# Chapter 6 JUDICIAL ACTIONS

NOTE: For actions resulting from a Current Good Manufacturing Practice (CGMP) or Quality System (QS) inspection of a domestic or foreign drug, biologics, or medical device facility, the firm's profile status information in the Field Accomplishment and Compliance Tracking System (FACTS) should be appropriately updated at each stage in the review process. (See "Firm Profile Updates in FACTS" in Chapter 4 for more information.)

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#### 6-1 SEIZURE

#### 6-1-1 Purpose

This section provides procedures and instructions for initiating, reviewing, approving, effecting, monitoring, and closing out seizure actions filed under 21 U.S.C. 334.

The United States of America, as plaintiff, proceeds under the Supplemental Rules for Certain Admiralty and Maritime Claims (Supplemental Rules) by filing a Complaint for Forfeiture and obtaining a warrant for arrest, directing the United States Marshal to seize (take possession or place in constructive custody of the court) the article. The theory in a Complaint for Forfeiture is that the article seized is the defendant, and that the government asks the court to condemn the article and declare forfeiture for violation of the law by the article itself. Any interested party, owner, or agent may appear to claim the article by filing a verified claim stating the nature of his/her interest in the article.

Only a proper claimant may litigate on behalf of the seized article. If there is no proper claimant, the United States is entitled to condemnation and forfeiture by default.

#### 6-1-2 General Guidelines for Seizures

Before initiating a seizure case, the compliance officer and the district's management must consider several factors.

#### 1. Prior Warning

See procedures under RPM, "Prior Notice," and RPM, "Warning Letters" and specific compliance program and policy guides.

#### 2. Home District Concurrence

A district proposing seizure of goods in another district of the Food and Drug Administration (FDA) is responsible for contacting the home district to determine whether the home district concurs with the proposed seizure and to obtain information pertaining to the firm's background: violations, prior warnings, current status, and pending and adjudicated actions involving the same charges. The district proposing the seizure is also responsible for ensuring that the seizure follows current guidelines.

#### a. Home District

The district in whose territory the alleged violation of the Act occurs, or in whose territory the firm or individual responsible for the alleged violation is physically located.

In the case of seizures of articles that were violative when introduced or offered for introduction into interstate commerce, the home district is the location from which the article was shipped, or offered for shipment, as shown by the interstate records; and the shipper of such article, as shown by such records, is usually considered to be the alleged violator.

In the case of seizures of articles which became violative after interstate shipment was made, or after reaching their destination (i.e., while in interstate commerce or while held for sale after shipment in interstate commerce), the dealer having possession of the goods at the time of sampling is usually considered the violator and the location of this dealer determines the home district.

## b. Seizing District

The district in whose territory seizure is actually accomplished. The seizing district is not necessarily the home district. Also it is not necessarily the collecting district, as in the case of in transit samples or when a collector from an adjoining district crossed the district boundary to collect a sample.

#### c. Supervising District

The district that exercises supervision over reconditioning lots in connection with seizure actions.

## 3. Voluntary Hold Or Embargo

If there is concern that the product will be distributed before seizure can be effected, FDA will determine if the dealer will voluntarily hold the product or if an embargo will be necessary. State embargoes should be requested only when there is assurance that the seizure will be approved by the Agency, or when Direct Reference criteria have been met. See 6-1-4, Direct Reference Seizure Authority.

For counterfeit drugs and the equipment used to make them, the FDA can first seize and then file a complaint later. See 21 U.S.C. 334(a)(2) and 372(e)(5).

Also, there are provisions in the statute providing for administrative detention of devices or tobacco products [21 U.S.C. 334(g)], and food [21 U.S.C. 334(h)]. The RPM sections "Administrative Detention of Food" and "Administrative Detention of Devices" contain the specifics of the administrative detention procedures.

## 4. Size Of Lot To Be Seized

Where the retail value of the lot in question is less than two thousand dollars (\$2,000) and when the violation does not involve a hazard to health, refer the facts relating to the violative goods to state or local officials wherever possible.

In some instances, lots larger than \$2,000 may also be disposed of by state or local action and lots smaller than \$2,000 may be seized. For example, seizure of lots valued at under \$2,000 may be appropriate when: there is a documented hazard to health; when the violative product will be incorporated into other products, thus receiving more extensive distribution (e.g., flour containing pesticides is used as an ingredient in baked goods); or when the seizure is necessary to establish a legal precedent.

Certain programs and policy guides, such as the Compliance Policy Guides (CPG) Manual "Sec. 120.500 Health Fraud – Factors in Considering Regulatory Action," may also have governing limits or conditions for seizure action.

#### 5. Violations Which Appear Easily Corrected

On occasion, seizures may be instituted against articles for violations that could have been easily corrected by the owner without litigation, such as violations of the Fair Packaging and Labeling Act (FPLA). If seizures of this nature are questioned by U.S. Attorneys and judges, it may be pointed out that the violator has refused to correct after prior notice and that, when informal procedures are followed, the expenses incurred to ensure that the goods were in fact brought into compliance would be borne by the government, rather than the violator. In addition, when informal reconditioning is attempted, the violator may ship the goods without bringing them into compliance.

21 U.S.C. 334(d) of the Federal Food, Drug, and Cosmetic Act (Act) sets forth the procedure to be followed for attempted reconditioning of articles found in violation.

The bond required of the claimant and the supervisory powers given to FDA at the claimant's expense is intended to minimize the chances that the seized goods will be marketed without being brought into compliance.

#### 6. Violations When Agency Has Other Means Of Control

Seizure may not be the most appropriate means of control when the Agency has control over products through other means. An example would be halting a sponsor's unlawful shipments of unlicensed biologics due to possible interference with an ongoing attempt to obtain a license.

## 7. Voluntary Reconditioning (except for unapproved drugs)

Voluntary destruction of violative lots before seizure should be encouraged; however, any person destroying a lot should be made aware of the National Environmental Policy Act (NEPA) requirements. A copy of the requirements may be obtained from the ORA Safety Management Officer, HFC-21.

Under no circumstances should FDA witness the voluntary reconditioning of unfit goods, regardless of the nature of the violation or the size of the lot. If a lot is reconditioned, do not recommend seizure unless it is confirmed by examination that the lot is still in violation. If the goods are unapproved drugs, reconditioning is not considered.

## 8. Continuing Violations

When considering a seizure case for which there is evidence (or the likelihood) of repeated or continuing violations, the district should also consider whether the public could be better protected by alternative or simultaneous injunctive action. Consideration may also be given to initiating seizure to quickly obtain control of the articles and, either attempting to obtain injunctive relief in a consent decree or amending the complaint for injunctive relief.

#### 9. Section 702(b) Samples

Section 702(b) of the Act [21 U.S.C. 372(b)] requires that a part (portion) of the sample of a food, drug, or cosmetic collected for analysis must be provided, upon request, to any person named on the label or the owner thereof, or his attorney or agent. The regulation at 21 CFR 2.10(c) provides certain exceptions to this requirement, but duplicate samples must be available, unless exempted. Failure to provide a part of the sample may jeopardize the seizure action as well as any future action based on analysis of that sample.

## 10. Preservation Of Shipping Records

The Interstate Commerce Commission regulations (49 CFR 1220.6) require common carriers to keep their records only for one to three years, depending on the type of carrier and record to be kept.

Contested seizure cases or prosecutions following the seizure are often delayed and may not go to trial until more than three years after the shipments were made. In such instances involving shipments by common carrier, steps should be taken to preserve the records that will be essential to prove interstate shipment at the time of trial.

## 11. Venue, (Place Of Trial) In Actions Arising Under The Federal Food, Drug, And Cosmetic Act

"Venue" means the place or locality of trial. In all seizure actions arising under the Act, the case is initially brought in the court where the goods are located. The court in which the seizure is accomplished has jurisdiction.

21 U.S.C. 334(a) of the Act states an article may be seized and condemned by any district court of the United States in whose jurisdiction the article is found.

It is possible under 28 U.S.C. 1404(b) to obtain a transfer of proceedings in rem from one division to another division within the judicial district without the consent of the government.

21 U.S.C. 334(a) and (b) describe situations in which venue can be changed. 21 U.S.C. 334(a) applies to situations in which the number of proceedings is limited by law, i.e., misbranding. 21 U.S.C. 334(b) applies when two or more proceedings involving the same claimant and the same issues are pending, and is concerned primarily with consolidation of cases for trial.

In all requests for change of venue, any FDA staff who become aware of this change should promptly advise the Office of Chief Counsel (OCC) attorney assigned to the case.

## 6-1-3 Types of Seizures

## 1. Mass And Open-ended Seizures

The terms "mass" and "open-ended" are used by FDA to distinguish these seizures from "lot-specific seizures," in which a specific lot or batch of a product is seized. These are internal classifications without independent legal status. They do not appear in the Letter to the U.S. Attorney or in the pleadings, but simply allow the agency to track seizure actions by size and/or impact.

A mass seizure is the seizure of all FDA-regulated products at an establishment/facility. Mass seizures might be conducted when all of the products are

held in the same environment (e.g., a filthy warehouse) or are produced under the same conditions (e.g., non-conformance with current Good Manufacturing Practice). A seizure of products in a filthy warehouse is considered a "mass seizure" even though it does not include products that are not susceptible to contamination because of their packaging (e.g., canned goods) or location (e.g., products kept in a freezer or on a floor of the facility where there was no evidence of rodent or insect infestation). Special considerations for mass seizures are described below.

An open-ended seizure is the seizure of all units of a specific product or products, regardless of lot or batch number, when the violation is expected to be continuous. An open-ended seizure may be conducted when a specific product is not approved or bears violative labeling, or when the violation otherwise extends to all lots or batches of a product, but not to all of the products in the firm. For example, seizure of all lots or batches of oxygen in a medical gas facility that produces other types of gas would be an open-ended seizure rather than a mass seizure. A mass seizure at this facility would encompass all gasses produced by the firm. Recommendations for open-ended seizures are processed in the same fashion as lot-specific seizures.

## 2. Multiple Seizures

The term "multiple seizures" is used to describe the seizure of the same product in more than one district court. Multiple seizures may be initiated to prevent the continued distribution or use of violative product at more than one location, particularly product that is dangerous.

Section 304(a)(1) of the Act imposes restrictions on certain multiple seizures, if they are based on the same alleged misbranding and other conditions are not met. Consult this section of the Act (and Office of Enforcement and Import Operations (OEIO), Division of Enforcement (DE), if necessary), before pursuing an enforcement strategy that will involve multiple seizures of misbranded product.

#### 3. Mass Seizure — Special Considerations

Mass seizures are different from lot-specific seizures because pertinent events and evidence frequently change from the time the investigator documents the violative conditions until the seizure is effected; for example, new lots arrive, FDA-documented lots may have been distributed, and some corrective action may have been taken. These factors can complicate the case and interfere with prompt settlement or other disposition. Thus, prompt action by the agency and the Department of Justice is necessary to effect seizures while the evidence is fresh and accurately reflects the conditions under which the goods are prepared or held.

Therefore, as a general rule, the evidence of violative conditions supporting mass seizure, usually determined on the last day of the Establishment Inspection (EI), should not be more than 30 days old when the case is transmitted to the U.S. Attorney's Office for filing. The 30 day rule does not apply if the deviation is a failure that cannot be corrected within 30 days, for example, the failure to validate a

particular procedure or the failure to have had an approval to market a new drug. Provide an explanation in the recommendation why this rule is not applicable when necessary.

Because of the effect that a mass seizure can have on a company, extra care should be taken to ensure that the evidence warrants the proposed action against all articles to be seized. The compliance officer assigned to the case should be thoroughly familiar with the facts. In addition, OCC will prepare a consent decree which may include provisions for injunctive relief, based on material provided by the district and Center.

Special considerations regarding evidence needed in 21 U.S.C. § 342(a)(4) mass seizures based on filth are as follows:

- a. There must be compelling evidence of significant insanitary conditions (e.g. current live rodent, insect, bird or other vermin activity in the location where the food is to be seized). Physical evidence of filth on each lot of food to be seized is not necessary.
- b. The evidence should demonstrate that the infestation has resulted in widespread 342(a)(4) adulteration or that the live infestation is sufficiently dense and can reasonably be expected to spread to the food to be mass seized.

Examples of mass seizure cases involving 342(a)(4) conditions are available from DE.

## 6-1-4 Direct Reference Seizure Authority

Direct Reference is an option used when there is clear agency policy, for example, actions based on contamination of certain commodities. Centers have already concurred with stated policy described in documents that provide for Direct Reference. When the CPG (under specific commodities guidance), or other guidance provides for Direct Reference, recommendations should be referred directly to DE. Prior to forwarding the recommendation, the district should determine that the article is available for seizure, and that all samples and charges meet the Direct Reference criteria.

## 6-1-5 Approval Process for Seizure and Injunction Cases

The approval process set forth below applies to both seizure and injunction cases. This process was established to increase collaboration and sharing of evidence at the early stages of case development, to reduce paperwork, to rule-out unsupportable cases, and to shorten approval times for all cases. This process is not meant to diminish the role or responsibility of any participant, nor does it diminish the expectation for quality. The district is not required to wait until a judicial action is likely to result before communicating concerns to any participants prior to the preliminary assessment (PA) call.

## 1. Preliminary Assessment (PA) Call):

If all participants have been in communication and are in agreement to move forward with a case, a PA call may be skipped. In such cases, the party proposing the action will prepare a document to be e-signed by the participants and will upload the signed document in MARCS-CMS (CMS) to document concurrence to move forward without performing the PA call. The party proposing the action will inform OEIO of the decision if it is not one of the involved parties. Given this documentation, the party proposing the action can proceed with uploading the Case Initiation Memo (CIM) and supporting evidence in CMS.

## a. Timing:

As soon as practicable after the possibility of conducting a seizure or injunction is first identified, the party proposing the injunction or seizure should arrange a PA call between the district(s) that would be involved in the proposed seizure or injunction, the relevant Center(s), OEIO, and OCC, or their designees. When appropriate, the call should occur before the inspection is over. In cases where there is no formal inspection, such as when evidence is developed by an online search, the call should occur after the evidence has been collected.

## b. Key Documents:

In advance of the PA call, the party initiating the call should create a preliminary assessment work activity in CMS. CMS is available from FDA's intranet site under *ORA Applications*. The party uploads any evidence supporting a seizure or injunction (e.g., proof of jurisdiction, photographs/videos, analytical worksheets, the 483, product label and labeling), and labels each entry clearly. Call participants should review the information in CMS information prior to the call when practicable.

## c. Participants:

The call should include the district(s), the relevant Center(s), OEIO, OCC Regional Counselors and other principals as appropriate. The district will select each participant in CMS. A principal may designate a representative authorized to act on behalf of the participant; for example, the Center may designate the appropriate Office of Compliance to represent the Center. OCC may be represented by the appropriate Regional Counselor.

## d. Topics:

Topics may include: the identity of the firm, type of product involved, problems revealed by the inspection, public health risk, jurisdiction and interstate commerce, potential violations of the statute, supporting evidence, relevant compliance policy documents, prior compliance history, scientific support, and potential for a corporate-wide action. A suggested PA call agenda check list would include, but not be limited to the following:

- 1. PA call-in phone number and pass code
- 2. List of district attendees (the compliance officer and the investigators would be expected to participate)
- 3. List of attendees from the Center(s), OEIO, OCC Regional Counselors, and other officials if necessary (and their telephone numbers to include in CIM)
- 4. Establishment(s) name(s), FEI number/registration number, city/state, and brief description of the firm's operation/processing
- 5. Product(s) description (thorough), including type of packaging and labeling
- 6. The overall and most significant problem(s)
- 7. Associated risk(s) and impact
- 8. Need for expert and/or health hazard evaluation
- 9. The recommended action
- 10. Overall charge scheme (e.g., 21 U.S.C. §§ 342 (a)(4) or 355)
- 11. A summary of the current significant violations observed and dates observed
- 12. A brief overview of the firm's compliance history, including recalls and reportable events
- 13. Relevant compliance policies
- 14. Sensitive or controversial issues and concerns
- 15. Appropriate notification of and coordination with tribal, state, territories, or local authorities
- 16. Supporting evidence in CMS, identified by the naming conventions
- 17. Additional evidence possessed by call participants important to the decision whether to proceed with the case (e.g., HACCP plan, process flow, floor plan, photographs, batch records, complaint records, SOPs).

