duces Tecum (Records Only)	Contact submitter to discuss and for consent to provide publicly releasable records. ▪ If consent given, determine if responsive records are available. If records are available, contact DFOI and forward subpoena or Subpoena Duces Tecum. ▪ If no consent given, contact OCC. ▪ If no publicly releasable records available, contact OCC (for testimony part), contact submitter (for records part) and, for testimony, process under § 20.1. ▪ Another government agency involved? If consent given, and records are available, contact appropriate FDA component and forward request. If no consent to publicly releasable records, but consented to accepting non-public records, may process under §§ 20.85 (federal), 20.88 (state), or 20.89 (foreign) or other law. If no consent to publicly releasable or non-public records, or no records are available, contact OCC (for testimony part), contact submitter (for records part), and, for testimony,

	process under § 20.1.
Subpoena Issued by a State Court For Testimony	Contact submitter to discuss and to request that it accept publicly releasable records. ▪ If consent given, determine if responsive records are available. If records are available, contact DFOI and forward subpoena. ▪ If no consent given, process under § 20.1. ▪ If no publicly releasable records, process under § 20.1. ▪ Another government agency involved? If consent given, and records are available, contact appropriate FDA component and forward request. If no consent to publicly releasable records, but consented to accepting non-public records, may process under §§ 20.85 (federal), 20.88 (state), or 20.89 (foreign) or other law. If no consent to publicly releasable or non-public records, or no records are available, process under § 20.1.
Subpoena Issued by a State Court For Testimony and Records, or Subpoena Duces Tecum (Records Only)	Contact submitter to discuss and request that they accept publicly releasable records. ▪ If consent given, determine if responsive records are available. If records are available, contact DFOI and forward subpoena or Subpoena Duces Tecum. ▪ If no consent given, process under § 20.1 (for testimony part), and for the records part, contact DFOI and forward the Subpoena or subpoena Duces Tecum ▪ If no publicly releasable records, process under § 20.1 (for testimony part), contact submitter (for records part) and, for testimony, process under § 20.1. ▪ Another government agency involved? If consent given, and records are available, contact appropriate FDA component and forward request. If no consent to publicly releasable records, but consented to accepting non-public records, may process under §§ 20.85 (federal), 20.88 (state), or 20.89 (foreign). For the testimony part: If no consent for publicly releasable or non-public records, or no records are available, process under § 20.1. For the records part: If no consent for publicly releasable or non-public records, consult with OCC, and if no records are available, contact the submitter.

Processing a Written Request for the Testimony of an FDA employee
And/or
A Written Request for FDA Records

NOTE:
1. DCP initially reviews a request from a person other than state government agency.
2. DFSR initially reviews a request from a state government agency. DFSR then prepares 21 CFR § 20.1 package for Director, DCP, review and signature. If OCC consult needed, DFSR notifies DCP.
3. FDA's regulations permit FDA to share non-public records with federal (21 CFR § 20.85), state (21 CFR § 20.88), or foreign (21 CFR § 20.89) government agencies.

Written Request For Testimony of FDA Employee	Contact requester to discuss and for consent to provide publicly releasable records. ▪ If consent given, determine if responsive records are available. If records are available, contact DFOI and forward request. ▪ If no consent given, contact OCC and process under § 20.1.

	▪ If no publicly releasable records available, process under § 20.1. ▪ Another government agency involved? If consent given, and records are available, contact appropriate FDA component and forward request. If no consent to publicly releasable records, but consented to accepting non-public records, may process under §§ 20.85 (federal), 20.88 (state), or 20.89 (foreign) or other law. If no consent to publicly releasable or non-public records, or no records are available, contact OCC and process under § 20.1.
Written Request for Records	▪ Member of public involved? Contact DFOI and forward request. ▪ Another government agency involved? Contact a non-FDA government agency requester to discuss to request that they accept publicly releasable records, if available. If consent given, and records are available, contact appropriate FDA component and forward request. If no consent to publicly releasable records, but consented to accepting non-public records, may process under §§ 20.85 (federal), 20.88 (state), or 20.89 (foreign) or other law. If no records are available, contact requester.
Written Request for Testimony and Records	Process according to the above two items.

10-9 APPLICATION INTEGRITY POLICY

The Application Integrity Policy (AIP) describes the Agency's approach regarding the review of applications that may be affected by wrongful acts that raise significant questions regarding data reliability. FDA published this policy, formally entitled, "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy" in the Federal Register on September 10, 1991 (56 FR 46191), and in Compliance Policy Guide (CPG) 7150.09 (see Sec. 120.100 of the Compliance Policy Guides publication). These documents, procedures to implement the AIP, and AIP information are available on the internet at: http://www.fda.gov/ora/compliance_ref/aip_page.html.

10-10 EXHIBITS

EXHIBITS:

10-1 TEXT OF 21 C.F.R. § 20.1
10-2 EXAMPLE: U.S. DISTRICT COURT (FEDERAL) SUBPOENA (FIRST PAGE)
10-3 EXAMPLE: STATE COURT SUBPOENA WHEN THE STATE IS NOT A PARTY (First Page)

Exhibit 10-1
TEXT OF 21 C.F.R. § 20.1

Section 20.1 Testimony by Food and Drug Administration employees.