#### e. Decision:

At the time of the call, the call participants should decide whether to further pursue the seizure or injunction or should identify additional evidence (e.g., sample results that are pending or an expert that is needed). If the participants identified in the PA call decide not to bring a seizure or injunction, the matter will not be processed unless an *ad hoc* committee decides otherwise using the procedures described below and in RPM <a href="Chapter 10-8">Chapter 10-8</a>, AD HOC COMMITTEE. The decisions of the participants are not final and may be changed as the case develops based on new information, evidence, or views.

#### f. Record of call:

The party proposing the action (usually the district) will take notes of the views expressed by the participants during the call and will circulate an e-mail or other informal communication briefly summarizing those views to the participants. This summary and any subsequent comments may also be inserted into the Case Initiation Memorandum (CIM) in the appropriate section, if the decision is to proceed with the case. Please note that these

materials may be subject to review in discovery. If you have any questions about what should or should not be shared, please contact OCC.

## g. Identify Lead Coordinators and Experts:

Following a decision to pursue a seizure or injunction, the district, the Center(s), OEIO, and OCC should each assign a lead coordinator who will retain the role of lead coordinator throughout the case wherever possible. The lead coordinator need not have been a call participant. For OCC, the lead coordinators will be the Designated Regional Counselor. For the Centers, the lead coordinators may be from the Office of Compliance. The Center must begin to identify, retain, or assign an expert in all cases requiring expert support. Following the call, any new evidence should be uploaded into CMS and a task should be created and the lead coordinators should alert participants to review the new information.

When requesting an expert from the program offices or an outside expert, the center must:

- i. clearly establish what the expert will need to be able to testify about.
- ii. review the qualifications of the expert to determine if the expert has the appropriate knowledge and experience based on the facts in the case.
- iii. Once the expert has an opportunity to review the evidence, discuss with the expert his/her opinion of the case and identify the strengths and weaknesses in the case. if there are weaknesses identified by the expert, the Center must clearly delineate them to OCC and advise if the Center believes the case should proceed.

#### h. New Evidence:

Following the call, any new evidence or information should be uploaded into CMS and a task should be created; the lead coordinators should alert participants to review the new information. Notify OCC using the address "OC OCC Case." mailbox in Outlook.

## 2. Case Initiation Memorandum (CIM)

As soon as practicable and, at the latest, within 10 working days of the last day of inspection, date of receipt of sample analysis, or date of evidence collection, the party proposing the action should draft a CIM that includes the views of the participants. The party proposing the action should upload the CIM and supporting evidence into CMS and should notify participants. Notify OCC using the address "OC OCC Case." mailbox in Outlook. The district should convert the PA Work Activity to a case in CMS for concurrent review by the Center, DE and OCC. The Center, DE, OCC, and other participants will not be expected to write separate memoranda, but an expert opinion may need to be obtained and if so should be added to CMS.

See Exhibit 6-1B for Format for CIM.

## 3. Concurrent Review and Use of CMS:

Generally, the lead coordinators should review the CIM and supporting evidence concurrently. They should use CMS to transfer, store, and retrieve relevant documents, set up tasks and log activities.

Each participant must approve the action with regards to the areas within its responsibilities for the case to move forward in the absence of the ad hoc proceeding. If a lead coordinator or any participant believes the case should not move forward, he or she should advise the others assigned to the case as soon as possible. If agreement can not be reached, the participant(s) with the dissenting view could then write a brief memorandum requesting review by an *ad hoc* committee (see RPM 10-8, AD HOC COMMITTEE). At the time the request for an *ad hoc* committee is made, the review clock will be tolled and remain tolled until the dispute is resolved. The committee will immediately establish a time schedule for its review of the case. The time schedule and the decision remarks made by the *ad hoc* committee should be made available in CMS.

If the lead coordinators or the *ad hoc* committee decide to proceed with a seizure, DE will prepare the final letter and legal pleadings and upload them for OCC review. Upon OCC clearance, DE will forward the legal pleadings and United States Attorney letter to the seizing district and the district will submit these documents along with an evidentiary package to the US Attorney's Office/Department of Justice (DOJ) for filing with the Courts. If the lead coordinators or *ad hoc* committee decide to proceed with an Injunction, OCC will draft the DOJ referral letter and legal pleadings and upload them in CMS. OCC will submit the letter, legal pleadings, and evidentiary package to the Office of Consumer Protection Litigation (OCPL)/DOJ for further review and concurrence. The final signed USA Attorney letter and the filed complaint will be uploaded by the district in CMS.

For seizure actions, the seizing District is expected to submit via CMS a draft Letter to the U.S. Attorney and Complaint for Forfeiture in the form required by the local judicial district in order to assure that there is a clear understanding of the scope and basis for the seizure action. DE will prepare final documents based on the District's draft. For Injunction actions, OCC will draft the legal pleadings.

Except for the CIM, formal memoranda are not required; however, it is expected that there are times when additional written documents or opinions may be needed to move the action forward. The participants may use their discretion as to the written form used for such documents, which should be brief and generated within the established time frames. The need for these documents will be determined on a case-by-case basis. To the extent possible, though, the goal is to keep required writing to a minimum.

All written opinions will be available in CMS.

#### 4. Deadlines:

The default timeframe for the two-step process is 10 working days from the latest of the date of the last date of the Establishment Inspection (EI), or sample analysis, or evidence collection for the District to submit a CIM and 13 working days from the date of the CIM until the time the case and all material or significant evidence including the expert opinion is submitted to DOJ. The deadline may be extended on a case by case basis where circumstances warrant an extension (e.g., because of laboratory results that require additional time, especially complex or voluminous evidence, or an unavoidable logistical delay).

If the deadline is extended, the requestor develops a time extension plan (TEP) for the case which includes deadlines for specific tasks and uploads it in CMS. In emergency situations, the deadline would be shortened as needed. Where possible, the review of routine cases should be completed in the most expeditious manner possible; routine cases may require less than the total of 23 working days.

#### a District:

The district should submit a CIM and all available material and evidence within 10 working days of the last day of inspection, date of receipt of sample analysis, or date of evidence collection.

#### b. Other participants:

The concurrent review and submission of the case and all material or significant evidence including the expert opinion to the Department of Justice or the onset of negotiations for a consent decree with a firm's counsel should occur within 13 working days after submission of the CIM.

## 6-1-6 Responsibilities for Seizure Actions

#### 1. District Responsibilities:

Prior to creating a PA work activity in CMS, the compliance officer should consult with the DCB and other district management to obtain support for the proposed action. The district should then create the PA work activity and upload key documents that support the most significant violations, initiate the PA call and PA Work Activity in CMS, and upload a document describing summary views expressed during the PA call.

If the participants agree that a seizure is warranted, the district is responsible for writing and uploading the CIM into CMS and notifying the participants. Notify OCC using the address "OC OCC Case in Outlook. The contents of the CIM are described below (see Section 6-1-5) [Exhibit 6-1B].

## Additional responsibilities may include:

- a. Significant changes to the fact pattern that take place after the initial preliminary assessment call should be communicated to the lead coordinator as soon as possible. The District lead coordinator is responsible for uploading the new information and evidence as soon as possible. A new task should be created and participants should be alerted about the changes.
- b. A district proposing seizure of goods in another FDA district is responsible for determining whether the home district concurs with the seizure, and whether the case follows current guidelines, including that of prior warning when necessary. In CMS, the district proposing an action should create tasks for any other districts that should have a role in the action and should coordinate evidence and information collection with the other districts (see Section 6-1-2).
- c. The seizing district must determine whether the lot is available for seizure. The seizure recommendation should not be forwarded to the U.S. Attorney unless the lot is available. The district must prepare the appropriate number of copies of the complaint and the letter to the U.S. Attorney on OCC letterhead. The U.S. Attorney letter will be signed for Chief Counsel by the Compliance Branch Director with his/her initials next to the signature. The documents will then be hand delivered, if practicable, to the U.S. Attorney. All documents should be available in CMS and the parties should be notified when these documents have been made available.
- d. When it receives notice that a seizure will be executed, the seizing district is responsible for promptly notifying the appropriate Centers, DE, OCC and any other districts or other tribal, state, local and territorial officials that may be involved in the case. The seizing district is also responsible for adding an activity note in CMS and updating the date fields. The district, Centers and DE will work together to determine whether a press release should be drafted, consistent with the procedures outlined in Exhibit 6-10 of this Chapter, Procedures for Issuing Press Releases on Enforcement Actions (Seizures & Injunctions). If a press release is issued, it should be uploaded in CMS.
- e. The seizing district is responsible for ensuring appropriate follow-up on seizure actions until the action is adjudicated, and for promptly notifying the home district, appropriate Center, DE, and OCC of the current status of the case. The seizing district should log its activities using the activity notes.
- f. The seizing district is responsible for uploading "filed legal documents" and identifying the dates on which the documents were filed in CMS.

## 2. Center Responsibilities:

- a. Appropriate Centers are responsible for providing and obtaining technical/scientific review and support of the case, for assuring that the case meets regulatory policy requirements and for providing a clear indication of scientific support for each charge and each article.
- b. The Center is responsible for preparing for and participating in the PA call, assigning a lead coordinator (who will retain that role throughout the review process), assigning a technical/scientific expert and retaining and obtaining the concurrence of an outside expert when needed, providing views to the district for incorporation into a subsequent summary of the PA call in CMS, and providing input for the CIM to include with specificity those charges that can be supported, those that cannot and the rationale within the time frames outlined above.
- c. The Center, with input from the district and OCC as appropriate, is responsible for determining whether outside experts are necessary to support a case and, if so, for promptly taking steps to secure such support. See Chapter 10 "Expert Support for Cases" for further information, including information on paying for expert support.
- d. In those situations where an expert memorandum or declaration is needed in order to move the action forward, such as in GMP, HACCP, or similar complex cases, a brief memorandum would be provided by the expert. Experts to be used, whether from the Center or outside, should prepare a brief statement that they have read the EIRs, CIM, and analytical worksheets, and that based on this review they can support the following conclusions that are specifically listed. If they cannot support any particular conclusions, those should also be listed. The document should state that they are prepared to testify to the above conclusions (in court and by sworn declaration). The Center lead coordinator should upload the expert's CV and bibliography into the CMS case file. The concurrent review process encourages increased communication and collaboration and should allow for early identification of this need for a written opinion/commentary, as well as other requirements needed to move a case forward.

Note: Referral of the case will not be delayed by the Center if an expert has not been identified. However, the Center must be actively pursuing this matter and providing status reports to OCC. The Center will alert OEIO and OCC promptly if there is difficulty in processing an FDA approval to retain an outside expert. However, OCC may not be able to proceed without the support of expert opinion.

e. Each Center is responsible for monitoring industry-wide state of compliance to determine whether an enforcement strategy should be developed or revised. Consideration should be based on priorities, prior similar actions, nature and scope of the industry. This is necessary to avoid multiple seizures which may

have little effect on correcting the problem. In cases involving widespread problems, single device seizures, or multiple seizure campaigns, the seizure should fit into the overall enforcement strategy to correct the problem.

## 3. OEIO, Division of Enforcement (DE) Responsibilities:

- a. Coordinating, reviewing, and consulting with the other participants during the concurrent review process.
- b. Ensuring uniform application of policy and procedures across FDA Centers.
- c. Reviewing final agency action; preparing seizure documents, as required, in final form; determining which cases require an availability check or an updating inspection (in conjunction with Center), making any medical or technical changes in the complaint for Forfeiture; obtaining Center concurrence for any transmittal letters or ancillary documents DE created. For seizure actions, DE will insert the FDC number in the letter to the U.S. Attorney, and make any other necessary changes in the documents.
- d. Upon approval of a seizure action, DE will transmit the final complaint, transmittal letter and ancillary documents to the district where seizure will be made, with a copy to the designated OCC contact persons, DOJ/OCPL, and FDA's Office of Public Affairs. DE should note the date in CMS that the complaint, transmittal letter and ancillary documents were submitted to the district and should also make PDF versions available in CMS. DE will upload a PDF version of the signed USA letter and the complaint in CMS. The e-mail will acknowledge that DE has received the approval from OCC and should identify the attorneys assigned to the particular case.
- e. Distribution of the approved seizure, by referencing the location of approved seizure documentation in CMS.

## 4. Office Of Chief Counsel (OCC):

- a. For seizures, OCC will participate in concurrent review and provide final legal review of legal documents prepared by DE. OCC will provide the legal assistance necessary for presentation of the action, including direct assistance to the U.S. Attorney and the district compliance staff.
- b. Upon approval, OCC will send copies of the approved documents (complaint and letter and ancillary documents) to DE.

## 5. New Information:

If significant changes to the fact pattern take place after the initial call, Centers and districts should immediately notify the lead coordinators and indicate the location of

the new information in CMS. Examples include correspondence from the regulated entity or its counsel, memoranda of meetings, requests for meetings, or additional evidence that has come to light since the referral to headquarters.

#### 6. Independent Judgment:

All reviewing officials (whether in the district, the center, or DE) are expected to exercise independent judgment as to whether an action or a specific charge should be approved or not approved.

## **6-1-7** Update Inspections

In situations in which there is a question about the continued existence of a violative condition at a firm or about the availability of violative goods to be seized, the district office may be asked to conduct an update inspection (or a buy, sample collection, or similar activity) to confirm that the product or problem affecting products still exists. If the Center, DE, and OCC agree that the evidence must be updated for an action to be brought, DE should update the inspection assignment and upload the assignment in CMS. DE will create a task for the district to perform an update inspection in CMS and provide instructions in the task instructions text box.

NOTE: As a general rule, the evidence of violations, when presented to the U.S. Attorney, should be no older than 60 days. For mass seizures or seizures based on GMP violations, there should not be more than 30 days from the last date of the inspection to the time the case is submitted to the U.S. Attorney's Office. If the violations are such that the district or Center can provide assurance that the articles to be seized could not be brought into compliance within these time frames, the request for update may be waived.

The update (and any resulting report) will focus on documenting the continued existence of originally identified problems. The update findings and the district's comments should be transmitted concurrently to DE, the Center, and OCC via CMS.

## 6-1-8 Seizure Accomplishment and Close-Out Documentation

After seizure has been approved, it is the seizing district's responsibility to provide all litigation support, monitoring and follow-up, to encourage expeditious handling of the seizure, to track the action to its conclusion, and to report current status to the home district, OCC, the U.S. Attorney, the Center, and DE.

#### 1. Contacts with the U.S. Attorney

Seizure actions involving health hazards require prompt action. The U.S. Attorney's Manual states: "Forfeiture actions should be commenced as soon as possible, particularly where continued distribution of the article may threaten the health of the public."

The district compliance officer should encourage the U.S. Attorney to promptly file the complaint and to forward a copy of the complaint as filed, with the civil number and the date of filing, to OCC and to the district office. The district should forward a copy of the filed complaint to DE.

#### 2. Contacts with The U.S. Marshal

After filing the Complaint for Forfeiture, the district may make arrangements with the U.S. Marshal to effect seizure when, in the district's judgment, such arrangements are needed to ensure that the seizure is carried out satisfactorily. The district may have to use its personnel to expedite seizures in the following situations:

- a. When a question of the proper identity of the lot exists (e.g., commingled lots or complicated labeling).
- b. When a mass seizure is involved.
- c. Lack of cooperation by the dealer. Title 18, U.S.C. 401 provides as follows:

"A court of the United States shall have power to punish by fine or imprisonment, at its discretion, such contempt of its authority, and none other, as —

\* \* \*

(3) Disobedience or resistance to its lawful writ, process, order, rule, decree, or command."

Under this statute, interference with a U.S. Marshal in locating goods may be charged as contempt of court. The facts should be referred to the U.S. Attorney and OCC.

NOTE: Considerable time can be expended in assisting the U.S. Marshal's Service in effecting seizure and taking inventory of the goods. The standard FDA consent decree provides that the government shall recover from the claimant court costs and fees, and storage and other proper expenses. The term "other proper expenses" found in 21 U.S.C. 334(e) constitutes an adequate basis for recovery of the costs involved in assisting the Marshal in effecting and taking inventory of the goods seized. The actual hourly salary rate of the investigators rather than the rate for supervision of reconditioning should be charged.

## 3. Seizure Action Report

As soon as the articles have been seized, the seizing district will promptly notify the OCC attorney, the home district, the Center, and DE of the amount and value of each lot seized, and the Marshal's return date. The district should upload a copy of the email in CMS under the "Final" Tab.

The information necessary to complete this report is obtained by the investigator accompanying the U.S. Marshal or directly from the Marshal. Use Form FD-487 (see

Exhibit 6-2). If the seizure is not accomplished, the report should so state and explain briefly why the lot was not available or could not be attached. If the article is still violative, provide all known details as to where it went and how to trace or identify it.