(a) No officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health and Human Services, except as authorized by the Commissioner of Food and Drugs pursuant to this section or in the discharge of his official duties under the laws administered by the Food and Drug Administration, shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information acquired in the discharge of his official duties.

(b) Whenever a subpoena, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the giving of any testimony, such officer or employee shall, unless otherwise authorized by the Commissioner, appear in response thereto and respectfully decline to testify on the grounds that it is prohibited by this section.

(c) A person who desires testimony from any employee may make written request therefor, verified by oath, directed to the Commissioner setting forth his interest in the matter sought to be disclosed and designating the use to which such testimony will be put in the event of compliance with such request: Provided, That a written request therefor made by a health, food, or drug officer, prosecuting attorney, or member of the judiciary of any State, Territory, or political subdivision thereof, acting in his official capacity, need not be verified by oath. If it is determined by the Commissioner, or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose, that such testimony will be in the public interest and will promote the objectives of the act and the agency, the request may be granted. Where a request for testimony is granted, one or more employees of the Food and Drug Administration may be designated to appear, in response to a subpoena, and testify with respect thereto.

Exhibit 10-2
EXAMPLE: U.S. DISTRICT COURT (FEDERAL) SUBPOENA (FIRST PAGE)

Issued by the

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ALABAMA

Smith
v.
Drug Firm, Inc.

SUBPOENA IN A CIVIL CASE

Case Number:[1] CV-01-23456-NE

TO: Food and Drug Administration
Attn: John Doe
5600 Fishers Lane
Rockville, MD 20850

☐ YOU ARE COMMANDED to appear in the United States District Court at the place, date, and time specified below in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☐ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION	DATE AND TIME

☐ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (LIST DOCUMENTS OR OBJECTS HERE, IN ANOTHER ITEM OR IN AN ATTACHMENT):

All of the items described in Exhibit "A" attached hereto and incorporated herein as fully rewritten

PLACE:	DATE AND TIME

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	Date
Harry Smith, Attorney for Plaintiff	

ISSUING OFFICER'S NAME, ADDRESS, AND PHONE NUMBER
Harry Smith, Smith & Smith LLC
12345 Rough Road, Hometown, MD 12345

[1] If action is pending in district other than district of issuance, state district under case number.

Exhibit 10-3
EXAMPLE: STATE COURT SUBPOENA WHEN THE STATE IS NOT A PARTY (First Page)

Harry Smith, Esq. Smith & Smith Attorneys at Law 123 Fourth Street San Francisco, CA 12345 Telephone No. (415) 123-4567 Fax No. (415) 123-6789 Attorney for: John Doe	For Court Use Only
Name of Court: SUPERIOR COURT OF THE STATE OF CALIFORNIA STREET ADDRESS: 456 Ninth Street MAILING ADDRESS: 456 Ninth Street CITY AND ZIP CODE San Francisco, CA BRANCH NAME: Civic Center Courthouse	
Plaintiff/Petitioner: MARY JANE DOE On behalf of themselves DEFENDANT/RESPONDENT: MEDICAL DEVICE FIRM, INC.	
CIVIL SUBPOENA **For Personal Appearance at Trial or Hearing**	Case Number:

THE PEOPLE OF THE STATE OF CALIFORNIA, TO (name, address, and telephone number of witness, if known):
John Jones, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, California 94502 (510) 123-4567

1. YOU ARE ORDERED TO APPEAR AS A WITNESS [testify at the taking of a deposition] [produce and permit inspection and copying of the documents] in this action at the date, time, and place shown in the box below UNLESS you make an agreement with the person named in item 2.

[DESCRIPTION OF SUBJECT MATTER HERE, IN ANOTHER ITEM, OR IN AN ATTACHMENT.]

a. Date:	Time:	Dept.	Div.	Room
b. Address: San Francisco Superior Court, 400 McAllister Street, San Francisco. CA.				

2. IF YOU HAVE ANY QUESTIONS ABOUT THE TIME OR DATE TO APPEAR, OR IF YOU WANT TO BE CERTAIN THAT YOUR PRESENCE IS REQUIRED, CONTACT THE FOLLOWING PERSON BEFORE THE DATE ON WHICH YOU ARE TO APPEAR:

   a. Name of subpoenaing party or attorney: Harry Smith, Esq.
   b. Telephone Number (415) 123-4567

3. Witness Fees: You are entitled to witness fees and mileage actually traveled both ways, as provided by law, if you request them before your scheduled appearance form the person named in item 2.

DISOBEDIENCE OF THIS SUBPOENA MAY BE PUNISHED AS CONTEMPT BY THIS COURT. YOU WILL ALSO BE LIABLE FOR THE SUM OF FIVE HUNDRED DOLLLARS AND ALL DAMAGES RESULTING FROM YOUR FAILURE TO OBEY.

Date Issued:

Harry Smith, Esq…….. Harry Smith, Esq.

(type or print name) (SIGNATURE OF PERSON ISSUING THE SUBPOENA)

ATTORNEYS FOR DEFENDANTS, MEDICAL DEVICE FIRM, INC.