The U.S. is required by Supplemental Rule C (4) to give public notice through advertisement before the article may be forfeited. In most districts, the Marshal's office contracts for this at the direction of the U.S. Attorney.

## 6-1-9 Disposition of Seized Articles

#### 1. Potential Claimant's Disposition Options

Following seizure of any products there are three avenues available to a potential claimant. The claimant may:

- a. Do nothing, in which case the article will be disposed of by default;
- b. File claim to the article and enter into a Consent Decree, admitting the violation, agreeing to pay costs, and seeking to destroy or rehabilitate the article; or,
- c. File claim to the article and contest the action by filing an answer to the complaint.

Regardless of which avenue is chosen, it is the responsibility of the seizing district to monitor all activity to ensure a proper termination of the seizure action. The Center and OCC Attorney should be promptly advised of all events in the case.

NOTE: Any decree entered in a seizure case must contain a provision condemning the article as being in violation of the law. Without such a provision, there is no authority for the court to order destruction of the article or to permit its reconditioning.

The avenues available to a potential claimant are addressed further, as follows:

## 2. Disposal

If no claimant appears in the case, the government will move for default, condemnation, and forfeiture or destruction under a Default Decree (see Exhibit 6-3). The Decree is prepared by OCC. The Decree may be entered after the return date has expired (see RPM "Responsibilities in Default and Consent Decrees").

To prevent premature defaults, OCC prefers the use of a 30 day time frame following seizure as the return date. Local rules may differ in your area.

When a Default Decree is entered the U.S. Marshal disposes of the article. This disposal may take various forms, including the following:

- a. Constructive Destruction The article is destroyed by using it for a constructive purpose, such as donating misbranded but wholesome food to charity.
- b. Sale If the article may be legally sold, the Marshal may sell it to recover costs. Products in violation of the laws we administer normally would not be offered for sale after seizure
- c. Conversion Human food may often be converted to animal food, rather than destroyed. If conversion is the method of destruction, ensure that the product is physically treated to prevent its diversion to human food. Unless a recent precedent for conversion of a product to animal food is on file, the Center for Veterinary Medicine must approve of the reconditioning process.
- d. Destruction The article may be destroyed by burning, burial, or dumping. Ensure that the method of destruction is appropriate under NEPA, and that the article cannot be retrieved.

NOTE: Any Default Decree should contain a statement that the destruction of the article will be in accordance with relevant laws including NEPA. When questions arise concerning environmental impact, contact the ORA Safety Management Officer (HFC-21) for assessment of the proposed method of destruction.

## 3. Consent Decree Of Condemnation

- a. Claim Any potential claimant must first file with the court a proper, verified claim stating his interest in the property. Only after a proper claim has been filed may there be negotiations concerning disposition of the seizure. Should more than one claim be filed, the court may have to rule on who is the proper claimant (see Exhibit 6-4). Any FDA staff who learn that a claim has been filed should notify the OCC attorney immediately, and send a copy of the claim by facsimile as soon as it is obtained.
- b. Consent Decree Should a claimant appear, it may agree to the entry of a Consent Decree providing for attempted reconditioning of the article under seizure (see RPM "Compliance Officer and OCC Attorney Responsibilities in Default and Consent Decrees"). In the event that this method of response is chosen, there are several steps which the claimant must follow. These are discussed below:

The claimant (BUT ONLY THE CLAIMANT) may consent to the entry of a decree condemning the article under seizure and providing for attempted reconditioning or conversion. No discussion as to the provisions of a Consent Decree is to be undertaken before a claim is filed and concurrence from OCC has been obtained (see Exhibit 6-5).

The Consent Decree must provide for the following items:

- i. Condemnation of the article as being in violation of the law.
- ii. A penal bond approximately twice the retail value of the article under seizure.
- iii. Provisions for payment of costs for storage and handling by the U.S. Marshal and for supervision by FDA before release of the product.
- iv. A provision that claimant will attempt to bring the article into compliance under the supervision of, and to the satisfaction of, FDA. See the RPM section "Compliance Officer and OCC Attorney Responsibilities in Default and Consent Decrees."

NOTE: If recurrence of the same violations that resulted in the seizure is likely, consider including injunctive provisions to the decree.

#### 4. Bond

Following entry of the decree, the claimant is required to post a penal bond (see Exhibit 6-6). This bond should be twice the retail value of the goods. Its purpose is to ensure that the claimant complies with the conditions of the decree and performs the reconditioning in a satisfactory manner. If the bond is set too low, it might be profitable for the claimant, after securing release of the product from the marshal, to sell the product without bringing it into compliance.

## 5. Bond Forfeiture Procedures

When part of the seized article disappears or the terms of the decree are not complied with, the government may move for forfeiture of the entire bond. If, in the opinion of the district, a bond action should be sought, submit a recommendation for such action, along with the facts, to OCC for preparation of the necessary papers.

#### 6. Contest of Seizure

If a claimant chooses, claimant may contest the action, in part or in its entirety. To do this claimant must:

- a. File a proper, verified statement of interest to the article, and
- b. File an answer within 20 days after filing the claim denying any or all of the allegations in the government's complaint.

Should a contest arise, the matter will be handled the same as any civil trial and will conclude by a decision of the court after appropriate consideration of the case.

## 7. Reconditioning Operations

Upon entry of a court order permitting attempted reconditioning of seized articles, the seizing district will make the necessary arrangements for supervision with the claimant to ensure compliance with the decree. Before the reconditioning operation is begun, the district should make sure that the claimant has in its possession a formal release by the U.S. Marshal.

Reconditioning may be achieved by various means such as: segregation of codes, cleaning, reworking, relabeling, or physically modifying for use as animal feed, or fertilizer that brings the article into compliance with the law.

- a. Reprocessing by Reworking or Cleaning. Unless the district has a recent precedent case of a similar nature, proposals for reprocessing must be referred to the appropriate Center for guidance.
- b. Relabeling All proposals for relabeling of drugs, devices, tobacco products, cosmetics, special dietary foods, and fortified or infant foods, must be sent to the appropriate Center for prior comment unless guidelines exist. Other foods may be relabeled when the district has a clear precedent for the use of the proposed labeling, but doubts should be resolved by referral to the Center.
- c. Denaturing If there are outstanding instructions for the denaturing of the product involved, these should generally be followed. If no instructions exist, or if in the district's judgment the guidelines should not be followed, the proposal should be referred to the appropriate Center for consideration.
- d. When a court order is entered permitting release of seized articles to a claimant for reconditioning, it should provide for supervision of the reconditioning operation by the FDA, at the claimant's expense. As instructed in the Investigations Operations Manual Section 2.4.8, the investigator supervising the operation is required to submit a detailed report.
- e. When the court's decree permits the seized articles to be moved to another district for reconditioning operations, the district in which the operation is to be performed will supervise the reconditioning operation. In such cases, the seizing district should determine that the bond has been posted and the articles released by the U.S. Marshal before permitting the goods to be shipped. The seizing district will forward to the supervising district a copy of the decree and other pertinent data, before the seized article begins its physical move.

NOTE: All dispositions of seized goods other than destruction are to receive Center concurrence, unless otherwise noted.

## 8. Post Seizure Samples

When the district is considering a related criminal case or when additional analysis is necessary, determination should be made as to whether adequate reserve samples are available for court use. If not, steps should be taken to obtain additional samples before the Default Decree or Consent Decree of Condemnation is entered and the articles are destroyed.

If, after a seizure, the claimant obtains a court order to take a sample from the seized lot, the order should provide for a like sample to be drawn simultaneously by the government. Unless there is an immediate need for examination of the sample, it should be held, under seal, by the seizing district.

## 9. Notice to Claimant and Notice to U.S. Attorney

Upon completion of the reconditioning, prepare a Notice to Claimant listing the charges to be paid (see Exhibit 6-7). If no response is received in 30 days, send a second notice (see Exhibit 6-8). Upon receipt of payment (check made payable to the "United States Treasury"), the seizing district will advise the U.S. Attorney that the bond may be canceled insofar as FDA is concerned (see Exhibit 6-9). Copy OCC but do not send a copy of this letter to the claimant or its attorney.

## 10. Compliance Officer And OCC Attorney Responsibilities In Default And Consent Decrees

- a. General Principles: The general rules that follow (which are subject to exceptions in unusual cases) are intended to reflect two principles.
  - Every person in the agency, including the compliance officer in the district, the Center compliance officer, and the attorney in OCC has a legitimate interest in seeing that a seizure is processed correctly. Therefore, there should be full consultation (notification is not consultation) about the handling of a case, and each should respect the interest and expertise of the others.
  - ii. The maintenance of good working relationships with U.S. Attorneys' offices is a matter of concern to both the field and OCC. U.S. Attorneys' offices should be made aware that they can call upon the assistance of officers in the field and OCC attorneys at headquarters; both the field and OCC must affirmatively include the other in dealings with U.S. Attorneys' offices.

## b. Requirements:

i. All default decrees and consent decrees submitted to a U.S. Attorney's office for filing in court and decrees drafted by a U.S. Attorney's office and

submitted to FDA for comment shall be cleared through the assigned OCC attorney and the Center case officer, after full consultation with the district compliance officer.

- In the case of a default decree, the consultation and clearance shall at least consist of a telephone conversation among the attorney, Center case officer, and the compliance officer. They shall determine what additional consultation, if any, is needed.
- In the case of a consent decree, a copy of the decree shall be sent to the OCC attorney and Center case officer.
- ii. Where OCC is asked by the district office or by the U.S. Attorney's office to prepare a decree, the OCC attorney shall consult fully with the compliance officer and with the Center, concerning the decree and, after reaching agreement with the parties involved, shall transmit the prepared decree directly to the U.S. Attorney's office, with a copy to the compliance officer and Center.
- iii. No negotiation about the potential modes of compliance for consent decrees shall be conducted with any prospective claimant until after a proper claim has been filed.
- iv. Compliance officers shall not negotiate disposition of a filed case without prior approval of an attorney in OCC. Any such negotiation shall be conducted by an attorney from OCC with DOJ.
- v. As soon as it appears to the district compliance officer that special local customs or procedures may affect any case (for example, giving seized articles to charity), the compliance officer shall advise the OCC attorney of the local peculiarity. In participating in the disposition of cases involving a default or consent decree, OCC attorneys shall be sensitive to relevant local customs, and shall respect such customs except when they are contrary to law or agency policy.
- vi. When an attorney believes that a local custom is contrary to law or agency policy, the attorney shall bring the matter to the attention of responsible officials in the manner that will interfere as little as possible with effective working relationships between OCC, the district office, and the U.S. Attorney's office.

## 6-1-10 Costs of Supervision

The following rates shall be used in billing a claimant for supervisory services in connection with reconditioning, relabeling, or disposal of seized articles under a Consent Decree.

**Investigation time - 266% of GS 11/4** 

Analytical time - 266% of GS 12/4

The above time is figured at an hourly rate.

Per Diem - Specific rates (41 CFR Part 301) paid to employee, in high cost areas, per diem is higher

Travel - Current Rate per mile (plus tolls)

Miscellaneous expenses - Actual cost

The minimum charge for services shall be not less than the charge for one hour. Additional charges shall be in multiples of one hour, disregarding fractions of less than 1/2 hour, as follows:

1 to 1 hour 29 minutes -1 hour charge

1 1/2 to 2 hours - 2 hour charge

## **6-1-11 Monitoring Seizure Actions**

The seizing district should monitor the seizure action regularly to ensure the expeditious progress of the action. Actions taken during the course of the seizure adjudication should be processed through the field compliance officer to ensure up-to-date monitoring, accurate record keeping, and timely reporting.

## **6-1-12 Seizures Involving Other Agencies**

When the proposed seizure may involve another agency of the Federal Government, contact the appropriate Center for administrative clearance with the pertinent agency. Also see Memoranda of Understanding in Compliance Policy Guides.

## 1. National Marine Fisheries Service - U.S. Department Of Commerce

If the Center advises that the lot was involved in inspection or certification by National Marine Fisheries Service - U.S. Department of Commerce, include the following statement in the seizure recommendation and proposed letter to U.S. Attorney: "Although packed under inspection (or under Certificate No.\_\_), the Center for Foods and Applied Nutrition has discussed this matter with NMFS and that agency has no objection to seizure." See Memorandum of Understanding 7155a.02 and 7155j.01.

## 2. U.S. Department Of Agriculture

After clearance as under NMFS, include a similar statement in the seizure recommendation. See Memorandum of Understanding 7l55a.03 and 7l55a.04.

#### 3. Federal Trade Commission

See Memorandum of Understanding 7155m.01.

## 4. Environmental Protection Agency

See Memorandum of Understanding 7155b.03.

## 5. Department Of Labor

See Memorandum of Understanding 7155i.01.

#### 6-1-13 Issuing Press Releases

The recommendation to issue a press release is made jointly by the OCC attorney assigned to the case, the ORA case officers (the district compliance officer or OEIO), and the Center (Office of Compliance). The decision to issue a press release is made by FDA's Office of Public Affairs in accordance with the Transparency Initiative. The roles and responsibilities of these offices in making these decisions, and in drafting, clearing, and issuing press releases are described in "Exhibit 6-10 - Procedures for Issuing Press Releases on Enforcement Actions (Seizures & Injunctions)." Follow these procedures and the accompanying models for drafting press releases concerning seizures and injunction actions. Upload the press release in CMS.

## 6-2 INJUNCTIONS

## 6-2-1 Purpose

The purpose of this section is to provide instructions and define responsibilities for those field and headquarters units involved in the development, preparation, processing, and follow-up of injunctions.

#### 6-2-2 General Guidelines

An injunction is a civil judicial process initiated to stop or prevent violation of the law, such as to halt the flow of violative products in interstate commerce, and to correct the conditions that caused the violation to occur. See 21 U.S.C. 332; Rule 65, Rules of Civil Procedure. If a firm has a history of violations, and has promised correction in the past, but has not made the corrections, the injunction is more likely to succeed. However, the freshness of the evidence is critical.

For an injunction action to be credible in the eyes of the Department of Justice (DOJ), the U.S. Attorney, and the court, the evidence must be current. Timeliness is an important factor when considering an injunction action, with or without a Motion for Preliminary Injunction, or a temporary restraining order (TRO). However, case quality and credibility must not be sacrificed to meet guideline time frames. The purpose of the guideline time frames is to limit, as much as

can reasonably be expected, the need to update evidence. (Updating entails extra work at all levels of the case development and review process and, more importantly, delays obtaining an injunction, which is intended to stop violations that adversely affect the safety or quality of products in commerce.)

Once a complaint for injunction is filed by the United States, a hearing may be placed on the court calendar at any time with extremely short notice. It is imperative that the district compliance officer maintain close contact with the OCC attorney and the Assistant U.S. Attorney to be aware of any hearings on FDA actions.

When an injunction is granted, FDA has a continuing duty to monitor the injunction and to advise the court if the defendants fail to obey the terms of the decree.

Should the decree be violated, the agency must consider a civil or criminal contempt of court, or other regulatory action, in as timely a manner as used in initiating the injunction. It is, therefore, mandatory that FDA personnel responsible for initiating injunctions also adhere to the implementation procedure in "Compliance Follow-up."

#### 6-2-3 Definitions

## 1. Temporary Restraining Order

Temporary restraining orders are court enforced orders entered to control an emergency situation. A TRO seeks immediate, temporary relief (for a period of 10 days, which may be extended for 10 additional days) prior to the hearing for preliminary injunction.

FDA recommends a TRO when the agency believes that the violation is so serious that it must be controlled immediately. A request for a TRO also has the effect of expediting review of the underlying injunction case by the court. An inadequately documented TRO request may result in the court viewing the entire injunction action as lacking credibility.

At the court's discretion, the TRO request may be subjected to a hearing, which may be *ex parte* (without the defendants' presence), by reviewing the documents and questioning government counsel, the FDA investigator, the district compliance officer, or other FDA personnel.

## 2. Preliminary Injunction

Whether or not a TRO has been obtained, a Motion for Preliminary Injunction is subject to a full hearing in which (1) evidence by affidavit, or (2) testimony of witnesses is presented, depending on the practice of the court. Once the motion is granted, or the defendants consent to the entry of a decree, the preliminary injunction is in effect.

A preliminary injunction may stand indefinitely on the court record until the case is settled or a permanent injunction has been entered, after trial or further briefing. A preliminary injunction may be dismissed, or further proceedings for permanent injunction may be set by the court, at the request of either party, at any time.

## 3. Permanent Injunction

A Decree of Permanent Injunction may be entered at any time after the complaint is filed, either following a hearing or as a result of a negotiated settlement. Defendants in an injunction proceeding may consent to a Decree of Permanent Injunction just as they consent to a Consent Decree of Condemnation in a seizure action.

Should the defendant not consent to such a decree, a trial is held in which, to prevail, the government must prove each element of its case by a preponderance of the evidence. As its name implies, a Decree of Permanent Injunction remains in effect until it is dissolved by an order of the court.

#### 6-2-4 General Considerations

## 1. When An Injunction May Be Considered

An injunction may be considered for any significant out-of-compliance circumstance, but particularly when a health hazard has been identified. Proceeding by injunction does not preclude institution of additional or concurrent action such as recall, publicity, seizures, embargo by cooperating officials, or criminal prosecution.

In considering an injunction, the agency must evaluate the seriousness of the offense, the actual or potential impact of the offense on the public, whether other possible actions could be as effective or more effective, the need for prompt judicial action, and whether it will be able to demonstrate the likelihood of the continuance of the violation in the absence of a court order. Injunction will be the action of choice when:

- a. There is a current and definite health hazard or a gross consumer deception requiring immediate action to stop the violative practice and a seizure is impractical; or
- b. There are significant amounts of violative products owned by the same person, a voluntary recall by the firm was refused or is significantly inadequate to protect the public, and a seizure is impractical or uneconomical; or
- c. There are long-standing (chronic) violative practices that have not produced a health hazard or consumer fraud, but which have not been corrected through use of voluntary or other regulatory approaches.
- d. With respect to a and b above, it is helpful, but not mandatory, to show that there has been a history of prior violations, and that previous attempts to correct them through alternative warnings or sanctions have not been effective. A showing of a violative history should be made whenever possible, but especially in those cases where an imminent danger to health cannot be alleged.

## 2. Multi-District Injunctions

When similar violative practices are found at two or more facilities under the same corporate management, the home district where the corporate office is located should evaluate the compliance histories of corporate facilities located in other FDA districts to determine whether there are patterns of violations or trends that indicate the presence of systemic problems that should be addressed on a multi-district basis.

The Centers, districts, and OEIO have a significant role in assessing these situations and in developing and coordinating a regulatory approach. The initial and continuing roles of the various offices in multi-district injunctions are described in the procedures titled "Injunctions (Multi-district)." See exhibit 6-11. These procedures were developed to facilitate planning, and the timely preparation, processing and review of these types of cases. They must be followed as soon as a potential multi-district injunction is identified by a district or Center. At its discretion, the recommending district may invoke these procedures for a single district injunction involving multiple Centers.

#### 6-2-5 Adequate Notice Preceding Injunction Actions

FDA strengthens its injunction actions by demonstrating in the complaint that FDA made and has documented a conscious effort to get the objectionable products or practices corrected without court involvement. For example, the defendants were notified of the violations (by letter, FDA 483, meeting, telephone call) and, despite having an opportunity to correct the violations, failed to do so. Prior notice is not a legal requirement, but can demonstrate a defendant's resistance to compliance and enhance the agency's request for court intervention.

Although there is no legal requirement to name individuals in complaints for injunction, the agency believes that by doing so, individuals not named in the complaint will be more inclined to prevent violations from occurring in the first instance (general deterrence) and that named individuals will be more inclined to take immediate and active interest in seeing that the violation ceases (specific deterrence). Also, the identification of the responsible persons will prevent their pretense that they were not subject to the injunction, and will help prevent circumvention of the injunction by changing the name of the corporation. Therefore, the individuals who have the authority and responsibility to correct or prevent the violations should be named as defendants.

During its normal case-development process, FDA will therefore strive to identify the individuals with the authority to take corrective actions and prevent future violations and to develop evidence proving the individuals' authority and responsibility. Such individuals may be located at the sites of the actual or potential violation, at other offices and sites, or both. When there are questions concerning individual responsibility during the review process, assignments should be issued requesting further documentation. One principal purpose of these efforts is to ensure that individuals standing in positions of authority with respect to actual or potential violative conditions will be provided with adequate notice concerning the evidence found by FDA. The management officials believed by FDA to have the highest level of authority in an organization should always receive notice.

## 1. Methods of Giving Notice

Notice may take a variety of forms including letters and notices from other government agencies, recalls, issuance of FDA 483s, post-inspection discussions, meetings, and telephone calls. All persons receiving notice and the circumstances (date, time, place, and substance) of notice should be documented. Recognizing that firms under FDA jurisdiction include those ranging from owner-operator to large conglomerates and that the nature of violations will vary; what is deemed adequate notice will differ from case to case. Factors to be considered in determining adequacy include, but are not limited to, complexity of the organizational structure, duties and authority of persons believed to be responsible, nature of the violation, compliance history, and the length of time elapsed between notice and filing of the case. Also, see Chapter 10 "Prior Notice" and "Regulatory Meetings."

The factors listed below will apply in determining the adequacy of notice. Agency records should show that sometime during case development:

- a. The individuals with authority to prevent or correct violations have been given appropriate notice of the general conditions that are violative.
- b. There is sufficient information to conclude that proper action to correct the violations has not been taken or will not be taken promptly.
- c. Reasonable efforts on the part of the agency were made and documented to get the objectionable product and practice corrected without court involvement. Any attempts by the proposed defendants to correct the problem should also be reported.

NOTE: There may be cases where exceptions to the need to show notice through factors a-c are justified. Justification for such exceptions must accompany the case submission.

## 6-2-6 Prerequisites for a TRO or Preliminary Injunction

**Note**: Injunctions that include requests for a Temporary Restraining Order (TRO) have the highest priority ranking of all legal actions. Ensuring that criteria for TROs have been met and that strategies will be developed to halt the violative conduct usually requires knowledge of FDA issues and experience. For this reason, it is recommended that experienced compliance and legal personnel be involved in all TRO recommendations.

These persons should also be available from each reviewing unit to hand carry the case to each succeeding level, for review.

#### 2. Timeliness

As a general rule, a request for a TRO should be processed through the agency so that it may be filed no later than 30 days after FDA's most recent evidence that the violation is occurring.

Also, as a general rule, a request for a preliminary injunction is untimely if the evidence to support it is over 60 days old at the time of filing. The freshness of the evidence is important when the case includes a Motion for Preliminary Injunction, because the government is requesting that the matter be moved ahead of other cases on the court's calendar because of its urgency.

## 3. Seriousness of the Violation

In addition to considerations of timeliness, if there is a public health threat, that factor is something that should be emphasized. It is very important to remember that we do not need to show potential harm, but if that factor is present, it is very compelling. If the threat is severe enough, the court would consider a TRO for immediate relief.

The magnitude of the violation is another consideration. If the defendant is a small company with just a few employees and the violations cause little or no public health risk, a court may not grant preliminary relief, but may be receptive to granting a permanent injunction. If the violations are significant and the defendant is a major presence in the industry, the fact that the violations may have far-reaching consequences may be a compelling factor in support of preliminary relief, even if there is no direct evidence of harm.

## 4. Adequate Notice

To avoid the need for updating the evidence in requests for TRO or preliminary injunctions, the agency is committed to prompt review when all of these prerequisites are met. The absence or weakness of a prerequisite may preclude review of the request and the transmission of the case to DOJ until the information is obtained, unless adequate justification for its omission has been provided.

When initiating requests for injunction with a TRO and in implementing compliance follow-up, all personnel will perform the investigational, analytical, and administrative tasks with a high degree of urgency. Advance notice to all involved units is necessary, so that plans for expedited processing and review may be agreed upon and accomplished.

A request for a TRO or preliminary injunction must be accompanied by the DD's Affidavit and where appropriate (for example new drug violations), the affidavit of Center personnel attesting to certain facts. Supporting affidavits of experts should be obtained as soon as possible either by the district or the Center.

Expert witness support is necessary in all cases except when the violations are so gross and apparent that a reasonable judge who is not familiar with the technical or scientific issues in the case would not hesitate to grant the relief without expert testimony. Because expert testimony takes time to obtain, the district or the Center should begin identifying suitable candidates and forwarding the necessary background material to them at the earliest possible time. Please note that any materials provided

to experts must be shared with the defendants in discovery. If you have any questions about what should or should not be shared, please contact OCC.

## **6-2-7** Refreshing Evidence - Updating Inspections

The referral of a Complaint for Injunction to DOJ should follow closely in time the last evidence of violations (inspectional evidence, laboratory analysis, or undercover buy), or the last communication from the proposed defendants which reveals that the violative conduct will continue. This can be controlled to a certain extent by well-timed reinspection, buys, or similar activities.

Requests for reinspection, undercover buys, or similar activities should be coordinated with the Center and OCC. Assignments for update inspections will be issued directly from the Center after consultation with OCC. The update findings and the district's recommendation based upon this most current evidence should be transmitted concurrently to OCC and the Center.

## 6-2-8 Approval Process for Seizure and Injunction Cases

See 6-1-5 for the steps to be included for Injunction cases.

## 6-2-9 Responsibilities for Injunction Actions

## 1. District Responsibilities:

Prior to creating a PA work activity in CMS, the compliance officer should consult with the DCB and other district management to obtain support for the proposed action. The district should then create the PA work activity and upload key documents that support the most significant violations, initiate the preliminary assessment call and PA Work Activity in CMS, and upload a document describing summary views expressed during the PA call.

Note: As described in <u>6-1-5</u> above, when the participants have been working closely on a compliance issue that will lead to a possible injunction case. the party proposing the injunction can create an injunction case record in CMS and upload the CIM and supporting evidence into that record instead of creating a preliminary assessment work activity.

The district, along with the Center, is responsible for identifying the relevant statutes and regulations they seek to charge and with specificity the relief sought.

If the participants agree that an injunction may be warranted, the district is responsible for writing and uploading the CIM and supporting documents into CMS. Notify OCC using the address "OC OCC Case." mailbox in Outlook. The contents of the CIM are described in Exhibit 6-1B.

When significant changes to the fact pattern that take place after the initial PA call, these changes should be communicated to the lead coordinator as soon as possible. The District lead coordinator is responsible for uploading the new evidence as soon as

possible. A new task should be created and participants should be alerted about the changes.

## 2. Center Responsibilities:

- a. Appropriate Centers are responsible for providing and obtaining technical/scientific review and support of the case, for assuring that the case meets regulatory policy requirements and for providing a clear indication of scientific support for each charge and each article.
- b. The Center is responsible for preparing for and participating in the PA call, assigning a lead coordinator (who will retain that role throughout the review process), assigning a technical/scientific expert and retaining and obtaining the concurrence of an outside expert when needed, providing views to the district for incorporation into a subsequent summary of the PA call in CMS, and providing input for the CIM to include with specificity those charges that can be supported, those that cannot and the rationale within the time frames outlined above.
- c. The Center, with input from the district and OCC as appropriate, is responsible for determining whether outside experts are necessary to support a case and, if so, for promptly taking steps to secure such support. See Chapter 10 "Expert Support for Cases" for further information, including information on paying for expert support.
- d. In those situations where an expert memorandum or declaration is needed in order to move the action forward, such as in GMP, HACCP, or similar complex cases, a brief memorandum would be provided by the expert. Experts to be used, whether from the Center or outside, should prepare a brief statement that they have read the EIRs, CIM, and analytical worksheets, and that based on this review they can support the following conclusions that are specifically listed. If they cannot support any particular conclusions, those should also be listed. The document should state that they are prepared to testify to the above conclusions (in court and by sworn declaration). The Center lead coordinator should upload the expert's CV and bibliography into the CMS case file. The concurrent review process encourages increased communication and collaboration and should allow for early identification of this need for a written opinion/commentary, as well as other requirements needed to move a case forward.

Note: Referral of the case will not be delayed by the Center if an expert has not been identified. However, the Center must be actively pursuing this matter and providing status reports to OCC. The Center will alert OEIO and OCC promptly if there is difficulty in processing an FDA approval to retain an outside expert. However, OCC may not be able to proceed without the support of expert opinion.

- e. The Center is responsible for reviewing the district's proposal regarding conduct to be enjoined, ensuring that the proposal is adequate and reasonable.
- f. The Center is responsible for identifying which statutes and regulations they seek to charge, and with specificity the relief sought.
- g. Each Center is responsible for monitoring industry-wide state of compliance to determine whether an enforcement strategy should be developed or revised. This includes a multi-facility firm that may lead to a multi-district injunction action (see exhibit 6-11). Consideration should be based on priorities, prior similar actions, nature and scope of the industry.

## 3. OEIO, Division of Enforcement (DE):

- a. Coordinating, reviewing, and consulting with the other participants during the concurrent review process.
- b. Ensuring uniform application of policy and procedures across FDA Centers.
- c. Reviewing final agency action and determining which cases require an update inspection (in conjunction with Center).
- d. Upon approval of an action, DE will transmit the final complaint, transmittal letter and ancillary documents electronically to the district where action will be taken, with a copy to the designated OCC contact persons, DOJ/OCL, and FDA's Office of Public Affairs. DE should note in CMS the date that the complaint, transmittal letter and ancillary documents were submitted to the district. The District will upload a PDF version of the signed USA letter and the complaint in CMS. The e-mail will acknowledge that DE has received the approval from OCC and should identify the attorneys assigned to the particular case.

#### 4. Office Of Chief Counsel Responsibilities:

For injunctions, OCC will participate in concurrent review and provide legal review, prepare pleadings and other legal documents, and provide legal assistance necessary for presentation of the action, including direct assistance to the Office of Consumer Litigation and/or the U.S. Attorney's Office and the district compliance staff.

#### 6-2-10 Cover Letter to DOJ

The cover letter transmitting the case to the Department of Justice/Office of Consumer Litigation, Civil Division, will be prepared by OCC and will identify the action sought (TRO, preliminary injunction or permanent injunction), briefly summarize the case, highlighting legal, evidentiary, and tactical issues worthy of note including the significance of the evidence.

## 6-2-11 Complaint for Injunction

OCC will prepare the Complaint for Injunction, in accordance with the requirements of the Federal Rules of Civil Procedure and any particular requirements of the relevant district court.

The complaint will generally include sections covering jurisdiction, venue, identification of defendants, a statement explaining the nature of the products involved, the purpose of the law that is being violated, a summary of evidence of the violations alleged, a brief reference to prior inspections, prior warnings, and historical non-compliance, and a short- form prayer for relief. See exhibit 6-19.

## 6-2-12 Declarations

Most jurisdictions will accept declarations in support of a motion for preliminary relief or for a Temporary Restraining Order. If the court requires live testimony in support of a motion for TRO or preliminary injunction, the declaration may be converted to testimony. Please note that declarations are testimony given under oath. Declarants should be prepared to testify in court to all statements made in a declaration.

NOTE: 28 U.S.C. 1746 provides for the optional use of declarations in lieu of affidavits, thereby avoiding the need for a notary public. This is particularly useful for experts and resident investigators when a notary is unavailable. Declarations filed under 28 U.S.C. 1746 have exactly the same legal weight and significance as affidavits. Where either an affidavit or declaration is used, follow Exhibit 6-20. The 28 U.S.C. 1746 declaration should state, "Pursuant to 28 U.S.C. 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on (date)."

If the court requires affidavits from investigators or analysts or others having firsthand knowledge of the facts, they should be furnished by the district or persons performing the work. However, where significant information is discovered in the course of the inspection and is not contained in the FDA 483 or other document, but is within the personal knowledge of the investigator, that observation, discussion of event, or incident should be the subject of a brief declaration by the investigator. Where a separate declaration is used for an investigator, the relevant FDA 483 issued by that investigator should be attached thereto. In some cases, a declaration may also be necessary for the investigator to summarize and explain the significance of the most recent inspectional findings consistent with his or her experience as an FDA investigator.

The only declarations that will routinely be used in support of injunctions are the declarations of: (1) the district director or designee; (2) an investigator (where necessary to support information in the complaint not contained in the FDA 483 or to summarize the significance of the findings); (3) appropriate Center official (to document such things as the lack of an NDA or the failure to register a product or facility); and (4) experts.

The declarations should be factual and, except in the case of declarations by experts, not contain conclusions, or opinions. In all cases, each declaration must provide clear, succinct, and strong factual support for the complaint.

The declarations should set forth the identity of the declarant; his/her position with FDA and his/her duties in that position. If it is an expert's declaration, his/her qualifications to draw conclusions or offer opinions must be summarized at the beginning of the declaration and should be supported with an attached copy of the expert's curriculum vitae.

Because the granting or denial of a TRO or preliminary injunction may rest upon the sufficiency of the declarations submitted with the complaint, care should be taken to ensure that every statement in the complaint is covered with equal or greater specificity in the declaration. Violative conditions unrelated to the charge should not be included. Unimpressive violative conditions should not be included; however, a number of less impressive violative conditions may often be grouped to become more impressive when their combined effect is to make a potentially hazardous condition.

NOTE: Listing a series of minor infractions has the effect on a court of minimizing the significance of the case and distracting the focus away from the significant problems.

The facts in the district director's declaration are derived from a review of documents contained in the district files and the declaration should so state. A district director or investigator may not rely on oral statements made to him or her by other agency personnel. The following specific information should be covered in the declaration:

- 1. statement of the position occupied by declarant;
- 2. duties of the declarant in that position;
- 3. legal status or business of the defendant firms;
- 4. address of business;
- 5. identity of individual defendants, where they perform their duties, and in at least as much detail as in the complaint, their authority and responsibilities;
- 6. a statement that the defendants are doing (or do) interstate business in a product known as (brand name);
- 7. the label and labeling of the products (If the labeling is available, it should be attached to the declaration, appropriately identified. If exhibits are not available, relevant portions of the labeling should be quoted when applicable to the charges in the complaint);
- 8. if relevant to the charges, establishment inspections performed and the facts revealed thereby;
- 9. a statement that samples from recent interstate shipments have been obtained, briefly citing the labeling accompanying the shipments, if pertinent;

- 10. sample evidence (include the name of product sampled, and the laboratory findings that confirm the alleged violations);
- 11. prior actions such as warnings, notice, seizures, and FDA attempts to obtain correction, broken promises or other evidence of bad faith, such as statements by defendants clearly showing an intent to continue the violations, in detail as pertains to each defendant; and,
- 12. a statement that, despite the previous actions, the defendants are still engaged in violative conduct.

NOTE: All declarations should be prepared in final form, but not be signed, and should be double-spaced. They represent the facts that can be sworn to by an individual. However, changes made in a case during the review process may require changes in the declarations.

To ensure that the declarations remain accurate, the following will apply:

- 1. The declarant will carefully review the final copy before the case is submitted. The only signed version should be the final version after all changes have been agreed upon, reviewed, and cleared by the signer.
- 2. If substantive changes are made in the declaration, the reviewing office proposing the change will check with the district to ensure the individual can attest to the truthfulness and accuracy of the added material. OCC will be responsible for incorporating all approved changes into the final.
- 3. In no case will a declaration be modified without the knowledge and express consent of the declarant.

#### 6-2-13 Consent Decree

OCC will prepare the proposed consent decree, using the section in the district's CIM titled "Violations," and additional information provided by the Center.

The District and the Center are jointly responsible for providing OCC with the information necessary to support the specific substantive relief sought. See Exhibit 6-18.

In drafting a consent decree, OCC will seek Center approval on matters germane to its original review, including reconditioning or reprocessing plans, CGMP requirements, reviews of the corrective actions of defendants, recalls, cessation of product manufacturing or distribution operations, and measures that could affect availability of medically necessary products. OCC will seek the district's approval on matters requiring district follow-up activities, such as reinspection frequency and rates, reviews of defendant's corrective actions if any were requested by Center, and witnessing destruction and disposition of goods.

Also, during litigation, representatives of those offices with a direct interest in the case will keep each other informed of developments, including changes proposed by DOJ attorneys, to ensure that a consent decree is filed that are acceptable to the agency (district, Center, and OCC).

FDA should not seek relief if it cannot be obtained (e.g., do not propose to allow reconditioning of a product if it cannot be accomplished). Also, if the relief provides for the company to obtain a consultant, do not require, as part of the relief that FDA approve of the consultant.

# 6-2-14 Costs of Supervision

All injunction actions should provide for the payment of costs incurred to ensure that the defendants are brought into, and remain in compliance with terms of, the court's order before they can resume operations subject to the order.

The following charges apply to all injunctions:

*Investigation time*: 266% of GS-11/4 hourly rate

Analytical time: 266% of GS-12/4 hourly rate

Per diem actually paid to an FDA employee will be paid at the current existing rates expressed in GSA's Federal Travel Directory.

Miscellaneous expenses: actual cost

The minimum charge for services shall be not less than the charge for one hour. Additional charges shall be in multiples of one hour, disregarding fractions of less than 1/2 hour, as follows:

1 hour through 1 hour, 29 minutes - charge 1 hour

1-1/2 hours through 2 hours, 29 minutes - charge 2 hours

Consult with OCC before notifying the firm by letter that it may resume operation (see Exhibit 6-12) and before sending an initial bill setting forth the charges for all work performed to get the firm in compliance (see Exhibit 6-22). Do not use a letter to notify either the firm or the U.S. Attorney that costs have been paid, because this may result in the injunction being inadvertently canceled.

#### 6-2-15 Compliance Follow-Up

Once the injunction has been granted, the Court and the public rely on FDA to conscientiously monitor the defendants' compliance and to advise the Court on compliance with the terms of the injunction.

It is the responsibility of the district to ensure that prompt attention is given to the following:

- 1. Consult with OCC as to service of copies of the court's decree.
- 2. Determine the firm's plans to bring the operation into compliance and, where applicable, the plans for destruction, reconditioning, or recall of material on hand and finished goods in the market place.

- 3. Where the injunction contains a provision for the firm to designate an expert to supervise compliance with the terms of the decree, it should specify that the expert must certify in writing to FDA that the terms of the decree have been complied with before FDA makes any inspection, and that the firm must submit a written list of corrections to FDA.
- 4. Find out whether the firm has hired a qualified expert, and determine his/her qualifications. FDA does not approve or disapprove of experts selected by defendants when defendants are required by a consent decree to retain expert consultants. However, FDA may elect not to accept a consultant's report of findings. FDA acceptance of the consultant's findings may include consideration of such factors as the adequacy, completeness, or accuracy of the filed report, if an obvious conflict of interest is uncovered, or if the consultant's competency does not meet a regulatory standard (for example, as required in the drug CGMP regulations at 21 CFR 211.22). The district should share the follow up findings with the Center either by email or telephone.
- 5. Monitor status of the accomplishment of the above. Promptly advise OCC and the appropriate Center of any problems regarding non-compliance with the decree. Maintain close contact, including visits, as necessary, to ensure that the firm is brought into compliance before operations subject to the injunction are resumed.

NOTE: Inspections made under an injunction are performed under the authority of the appropriate Act and the decree entered by the court. When visiting the firm, provide a copy of the decree and FDA 482 to managerial personnel and document that you have done so. This will facilitate any contempt action that may be necessary.

Following determination by the district that the defendants appear to be in compliance with the requirements of the "unless and until" provisions of the decree, the defendants should be so notified in writing and advised that such determination does not, however, relieve them of their responsibility for compliance with the Act or other provisions of the decree that continue in effect (see Exhibit 6-12 Model Letter Acknowledging Compliance). Consult with OCC before notifying the firm by letter (Exhibit 6-12) that it may resume operations and before sending an initial bill setting forth the charges for all work performed to get the firm in compliance (Exhibit 6-22).

NOTE: If a copy of the above letter is furnished to the U.S. Attorney, it may inadvertently trigger a dismissal action unless the U.S. Attorney is also reminded that there are other provisions of the injunction that remain in effect.

If the district's follow-up discloses that the firm has met the provisions of the decree and notice has issued, the district will schedule a follow-up inspection to be performed in 3 to 4 months and quarterly thereafter until the firm maintains a continuous state of compliance for one year. The firm shall be inspected at least annually thereafter. Deviation from this schedule is appropriate in those instances where plant operations are on a seasonal basis. In that event, the firm shall be scheduled and inspected at the beginning of the next operating season.

Should any reinspection or analysis of samples disclose that the defendants are not meeting the terms of the decree, a variety of regulatory actions are available to FDA, including:

# 1. Reinstatement of Decree

Motion to petition the Court to implement the shut down provisions of the decree, based on the fact that defendants regressed from an in-compliance state (as certified in formal notice) to an out-of-compliance state. The effect of this action is to again close the firm until corrections have been made and verified. If the decree allows for a recall, upon request by FDA, this, too, may be considered.

#### 2. Seizure

# 3. Civil Contempt

A civil contempt is a forward looking action to force compliance, requesting the court to impose a penalty upon the defendant for continued noncompliance. The penalty may be monetary or confinement of individual defendants for each day or for each violative act until the terms of the decree are met.

#### 4. Criminal Contempt

A criminal contempt action is not to coerce compliance, but to punish prior behavior. The penalty does not depend upon future actions.

#### 5. Prosecution

# 6. Civil money penalties (for example, for medical devices or tobacco products)

#### 7. Administrative sanctions such as Withdrawal of Applications.

NOTE: The foregoing regulatory actions may be applied individually, sequentially, or concurrently. The consideration of any regulatory action should be discussed with the Center, DE, and OCC.

Recommendations for any action taken as the result of a violation of a decree shall be processed with the same urgency as the original injunction, and in accordance with the procedures in this chapter. The district compliance office will prepare a recommendation. For criminal contempt, see the RPM section "Contempt of Court; Violation of Probation". For prosecution see the RPM section, "Criminal Prosecution After 305 Notice". Should contempt be the action of choice, the district will also prepare a Petition for Order to Show Cause why the defendants should not be held in contempt. See Exhibits 6-23 and 6-24.

Change in ownership or identity of defendant firm should be noted. In the case of a change in ownership or corporate identity of the firm, report detailed facts on the changes to the Center and the OCC for a determination whether the new ownership or corporate entity are covered by the

injunction. Rule 65(e), Federal Rules of Civil Procedure, discusses persons covered by injunctions.

If a firm under injunction goes out of business, take the following steps:

- 1. Maintain the file as an open injunction for one year.
- 2. Check the status of the firm at the end of six months and one year after being reported out of business.
- 3. Make an effort to determine whether the firm has moved to another location and another district should be notified of the status of the firm. Notify any such district about the injunction.
- 4. If the injunction is against an individual as well as a firm, determine the individual's present occupation, and whether or not it is similar to the type of business for which he/she was enjoined. If so, notify the Center and OCC.
- 5. If the firm remains out of business after one year, notify OCC and the appropriate Center of your intention to close the file in 60 days unless either component has further information which requires consideration.
- 6. After the 60 day waiting period, if no further information is received, and the injunction was a preliminary one, notify the U.S. Attorney in writing that the firm has ceased operations and the government recommends closing the injunction file.

#### **6-2-16 Vacating Injunctions**

FDA does not ordinarily initiate requests to vacate injunctions whether issued by consent decrees or court orders. Nor will the agency join with a defendant in filing a motion to request such relief. However, if all of the following apply, FDA may agree to not oppose such a motion: (1) the agency has recent evidence (e.g., within the last 6-8 months) that the defendant is in compliance with the Act, applicable regulations, and the decree or order; (2) the defendant has remained in continuous compliance with the Act, applicable regulations, and the decree or order for the life of the sunset provision (virtually always five years); and (3) the defendant has given FDA an opportunity to consider whether or not to object to the motion. A long violative history or lack of cooperation by the defendant will also affect FDA's response to a motion seeking to have an injunction vacated.

If a defendant contacts the appropriate district(s) to discuss the possibility of vacating an injunction, the defendant should be instructed to prepare a written request specifically describing the evidence to show how it has met each of the foregoing criteria. The district and Center should not discuss their views about vacating a decree with the defendants or their counsel. That request should be forwarded to OCC (Deputy Chief Counsel and Associate Deputy Chief Counsel for Litigation), the relevant Center(s), and OEIO, together with the district's views, which should include a description of the results of the most recent inspection and the defendant's overall

inspection history since the injunction was entered. If OCC, the district, the Center, and OEIO do not object to vacating the injunction, OCC will inform the defendant's counsel that FDA will not oppose a motion requesting such relief.

Thereafter, the defendant's counsel should prepare, in draft, a short motion briefly describing the sunset provision, the defendant's compliance therewith, and the fact that FDA has read the motion and does not object to the relief sought. If OCC agrees with the motion, it will take steps to contact the Department of Justice so that the motion may be filed without opposition from the United States.

#### 6-2-17 Issuing Press Releases

The recommendation to issue a press release is made jointly by the OCC attorney assigned to the case, the ORA case officers (the district compliance officer or OEIO), and the Center's compliance office. The decision to issue a press release is made by FDA's Office of Public Affairs in accordance with the Transparency Initiative. The roles and responsibilities of these offices in making these decisions, and in drafting, clearing, and issuing press releases are described in "Procedures for Issuing Press Releases on Enforcement Activities (Seizures & Injunctions)." (See Exhibit 6-10) Follow these procedures and the accompanying models for drafting press releases concerning seizures and injunction actions. Upload the press release in CMS. See 6-1-13 and Exhibit 6-10 Issuing Press Releases

#### 6-3 INSPECTION WARRANTS

#### 6-3-1 Purpose

To provide procedures for obtaining inspection warrants. Procedures for Search Warrants are discussed in section 6-4.

#### **6-3-2** Inspection Warrants

The Food and Drug Administration (FDA) does not routinely request inspection warrants in order to conduct investigations or inspections of regulated industry. However, warrants have been used effectively to gather information that has been refused improperly. Inspection warrants should be recommended as soon as possible after a refusal is encountered. A past refusal is not a prerequisite to seeking an inspection warrant. (NOTE: "Inspection warrant" and "administrative inspection warrant" have the same meaning.)

Inspection warrants may be sought when inspection has been refused completely or when refusals have been encountered in limited areas; for example, when photography or sample collection has been refused.

There are situations where FDA will seek a preemptive inspection warrant; for example, when there is a history of prior refusals from a firm and FDA anticipates a current refusal to inspect. Also, FDA may seek a preemptive inspection warrant prior to initiating a scheduled inspection when there is a documented corporate policy mandating refusal in a particular area (such as photography, sample collection, or copying of records), or there is good reason to believe that

required information will be refused and that information will then be destroyed before an inspection warrant can be obtained.

Before seeking an inspection warrant, the agency needs to ensure that:

- 1. FDA is entitled by statute or regulation to inspect the facility and to have access to the information which has been refused; and
- 2. there is a compelling FDA need for that information, and
- 3. the firm/individuals have refused to allow inspection or access to information in spite of a clear demonstration or explanation of appropriate statutory authority.

#### 6-3-3 Responsibilities

Recommendations for inspection warrants are given high priority and handled expeditiously by all offices involved in their review. Under ordinary circumstances, OCC is not involved with the procedures for determining the need for an inspection warrant until the responsible center and OEIO determine that the application should proceed.

#### 1. District

# a. Preliminary Steps

When the criteria for requesting an inspection warrant are not clear, the district should consult with OEIO/DE prior to submitting a request for an inspection warrant. DE is located at 10903 New Hampshire Avenue, Silver Spring, MD, 20993. Telephone 301-796-8200; FAX 301-847-8635.

When the district decides to recommend an inspection warrant, the district should contact DE by telephone, provide advance notice, ascertain the DE contact person, obtain any additional guidance, and upload the documents listed below into CMS (Compliance Management System).

The district should transfer the case to DE by changing the current owner to DE pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DE designated to receive notification when actions have been submitted to that office. Prior to changing ownership for submission of the action, the district should identify all potential or suspect adulteration and/or misbranding charges cited in the subject action under the Act/CFR tab in CMS.

#### b. What to Include

- i. Cover Memorandum. The cover memorandum should summarize the circumstance(s) justifying the need for an inspection warrant. The memo must cover the following elements:
  - The statutory or regulatory authority to conduct the inspection or to obtain the information.

- Why there is a compelling need to conduct the inspection or obtain the information
- A clear description of the refusals encountered or, if refusals are anticipated, the reasons why a refusal is expected. Include a description of the efforts to explain our statutory authority and the firm's continued refusal in spite of this explanation
- Each type of information sought and refused, and an explanation why the information can not be obtained through other means
- The status of the inspection (ongoing, terminated, or anticipated)
- The reason for the inspection; prior warrants obtained; and, if applicable, violations observed
- Any situation that may result in a refusal or delay of an inspection conducted under a warrant.
- Any other pertinent information, for example, the location is a
  personal residence or the district anticipates resistance during
  execution of the inspection warrant, in which case a strategy for
  dealing with the anticipated resistance should be outlined
- Factors that are known to involve danger to the public, the inspecting persons, or others, (for example, weapons, guard dogs, or hazardous chemicals).
- ii. Draft Application for Inspection Warrant. The application for inspection warrant forms the basis for the agency's request to the Court. If there are multiple locations under the control of the same firm, prepare individual applications and warrants to cover each location. The application must include the following elements:
  - The correct address of the premises to be inspected. If the inspection is to extend to a vehicle, a precise description of the vehicle, including the color, make, model, and license number of the vehicle.
  - The statutory authority to inspect the establishment and the items sought.
  - Any violations observed during the course of the current investigation or the most recent inspection, specifically citing the language and section of the Act being violated. Although it is not

required that a violation has occurred in order to obtain approval of an inspection warrant, the Department of Justice (DOJ) has asked that such information be included in the Application, when available.

- A detailed description of any relevant refusals, including, for example, and not limited to: the individuals making the refusals, their titles, the dates of the refusals, any additional responsible individuals involved in or consulted about the refusals, the reasons given, any written corporate policy regarding the refusal, the names of investigators to whom the refusals were addressed.
- A detailed description of the reason for our inspection, or investigation during which the refusal was made, emphasizing that inspection was made at a reasonable time, in a reasonable manner, and describing any agency directives or programs which authorized the inspection and its scheduling.
- A description of the items that will be sought during the execution of the warrant.
- A description of the manner in which the requested inspection will be conducted pursuant to the warrant, such as the use of one or more investigators or U.S. Marshals to accompany the requesting investigator on the inspection, sample collection, and photography, and, where appropriate, copying of records.
- iii. A Draft Warrant. Include a draft copy of the inspection warrant.
- iv. Other Information and Documentation. Include any pertinent supporting documentation or background information.

\*NOTE: Recent models of Warrant Applications and Warrants may be available from ORA/DE, telephone 301-796-8200.

#### c. Processing

The district should transfer the case to DE by changing the current owner to DE pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DE designated to receive notification when actions have been submitted to that office. Prior to changing ownership for submission of the action, the district should identify all adulteration and/or misbranding charges cited in the subject action under the Act/CFR tab in CMS.

The district will promptly alert DE of copies of approved, filed warrants uploaded in CMS and keep DE informed of the progress of the inspection under the warrant.

DOJ prefers, and FDA encourages, that U.S. Marshals accompany FDA investigators when warrants are executed. If this presents a problem for the district, DE should be notified immediately. The recommending district should anticipate and set forth in the cover memorandum any situation that may result in a refusal or delay of an inspection conducted under a warrant. Whenever possible, an agency decision and implementation strategy regarding anticipated resistance, possible arrests, or use of force during execution of the inspection warrant should be considered and made prior to execution of the warrant.

If problems are encountered during the application for or execution of the warrant, DE should be contacted immediately. If there is a legal issue, contact Office of Chief Counsel and DE immediately. A return (a statement indicating completion of the inspection conducted under warrant) must be made to the Court within 10 days of completion of the inspection. The return is a separate document prepared as part of the draft warrant application. It is simply a statement from the Investigator who was authorized to conduct the inspection that the inspection was made on a certain date(s). The document is filled in with the date of inspection, signed by the Investigator, and returned to the Court. A copy of the return should also be uploaded into CMS and a hardcopy should be forwarded to OCC.

# 2. Division of Enforcement (DE)

When a recommendation for an inspection warrant is transferred, DE maintains ownership but will send a task in CMS to the responsible centers for concurrent review. The centers and DE will review the recommendation and proposed documents to assess the need for the action, the agency's statutory authority, completeness, accuracy, format, and conformance with current DOJ requirements. The center indicates the completion of their review by uploading associated documents into CMS and closing the "task" pursuant to procedures in CMS. DE will provide hardcopies of the revised documents to OCC. Throughout the process, DE will monitor and coordinate the concurrent review and processing of the inspection warrant with the recommending district, center, and subsequently with OCC, and DOJ. If a warrant application is not approved, a written explanation of the decision will be uploaded into CMS and DE will indicate "Non-Concur" in the internal decision field, adding the completed date and changing the current owner to the District. CMS will automatically send an e-mail to the person in the district designated to receive notification when ownership of a case has changed to that office. The District should close out the case pursuant to CMS procedures.

If through concurrent review by the center and DE, a warrant application package is approved, DE will revise the documents as needed, upload them into CMS and indicate "Concur" in the internal decision field, add the completed date and update the FDA Final Decision to Approved. DE will forward hardcopies of the revised documents to the Deputy Chief Counsel for Litigation, OCC. After review and approval of the warrant

application package by OCC, DE will prepare a transmittal memorandum addressed to DOJ from the Director, Division of Enforcement (DE) and upload this document into CMS.

DE transmits the warrant package approved by the Director, DE to DOJ by fax, electronically, courier, or overnight delivery and coordinates final revision and processing of the warrant application package with DOJ and OCC. Following DOJ review, DE uploads into CMS the DOJ approved (or denied) warrant application package, including any necessary guidance or instructions for the application and execution of the warrant. Action ownership will end with DE.

DE notifies the Associate Commissioner for Regulatory Affairs (ACRA) and designated contacts in the Office of External Affairs of the strategy and impending action immediately after forwarding a warrant application package to the district for filing with the court. DE uploads into CMS the files of all warrant recommendations.

#### 3. Center

The responsible center promptly reviews all warrant application documents forwarded to it by DE, ensuring center support (or providing reasons for disapproval) and the accuracy of statutory references, with special emphasis on the authority for access to those items sought to be inspected. Where possible, revisions to documents should be highlighted and uploaded into CMS. Disapprovals are documented in writing and uploaded into CMS over the signature of the Director, Office of Compliance, or his/her designee.

#### 4. Office of Chief Counsel

Office of Chief Counsel promptly reviews the warrant and application package for legal sufficiency. Revisions are forwarded to DE for typing and transmittal to DOJ. Any disapprovals should be documented in writing and DE should upload them into CMS.

# 6-4 SEARCH WARRANTS

#### 6-4-1 Purpose

To provide the procedures for obtaining search warrants. Procedures for Inspection warrants in Section 6-3.

#### 6-4-2 Search Warrants

Search warrants are effective tools for obtaining evidence of criminal conduct, and for seizing contraband or the fruits of a crime, property that has been or is intended to be used in the commission of a crime, or the arrest of persons based upon probable cause. See Rule 41, Federal Rules of Criminal Procedure. Also, see U.S. Attorneys' Manual (<a href="http://www.usdoj.gov/usao/eousa/foia\_reading\_room/usam/index.html">http://www.usdoj.gov/usao/eousa/foia\_reading\_room/usam/index.html</a>). Criminal search warrants are particularly useful when there is reason to believe that relevant evidence may be hidden or destroyed.

#### 6-4-3 Procedures

The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters. District management must communicate with its local OCI office, as instructed in <a href="mailto:section 6-5-2">section 6-5-2</a>
"Referral of Criminal Matters to the Office of Criminal Investigations" below, before pursuing a criminal search warrant.

#### 6-5 PROSECUTION

# 6-5-1 Purpose

This section establishes guidelines for the uniform submission and review of prosecution recommendations, including referrals for criminal investigation. A number of different procedures, depending upon the distinguishing case features, are included in order to eliminate unnecessary review and to expedite the case review process.

As described below, all criminal referrals, whether initiated by the District, the Center, or another FDA Headquarters component, must be sent to OCI for initial review in accordance with section 6-5-2 and 6-5-3. If OCI declines the referral, the Center or District may pursue the matter through the preparation of a Summary and Recommendation in accordance with section 6-5-5 et seq.

# 6-5-2 Referral of Criminal Matters to the Office of Criminal Investigations

The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters. FDA personnel must refer all criminal matters, regardless of their complexity or breadth, to OCI. This includes criminal search warrants, misdemeanor prosecutions, felony prosecutions, referrals for criminal investigation, and Section 305 meetings.

District management must communicate with the local OCI office before pursuing any criminal matter. Designated center and ORA and FDA Headquarters points of contact must communicate with their respective OCI Senior Operations Manager (SOM). This communication is absolutely essential to preclude potential interference with other on- going criminal investigations and to prevent confusion among the components of the Office of Chief Counsel and the Department of Justice that are responsible for handling FDA's criminal cases.

During this communication, OCI is to be provided with all of the facts of the potential case and any additional information that is relevant to, or could impact, the case in any way. In accordance with <u>SMG 9111</u>, district management should notify the local Special Agent in Charge, Assistant Special Agent in Charge, or Resident Agent in Charge of the referral via telephone. For referrals of *Park Doctrine* prosecutions, see the procedures below.

For all criminal referrals, OCI will decide promptly whether or not to pursue the case.

OCI will communicate its decision back to the referring Office. If OCI declines to pursue a referral, OCI will promptly convey its decision to the referring office, which may then proceed with the case and submit a formal summary and recommendation for prosecution in accordance with sections <u>6-5-5</u> and <u>6-5-13</u> of this chapter.

# 6-5-3 Special Procedures and Considerations for *Park* Doctrine Prosecutions

#### **Recommending Park Doctrine Prosecutions**

The *Park* Doctrine, as established by Supreme Court case law, provides that a responsible corporate official can be held liable for a first time misdemeanor (and possible subsequent felony) under the Federal Food, Drug, and Cosmetic Act ("the Act") without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense. A *Park* Doctrine prosecution, for the purposes of this section, refers to a recommended prosecution of a responsible corporate official for a misdemeanor violation of the Act.

Misdemeanor prosecution under the Act can be a valuable enforcement tool. Such prosecutions are referred to the Department of Justice. Once a person has been convicted of a misdemeanor under the Act, any subsequent violation of the Act is a felony, even without proof that the defendant acted with the intent to defraud or mislead.

Misdemeanor prosecutions, particularly those against responsible corporate officials, can have a strong deterrent effect on the defendants and other regulated entities. In some cases, a misdemeanor conviction of an individual may serve as the basis for debarment by FDA.

When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation. Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation.

Other factors to consider include but are not limited to:

- 1. Whether the violation involves actual or potential harm to the public;
- 2. Whether the violation is obvious;
- 3. Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
- 4. Whether the violation is widespread;
- 5. Whether the violation is serious;
- 6. The quality of the legal and factual support for the proposed prosecution; and
- 7. Whether the proposed prosecution is a prudent use of agency resources.

As the Supreme Court has recognized, it would be futile to attempt to define or indicate by way of illustration either the categories of persons that may bear a responsible relationship to a violation or the types of conduct that may be viewed as causing or contributing to a violation of

the Act. In addition, these factors are intended solely for the guidance of FDA personnel, do not create or confer any rights or benefits for or on any person, and do not operate to bind FDA. Further, the absence of some factors does not mean that a referral is inappropriate where other factors are evident.

When a district office is considering initiating a referral for a *Park* Doctrine prosecution, the district is required to consult with the appropriate center to ensure that the referral will align with agency priorities and that the center will support the referral and provide expert witnesses or other litigation support when necessary. Centers and district offices are also encouraged to consult with OCC and OCI HQ Special Agent in Charge (SAIC) and/or the Assistant Special Agent in Charge (ASAIC) Investigative Operations Division (IOD) early in the process for guidance and recommendations regarding optimal venue.

If the district or center is seeking a misdemeanor prosecution under the *Park* Doctrine, the initial referral to OCI should clearly indicate that a *Park* Doctrine prosecution is being sought and the reasons that a *Park* Doctrine prosecution would be beneficial. At the same time that the district refers a *Park* Doctrine prosecution to an OCI Field Office, notice of the referral also should be sent to the SAIC and/or the ASAIC OCI HQ IOD, and the applicable center. Notice of all *Park* Doctrine referrals, whether initiated by the district office or the center, should also be sent to the Deputy Chief Counsel and Associate Deputy Chief Counsel for Litigation in the Office of Chief Counsel (OCC), and the director of OEIO/DE.

Upon receipt of a *Park* Doctrine referral, OCI will promptly review the referral and will communicate with OCC and the referring office to obtain any information or assistance needed to present the matter for prosecution. In appropriate cases, the assigned OCC attorney and/or a representative from OEIO or other component should participate in the initial presentation of the *Park* Doctrine matter.

# 6-5-4 Communication Between OCI and Other FDA Components

The following Staff Manual Guides (SMGs) provide additional information on communications between OCI and other FDA components:

- SMG 9111 Sharing of Information Related to Criminal Violations http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm212504.
   htm This SMG requires that OCI be notified of potential criminal activity immediately if there is an imminent threat to public health and within 10 business days in all other cases and that OCI evaluate the information within 10 business days and notify the district office of its initial assessment. It also addresses information sharing between OCI and other FDA components.
- SMG 9110 Enhanced Communications with the Office of Criminal Investigations (OCI) and Improved Alignment of Criminal/Regulatory Priorities and Activities –

   <u>http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm212503.</u>

   <u>htm.</u> This SMG provides general procedures for the establishment of regularly scheduled meetings between OCI and center, ORA and other FDA components.

Notify OCI if you receive a request from a law enforcement agency (federal, state/local, or foreign) for non-public information related to a criminal case. Notification should be provided to the SAIC and/or the ASAIC, OCI HQ IOD. This is particularly important if the request relates to grand jury information, judicial proceedings under the Federal Food, Drug, and Cosmetic Act, or joint investigations with OCI and other law enforcement agencies about violations of the Federal Food, Drug, and Cosmetic Act. When OCI seeks non-public information on its own initiative or in response to a request described above, provide the information to the SAIC and/or the ASAIC OCI HQ IOD for their review and determination of appropriate written confidentiality assurances prior to disclosure. Indicate what information is non-public.

# 6-5-5 Processing a Summary and Recommendation

In cases where OCI has declined to pursue a referral, the recommendation for prosecution or for investigation with a view of possible criminal charges will be prepared in the format of a Summary and Recommendation (S&R). This document is a memorandum containing all information that would permit review and evaluation of the district's recommendation, including the reasons for not including samples or individuals cited in the Section 305 notice (when such a notice is issued) and information concerning any potential weaknesses in the case, anticipated defenses, or reasons why discretion may be exercised not to prosecute a person (such as, extreme age or very poor health).

It is important for the S&R to contain all facts pertaining to the recommendation, since it will be relied upon to determine whether a case is prosecutable and worthy of forwarding to the Department of Justice (DOJ). In prosecution cases in which FDA forwards counts in an Information or Indictment (as opposed to referrals for criminal investigation), the S&R should present the evidence of **each element** of the offense to be charged.

Where a district submitted the original referral or where the referral relates to an inspectional process, each recommendation must be accompanied by the written concurrence of the District Director (DD) and the Regional Food and Drug Director (RFDD). The DD's approval must state why prosecution is the action of choice, and the RFDD must concur. This concurrence will appear on the last page of the S&R. Where a center submitted the original referral and the referral relates to a center process, each recommendation must be accompanied by the written concurrence of the director of the center's office of compliance.

See section <u>6-5-13</u> for detailed guidance for preparing an S&R.

# 6-5-6 Criminal Prosecution after Section 305 Notice

Criminal referrals for which the agency has provided a notice and opportunity to respond, pursuant to Section 305 of the Federal Food, Drug, and Cosmetic Act (the Act), should follow the procedures described below:

1. When a district does not have direct reference authority to issue a Section 305 notice, the district will submit a citation recommendation to the appropriate center(s) for review,

after contacting OCI (as described in "Office of Criminal Investigations" above. Generally, the citation recommendation includes:

- a. the names and responsibilities of each individual and the charges to be presented in the notice;
- b. the full background history of notification of the persons to receive a notice; and,
- c. facts supporting the proposed charges, including assurance of interstate documentation. All pertinent evidence, such as work sheets, labels, and inspection reports, should be submitted with the recommendation. The center may request the interstate documentation if a special need to review it exists.
- 2. If the district or the center identifies an issue requiring consultation with the Division of Enforcement (OE), OCI, Office of the Chief Counsel (OCC), or an ad hoc committee, the component identifying the issue will obtain prompt resolution as early in the review process as possible.
- 3. If, following the meeting held in response to the Section 305 notice, there is no significant change in the facts, as set forth in the district's citation recommendation, the district will notify the center, which will promptly forward the district's citation recommendation package to OEIO/DE. Concurrently, a final S&R will be sent by the district to DE with copies to the center.

If there is a significant change in the facts or strength of the proposed case, the district will submit the prosecution recommendation package to the appropriate center solely to determine whether prosecution remains warranted in view of the new information. If prosecution is warranted, the center will promptly forward to DE the prosecution S&R and the center's approval memo presenting the basis for its decision in light of the new information.

NOTE: When a district has evidence sufficient to meet the requirements for direct reference authority to issue a Section 305 notice ("direct reference cite authority"), the procedures in # 1 above do not apply. (Except that OCI must be contacted, as described in "Office of Criminal Investigations" above.) After the Section 305 process has been completed and, if no new information is presented that affects the basis for the direct reference authority, the district should promptly submit its prosecution S&R directly to DE for a limited review. The district should concurrently send a copy of the S&R to the center.

If the response to the Section 305 notice reveals new information affecting the basis for the direct reference cite authority, the district must obtain center review and concurrence concerning that aspect of the recommendation before submitting it to DE.

4. DE will perform a limited review to determine whether the proposed prosecution conforms to agency policy and enforcement strategies and objectives. If DE concurs in the prosecution recommendation, it will forward all relevant materials to OCC, along

with a memo concerning the issues it has considered and that DE believes OCC should review

5. OCC will review the recommendation and, if it agrees that prosecution is supportable, prepare a referral letter and form of Information or Indictment.

#### 6-5-7 Criminal Prosecution without Section 305 Notice

Those instances in which the agency need not issue a Section 305 notice under the Act are codified in 21 CFR 7.84. No Section 305 notice is required in cases brought under Title 18 of the United States Code - as opposed to cases brought under the Act - or in cases exempt under 21 CFR 7.84(a)(2) and (3), based on the agency's belief that the notice might result in alteration or destruction of evidence or flight to avoid prosecution. Nor is a Section 305 notice usually provided when the agency is recommending further investigation.

Criminal referrals not preceded by a Section 305 notice should follow the procedures described below. OCI must be contacted early on in this process, in accordance with the procedures described in "Office of Criminal Investigations" above.

- 1. The district is to consult with DE, which will consult with OCC, to determine whether to issue a Section 305 notice or whether an ad hoc committee is needed to decide the issue. If DE and OCC agree that no Section 305 notice should be issued, DE will so notify the district. The district will then prepare an S&R and obtain approval from the Region before submitting the S&R to DE, with concurrent copies to the center and OCC for review. The district will explain under the heading "No Section 305 Notice" why such notice is not required. (Should DE and OCC decide that a Section 305 notice should be issued, DE will so notify the district who will then follow the procedure under RPM, "Prosecution after 305 Notice".)
- 2. If the center and DE concur in the recommendation, each will prepare a memo reflecting its views on the relevant issues. The center will forward its memo to DE.
- 3. DE will forward all relevant materials and memos to OCC and, if OCC agrees that prosecution is supportable, OCC will prepare a referral letter and form of Information or Indictment.

#### 6-5-8 Contempt Of Court; Violation of Probation

The district will prepare an S&R outlining the facts that establish the violative conduct and send it and a copy of the pertinent court order electronically via CMS to DE. Because DE and the relevant center are expected to conduct concurrent reviews, the S&R should include a request that DE send a task referral pursuant to CMS procedures to the center requesting its review.

Both the center and DE will have 10 working days to review the proposed action and upload their comments into CMS.

If no adverse comment is provided by either the center or DE, or if adverse comment was provided but a consensus to proceed is reached, the district will forward its S&R and supporting

evidence to DE via CMS for prompt forwarding to OCC for review. If OCC agrees that the action is supportable, it will prepare a referral letter.

# 6-5-9 Development of Felony Violation

Some investigations may reveal facts supporting potential felony charges under either Title 18 of the United States Code or 333(a)(2) of Title 21. A primary problem associated with these cases is determining the investigational end-point. When such situations are encountered, an **ad hoc** committee should be considered. This is because some potential cases should be referred at an early stage for a grand jury investigation, while FDA can carry others to investigational completion, prior to referral.

The following matters, among others, should be considered in these situations:

- 1. scope of the investigation;
- 2. status of current investigation, including identification of targets and of potential cooperating individuals;
- 3. strategy and timing in completing the investigation;
- 4. agency compliance policy in the area at issue;
- 5. preliminary evidence that violations are intentional;
- 6. identification of inspectional or investigational problems;
- 7. use of criminal search warrants;
- 8. need for or wisdom of a Section 305 notice citation; and,
- 9. recommendation for grand jury investigation (see RPM "Grand Jury Investigations").

For investigations subject to ad hoc committee oversight, the compliance branch in the managing organizational unit will prepare a status report whenever significant progress is made on an investigation or at least every 90 calendar days, whichever occurs first, and distribute it to DE, OCC, appropriate center, and affected regional/district offices.

# 6-5-10 Referrals for Criminal Investigation

A referral from a district or center to DOJ for further criminal investigation, including an investigative grand jury, should follow the process described below:

1. The initiating unit, district or center, will notify OCI in accordance with the RPM section "Office of Criminal Investigations." If OCI elects not to pursue the case, then the district or center may notify DE and request an ad hoc committee meeting, and provide a Summary and Recommendation Document (S&R) of the existing evidence. Relevant, organized, and tabbed background material will be assembled by the initiating unit and uploaded with the S&R into CMS. The district should transfer the case to DE by changing the current owner to DE pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DE designated to receive notification when ownership of

- a case has changed to that office. Information should cross reference and cite specific pages of the background material.
- 2. Prior to scheduling the meeting, DE will review the background package and ensure that it is in a form that will facilitate review and identification of issues.
- 3. DE will promptly notify the committee via e-mail of the availability of the background package in CMS and in the body of the e-mail provide a time and place for the meeting, and identify the principal issues to be decided. With very rare exception, a minimum of 10 working days will be provided for members to review the background package; center review will be given high priority and the meeting will not be scheduled until the center is ready to participate. A copy of this e-mail should be uploaded into CMS.
- 4. The committee members should be prepared to make agency decisions on the issues, including whether referral should be made on the basis of the evidence in hand, whether additional assignments should first be issued, completed, and reviewed by the committee, or whether a noncriminal disposition should be considered in lieu of or in addition to a prosecution.
  - a. Should the committee members concur in the recommendation for referral and believe that there is no need to gather further evidence or for a further meeting, DE will promptly prepare a memorandum of the decision, upload it into CMS and forward a hardcopy to OCC as the agency's recommendation. DE will maintain ownership of the case. OCC will revise the district's draft of the referral letter, as necessary. DE should upload this draft into CMS.
  - b. Should the committee believe that additional investigation is needed, the committee will issue the appropriate assignments, record them in a memo that is uploaded in CMS and set a tentative date to reconvene. Offices performing the additional work will be responsible for providing written summaries of the results and, when appropriate, recommendations to the committee in advance of the next meeting. These associated documents should be uploaded into CMS. DE will monitor the status of the assignments and schedule via e-mail the follow-up meeting. A minimum of 5 working days will be provided for members to review new information prior to the meeting. DE will prepare a memorandum of any subsequent meeting and upload it into CMS.

If the committee decides, either on the basis of its initial review or on the basis of additional data discussed at a subsequent meeting, that a request for criminal investigation should be referred, DE will promptly forward to OCC any relevant materials that may not have previously been provided along with a written request that OCC refer the matter to DOJ.

NOTE: When FDA participates in investigations in which another Federal agency has the lead and intends to request a criminal investigation, the district will work directly with the lead agency in developing evidence and in assisting in the investigation. In such cases, the district will promptly notify the relevant centers, DE, OCI, and OCC of the investigation, the district's role in it, and whether a grand jury investigation is contemplated.

As soon as the district determines that it would like to seek the prosecution of Title 21 or Title 18 charges based upon violations involving FDA regulated articles in an investigation where another Federal agency has the lead, it will notify DE, for an FDC number, the centers, and OCC of its intent to do so and will promptly forward a recommendation to DE, the center or, if appropriate, directly to OCC, to obtain approval to proceed with the case.

In some cases, an ad hoc meeting may be appropriate. If special time constraints are applicable because of the participation of other agencies, the recommendation should so state. Except for possible time constraints, joint investigations should be processed in the same manner as other FDA cases.

#### 6-5-11 Information And Indictments

These documents will usually be prepared by Office of Chief Counsel.

An Information is the formal legal document that is usually used to allege misdemeanor violations. An Indictment is the document in which felony violations are alleged, following presentation to the grand jury. This document is also referred to as a True Bill of Indictment. With the consent of a defendant, an Information may be presented to a grand jury, even though only misdemeanor violations are alleged.

# 6-5-12 Grand Jury Investigations And Secrecy

Grand jury investigations are subject to Rule 6 of the Federal Rules of Criminal Procedure (see Exhibit 6-29). The fact of grand jury investigations and the actions of a Federal grand jury are secret. Only persons whose names have been filed with the court pursuant to Rule 6(e) may know about the grand jury's activities, such as whether the grand jury has issued a subpoena to someone. For this reason, transcripts of testimony given before a grand jury can be read by or discussed only with persons who have been designated under Rule 6(e). Neither FDA colleagues nor supervisors may be advised of the substance of grand jury activities unless they have been designated under Rule 6(e).

As with any pending investigation, there should be no comment whatsoever to the media or to the general public about the existence or activities of a grand jury. Even if there has already been speculation in the press about a grand jury or reports about it from witnesses called to testify before the grand jury (who are not bound by the rule of grand jury secrecy), no confirmation or other comment on the grand jury should be made.

Strict adherence to the rule of grand jury secrecy protects not only the integrity of the government's investigation and the validity of any indictment the grand jury might return, but the rights of the persons accused.

Compromising the 6(e) rule is a very serious matter and could result in dismissal of the charges, the suppression of valuable information, and/or a contempt citation against persons violating Rule 6(e).

DOJ and the U.S. Attorney may request FDA to provide investigative support to conduct interviews, accompany U.S. Marshals to seize evidence, and so on. Any person who is involved in this type of investigation will be given a 6(e) designation where these actions involve matters occurring before the grand jury.

#### 6-5-13 Preparation of Summary and Recommendation

See Exhibit 6-25 for a model format for the summary and recommendation memorandum and Exhibit 6-26 for an example of a food sanitation case. The Sample Index is an outline of the support samples related to the prosecution.

# 1. Sample Number, Product, Date Shipped

The order of the counts in an Information or Indictment is variable, but should be determined by the significance or seriousness of the violations, rather than the sequential order of the sample numbers or the date of sample collection. However, where all samples or schemes have the same degree of seriousness, list in descending chronological order (most recent offense in Count I, next most recent offense in Count II, and so forth. The column headings may be changed to provide whatever information the district feels is significant. Beneath the sample number indicate the proposed count number. In cases where supporting samples are unnecessary, describe the scheme or violation and outline the elements of the offenses.

# 2. Citation Under Section 305 Of The FD&C Act

List complete names and addresses of all persons issued Section 305 notices. Prepare brief, concise paragraphs explaining significant new evidence obtained since the Recommendation for Citation was submitted. Also include any changes in the status of responsible individuals or the firm that have occurred since the center approved the issuance of 305 notices or, in the case of direct reference cite authority, since the Section 305 notice issued. See the RPM section "Criminal Prosecution after Section 305 Notice".) If this is a recommendation without a Section 305 notice, prepare a brief paragraph explaining the facts, including identifying the basis of concurrence with this approach, for example, "Ad Hoc meeting."

#### 3. Legal Status

Prepare a brief paragraph describing the legal status of the firm as of the date of the S&R and at the time of the violations. If there has been a change in the legal status in the interim, furnish complete information concerning the change. As soon as the decision is made to recommend prosecution of a corporation, request certified copies of the Articles of Incorporation and the most recent Annual Corporate Registration. The annual corporate registration may list the current corporate officers at the date of filing. This request may be made in writing as shown in Exhibit 6-27 or in person so that the records are received in a form suitable for introduction into evidence (see Exhibit 6-28). If the Articles of Incorporation have been received before the recommendation has been submitted, so state in this section and enclose photocopies of the Articles with the

recommendation. If they have not been received, include a statement that the Articles of Incorporation have been requested and photocopies will be submitted upon receipt.

When preparing photocopies of certified copies, the removal of any staples nullifies the certification. -- Caution the Legal Secretary/Technician about this.

If a corporation is dissolved, in most states it still legally exists for a period of time specified by the state in which it is incorporated and may be prosecuted during that period. In case of dissolution, submit copies of any notices thereof filed with the state and reports of any actions by the state on such dissolution.

# 4. Alleged Violation

Prepare a summary of what the case is about. Include a statement on how the problem came to the attention of the agency. List the violations under this heading. In the event the proposed counts are numerous and the violations involve several different sections of a statute, you may use an outline or tabular form. Adulteration and misbranding charges should be charged in separate counts. In cases involving fraud, a detailed statement of all pertinent data (who, what, when, where, why, and how) concerning the scheme, from its conception through its perpetration, should be prepared. The following questions should be considered:

- a. When was the scheme initially implemented? By whom?
- b. What were its primary objectives?
- c. What were the methods by which it was implemented?
- d. Where was it put into operation and for how long?
- e. What was the nature of the scheme, the types of merchandise or service involved?
- f. Describe the magnitude, nature, and characteristics of the scheme (for example, number of units shipped, and amount of money involved).
- g. Describe the victims as to health, economic status, or other features.
- h. Identify for each proposed defendant or target any evidence reflecting that the offense was committed knowingly and willfully (intentionally).
- i. Identify potentially cooperative witnesses.
- j. Describe any noteworthy investigational problems encountered.

#### 5. History

State briefly the regulatory history of the firm and the individual defendants. Point out any cooperative work FDA has done with the state or other Federal agencies. Indicate any

prior Federal action and any state legal action taken against the proposed defendants as well as any previous in rem actions.

#### 6. Prior Notice

As more fully explained in Chapter 10, 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.

Indicate how and to whom prior notice was provided. If formal prior notice has not been given, indicate how the proposed defendants are aware of the consequences of their violative acts, or explain why prior notice is not necessary or appropriate in this situation.

# 7. Other Correspondence

Provide reference to and copies of any correspondence that the agency (district, center, or other headquarters' unit) and state may have regarding matters subject to the recommended action.

#### 8. Witnesses For Inspectional And Analytical Findings

Arrange the samples (if any) by proposed count numbers listing the collecting investigator and the analysts. Identify the documentary and physical evidence associated with each witness and describe how this evidence was obtained, e.g., interview, inspection, surveillance, or other means. For a case with support samples, assign count numbers as in Exhibit 6-25.

#### 9. Other Witnesses

List the names, addresses, telephone numbers, and titles of any other known witnesses, including cooperating subjects of the investigation, FDA representatives from the center, and nongovernment expert witnesses with a summary of their anticipated testimony.

#### 10. Recommendation

List the persons being recommended for prosecution and the corresponding sample numbers (if any) or scheme that is the basis for prosecution. If any such persons have been previously convicted or are the subject of other legal action, include a paragraph stating the nature of the charge, the date the case was terminated, the disposition, the penalty imposed, the jurisdiction, and the case number (and an FDC, lead sample, or other FDA identifying numbers, if any). Indicate whether warnings were given and summarize the recommended defendant's response or corrective action. Indicate what

harm has or can result from the criminal activity at issue, such as, type and total amount of loss, number and type of victims, and similar information. See also the RPM <u>section</u> on <u>Prior Notice</u>.

# 11. Permanent Abeyance of Samples or Non-Inclusion of Individuals

If the district decides to place any of the samples listed in the Section 305 notice in permanent abeyance or to not include cited individuals as proposed defendants, the reasons for these decisions should be given in this section. Excluded samples should not be destroyed until the termination of the action by plea or trial. If all samples and individuals listed in the Section 305 notice are included in the prosecution recommendation, this section may be omitted.

# 12. Sample Data

This section is designed to furnish a brief summary of the available information in the file regarding each sample. Ordinarily, a criminal case should include more than one count and only in very unusual circumstances, which must be explained in the memorandum, will a one-count Information be referred to DOJ.

Thoroughly discuss any potential problem areas with respect to the samples, such as a modification of official analytical methods during analysis, deviations from normal procedures in the collection of the samples, errors in the collection records, seals, analytical records which had to be corrected, or any inconsistencies between affidavits and records.

- a. Date lot shipped/received: For 301(a) or (d) violations, state the date the defendants shipped the lot or delivered it for shipment. For 301(k) violations, state the date the defendants received the lot, and for 301(c) violations state the date the lot was received and the date it was delivered or profferred for delivery. Occasionally, the receiving date in a 301(k) violation is not available. In such a case, the date of the offense is the day on which the investigator can testify that she or he saw the subject lot at the proposed defendant's premises. Occasionally, a 305 notice will issue with the date of shipment being the date furnished in an affidavit signed by the dealer, but subsequent investigation uncovers records indicating that the lot was actually shipped or delivered on another date. As long as the 305 notice stated "on or about" with respect to the date, this is acceptable. The correct date will be listed in the Information or Indictment, even if it differs from that listed in the Section 305 notice. Complete information regarding the conflicting dates should be furnished under the caption "Documentation of Interstate Commerce."
- b. Date lot sampled/by whom: If the sampling of the lot takes place over a period of several days, that should be stated here. In the case of a 301(k) violation, if the lot remains in the regular storage area for saleable goods, the Information or Indictment will indicate that it was held for sale between the date of receipt and the last day of the inspection. If the lot is moved to a quarantine area and it is

clear that it is not to be sold, the day the product was moved (or destroyed, denatured, or embargoed) will be used in the Information or Indictment. In addition to the name of the collecting investigator, indicate where he or she is located at the time of the writing of the recommendation. If the investigator has transferred to another district, resigned, or retired, he or she should be contacted when the Information or Indictment is submitted to DOJ, advised that prosecution is pending, and requested to keep the district informed of his or her location so that the investigator can be contacted if the case goes to trial.

- c. Description of lot and sample size: The size of the lot should be listed and, in 301(k) sanitation cases, a brief description of the lot should be given. For example, the description should contain the statement that the investigator looked at (number of) bags, found urine on (number of) bags, (number of) bags were rodent gnawed, and should indicate whether filth was only on the exterior of the lot or on containers covered by other containers, whether or not the lot was received palletized, whether containers in the lot had been restacked by the firm, etc.
- d. Analysts: As with the collecting investigator, the current location of the analysts should be recorded and contact should be made with the analysts when the Information or Indictment is submitted to DOJ.
- e. Analytical methods: The method of analysis should be given. If there was any deviation from an official method, complete information concerning the modification and reasons therefore should be given. (In the analysis of official preparations, the method in the compendium should be followed.)
- f. Number of subs analyzed: If every sub has been analyzed, merely state "all." (It is incumbent upon the district's Compliance Branch to ensure that sufficient analytical work has been performed.)
- g. Analytical findings: The results of each analysis of the product should be listed. If the problems which were encountered necessitated additional work, or deviation in or from an official method such as new methodology or analysis to resolve discrepancies in analytical results, such matters should be disclosed and discussed. In cases involving filth in foods, the analytical findings should be broken into two groups; those demonstrating actual contamination in the product [402(a)(3)] and those demonstrating 402(a)(4) conditions. The results regarding the findings of actual product contamination should be summarized basically as follows:

# Subs,\_\_\_\_\_\_, and - gnawed -incisor marks - confirmed. Subs,\_\_\_\_\_, and- contained rat or mouse excreta or hair - confirmed. Sub - insects (identities, if possible)

# Section 402(a)(4) Verification

If there is substantial 402(a)(3) evidence, the subsamples collected from the surface and proximity of the lot need only be briefly summarized, covering each type of 402(a)(4) filth present. This includes rat or mouse excreta, rodent urine, and rodent nesting material as being confirmed or identified.

If the proposed charges differ from the data listed under "Analytical Findings" or the charge sheet that accompanied the 305 notice, the reasons for the differences should be discussed.

h. Section 702(B) Portion: In any case involving analytical work, a portion of the sample usually should be available for the defendant, should he or she request it. Verify whether the section 702(b) sample portion is available, and note the amount available. If a 702(b) portion does not exist, this fact should be conspicuously noted and an explanation provided.

Some exceptions to the requirement for 702(b) portions are codified at 21 CFR 2.10. If all subs have been analyzed, there is a presumptive 702(b) concern which should be addressed.

NOTE: Filth exhibits do not require a 702(b) portion.

- i. Seizure: If the lot forming the basis for a proposed count was seized, list the case number and the FDC number and state the disposition of the seizure.
- j. Documentation of interstate commerce: State the name and title of individuals signing dealer statements and affidavits, the name and address of the firm for which they work, and list the documents furnished, including information such as purchase order, invoice, freight bill, and bill of lading numbers, and the dates they were issued. Interstate commerce witnesses are sometimes called on to testify and supply the original documents in the event the case goes to trial.
- k. Remarks: This section should contain detailed information concerning any potential problem areas or weaknesses in the case not covered in the description of the individual counts. Include the ages of the proposed defendants and, if known, any physical problems they may have. Also, indicate that OCI was contacted regarding the case. Finally, state why prosecution is the action of choice.

# 6-5-14 Submission of Summary and Recommendation Documents

The summary and recommendation (S&R) documents are submitted to the center, DE and OCC, depending upon the instructions described in the applicable case procedure, "Criminal Prosecution Without Section 305 Notice", "Criminal Prosecution Without Section 305 Notice", or "Referrals for Criminal Investigation."

# 1. Prosecutions Requiring Center Approval

- a. Submit the S&R (prepared as described in "Preparation of Summary and Recommendation") and the supporting documents listed below by uploading them into CMS.
  - i. Section 305 Notice and Charge Sheet
  - ii. Record of Section 305 meeting and any documents presented at the meeting
  - iii. Written answer to the Section 305 notice (if meeting was not held)
  - iv. Any correspondence or memoranda of telephone conversations with proposed defendants since the Citation Recommendation was submitted.
  - v. Guaranty (if applicable)
  - vi. Articles of Incorporation (Photocopy can be submitted in CMS and district will maintain the original. DO NOT HOLE PUNCH the original document).

Centers should upload their approval memo into CMS.

NOTE: If the recommendation meets the circumstances outlined in "Processing a Summary and Recommendation" and does not require further review by the center, submit the S&R and supporting documents to DE as described in "Direct Reference Prosecutions" below.

# 2. Direct Reference Prosecutions

The S&R prepared as described in "Preparation of Summary and Recommendation" should be uploaded into CMS. The district should transfer the case to DE by changing the current owner to DE pursuant to CMS procedures. CMS will automatically send an e-mail to the person in DE designated to receive notification when ownership of a case has changed to that office. The S&R should contain the supporting documents listed above.

#### 6-6 CIVIL PENALTIES – ELECTRONIC PRODUCT RADIATION CONTROL

#### 6-6-1 Purpose

This section provides procedures and instructions for recommendations of civil penalties for violations of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) of Chapter V of the Federal Food, Drug, and Cosmetic Act (Act).

#### 1. General Statement

Please be alerted to the fact that the provisions for penalties for electronic products under Section 539 of the Act are such that they can not be correlated with penalties for devices under Section 303 of the Act. (See the Penalties Section.)

Any references simply to *manufacturer* that appear in this chapter include the words *assembler* and *importer*, since those words are included by definition in Section 531(3) [21 U.S.C. 360hh(3)] of the Act in the word *manufacturer*.

Any references to products in this chapter refer to an electronic product as that term is defined in Section 531(2) [21 U.S.C. 360hh(2)] of the Act.

# 6-6-2 Scope

These procedures are provided primarily for guidance in recommending a civil penalty action; however, instructions for incorporating injunction recommendations in the civil penalty recommendations are included. (See the Injunctions section.)

Injunction considerations are included because there is precedent where the recommended, approved, and executed action was a joint civil penalty and injunction action. (See Exhibit 6-31)

Documents attached as exhibits represent only some of the regulatory considerations under the Act. These procedures are designed to provide guidance in recommending an action involving any violation committed under the Act.

# 6-6-3 Legal Authority

Civil penalties are provided for in Section 539 [21 U.S.C. 360pp] of the Act. Action under this section may be brought in any district court of the United States in which any act or omission or transaction constituting the violation occurred, or in any such court where the defendant is found or transacts business. Process in such cases may be served in any district of which the defendant is an inhabitant, or wherever the defendant may be found.

#### 6-6-4 Criteria For Recommending Civil Penalties

The basic criteria for recommending a civil penalty are as follows:

# 1. A Violation Of The Act Has Been Established And Documented.

NOTE: It is not necessary to show a health hazard to initiate action; such hazards were recognized and implied in the enactment of the Act by Congress.

- a. Section 538(A)(1) [21 U.S.C. 360oo(A)(1)] Introduction Or Delivery For Introduction Into Commerce Or Importation Into The United States Of A Non-Compliant Product
  - i. This prohibited act only applies to a manufacturer, excluding diagnostic x-ray assemblers, of an electronic product.
  - i. A non-compliant product must have been delivered for introduction or introduced into interstate commerce.
  - ii. Penalty for committing a violation under this section does not require the manufacturer's prior knowledge of the noncompliant state of the product.

- Nevertheless, a penalties action is not usually initiated unless a violation has continued after notice/warning to the defendant.
- iii. An exception may be made in the case of manufacturers, where violations are a significant radiation hazard. (If the defendant(s) continue the violative practice(s) after notice/warning has been given, the instances of similar violation occurring prior to the notice/warning then become subject to inclusion as "counts" in the civil penalty action.)
- iv. Each violation is based on evidence that the product did not comply with an applicable standard when introduced or delivered for introduction into commerce by the manufacturer. Defects, as defined by 21 CFR 1003.2, are not subject to this charge, unless they constitute non-compliance with a standard
- b. Section 538(a)(2) [21 U.S.C. 360oo(a)(2)] Failure To Give Notification Or Take Corrective Action
  - i. The product must be shown to be noncompliant or defective as a result of its design, production or assembly by the alleged violative manufacturer. Significant radiation hazards may be considered for civil penalties without prior notice/warning. In all other circumstances, the manufacturer must have been given a reasonable period of time within which to refute any allegations that the product is noncompliant or defective.
  - ii. The agency should be in a position to demonstrate that the manufacturer was aware of the noncompliant or defective product either through the Food and Drug Administration's (FDA's) notification or otherwise if that question is raised.
  - iii. The manufacturer should be given a reasonable period of time within which to demonstrate that the noncompliant or defective product does not present a significant risk of injury to any person and apply for an exemption from notification and repair under 21 CFR 1003.30 and Section 535(a)(2) of the Act. An exception may be made in the case of manufacturers, where violations are a significant radiation hazard. In these cases civil penalty without prior notice/warning will be considered.
  - iv. The agency must be able to demonstrate that at least one of the following violations has been committed:
    - The manufacturer has not notified the agency of a defect or noncompliance
    - The manufacturer has not notified the known purchasers of the defect or noncompliance.
    - The failure of the manufacturer to repair, replace or refund the cost of noncompliant or defective products. This may involve either failure to

- submit a corrective action plan or failure to implement a plan approved by the agency.
- Charging of purchasers by the manufacturer for the repair, replacement or refund of a noncompliant or defective product, including charges for any portion of an approved corrective action plan.
- This section applies to dealers and distributors of electronic products for which there is an applicable performance standard in that it is a prohibited act for these individuals to fail to furnish the manufacturer with such information as may be necessary to identify and locate for purposes of Section 535, the first purchasers of noncompliant products.
- c. Section 538(a)(3) [21 U.S.C. 360oo(a)(3)] Failure To Maintain Records Or Permit Inspection
  - i. The manufacturer must maintain records of the locations of the first purchasers if the product is subject to the distribution recordkeeping requirement as specified in Table 1 of 21 CFR 1002.1. The manufacturer must also maintain records of the locations of any subsequent purchasers which have been provided to the manufacturer by dealers and distributors. However, the manufacturer is not responsible for the location of records of subsequent purchasers which are not provided to it by dealers and distributors. The agency may require the manufacturer to request dealers and distributors to provide this information to it in a corrective action plan in accordance with 21 CFR 1002.41(a)(1) and Section 537(f) of the Act.
  - ii. The manufacturer is required to maintain records which demonstrate the adequacy of its manufacturing practices to ensure the agency that its safeguards against hazardous radiation are adequate and that its products comply with an applicable performance standard.
  - iii. Dealers and distributors of electronic products subject to the distribution recordkeeping requirement as specified in Table 1 of 21 CFR 1002.1 must maintain records which identify the product and the location of all first purchasers and make these records available for inspection or copying by the agency. Failure to fulfill either of these two requirements would be considered a violation under this section. Dealers or distributors are not, however, required to obtain or maintain this information for subsequent purchasers.
  - iv. The manufacturer and dealer or distributors, after having been given reasonable notice, are required to make all required records available for inspection by the agency. The agency is not required to show cause for this request and failure to comply by the responsible person or company is a violation under this section.

- v. The agency can require a manufacturer to permit the inspection of its facilities as well as its required records if good cause is established. Grounds for establishing good cause include:
  - introduction of noncompliant or defective electronic products into commerce by the manufacturer;
  - disapproval of the manufacturer's testing program of products for which there is an applicable standard; or,
  - nonsubmission of assurance by the manufacturer in the form of a report of the adequacy of the product safeguards against hazardous electronic product radiation. Failure to permit inspection when good cause is shown is a violation under this section.

Dealers and distributors, other than those who are also considered to be manufacturers, are only required to permit inspection of records described in paragraph iii above.

- d. Section 538(a)(4) [21 U.S.C. 360oo(a)(4)] Reporting
  - i. It is a prohibited act for applicable manufacturers to fail to provide the agency with product, supplemental, abbreviated, and annual reports in accordance with 21CFR 1002.10, 1002.11, 1002.12, and 1002.13. Normally regulatory action should be pursued where the products have an applicable performance standard or, in the case of flagrant violations, where no standard has been issued for the product.
  - ii. It is a prohibited act for a manufacturer to fail to provide a report in conformance with guides or instructions which have been prescribed under 21 CFR 1002.7(b).
  - iii. It is a prohibited act for any manufacturer of electronic products to fail to report an accidental radiation occurrence with its product in accordance with 21 CFR 1002.20.
  - iv. It is a prohibited act for any assembler of diagnostic x-ray equipment to fail to provide the agency with a report of its assembly of an x-ray system or component in accordance with 21 CFR 1020.30(d) (1). This assembler's report is required in lieu of the reports cited in paragraph (b)(i) above.
  - v. It is a prohibited act for dealers or distributors of electronic products for which there is an applicable performance standard to fail to report the information required by 21 CFR 1002.40(b) to the manufacturer of the product in accordance with 21 CFR 1002.41(a)(1) when required for purposes of Section 535 of the Act and when it has been requested by either the manufacturer or the Director of the Center for Devices and Radiological Health (CDRH).

- vi. It is a prohibited act for a manufacturer or assembler to fail to report a defect or noncompliance in an electronic product, in accordance with 21 CFR 1003.20.
- vii. Section 538(a)(5) [21 U.S.C. 360oo(a)(5)] Product Certification i. It is a prohibited act under Section 538 (a)(5)(A) for a manufacturer to fail to certify that its product is in compliance with an applicable performance standard. The manufacturer must furnish the certification in the form of a label or tag, as prescribed by 21 CFR 1010.2.
- viii. It is a prohibited act under Section 538(a)(5)(B) for any manufacturer or importer to affix a certification label to a product which is not in compliance with an applicable performance standard or for which the testing program has been disapproved in accordance with Section 534(h) of the Act. The agency must be able to demonstrate that the manufacturer would have known, if it exercised due care, that such certification was materially false or misleading.

# 2. Prior notice/warning should have been given to the responsible individuals.

Prior notice may have been by Warning Letter, Notice of Noncompliance Letter, Program Disapproval Letter, or by any other method in accordance with <a href="Chapter 10">Chapter 10</a> of the RPM.

#### 6-6-5 Penalties

The Act provides that any person who violates any of the prohibited acts shall be subject to a civil penalty of not more than \$1000 for each count, with a maximum of \$300,000 for any person for any related series of violations. Where individual responsibility cannot be proven, civil penalty may be recommended for the firm only.

Counts - A count is based upon a violation with respect to each electronic product involved, or with respect to each act or omission made unlawful by Section 538. This means that the count is not determined by the product alone, but by the number of acts committed in conjunction with each product.

#### **EXAMPLE**:

An employee of XYZ Company installs certified components into a diagnostic x-ray system and fails to file a Report of Assembly (Form FDA 2579) in accordance with the implementing regulations (21 CFR 1020.30(d)). The prohibited act is Section 538(a)(4) of the Act for failure to make or provide a report required pursuant to Section 537(b). The required distribution of these reports is to (1) FDA, (2) the state agency for the installation site, (3) the owner/user of the system, and (4) either the component manufacturer or XYZ Company. The distribution of the forms is required within 15 days from the date of assembly. The responsibility of completing the forms falls on the individual (employee) who actually performs the installation and the supervisor or company president who is responsible for compliance with the standard. In addition the firm also has an obligation and responsibility in the filing and maintenance of required documents.

Consequently, the following counts in this specific case could be charged:

Firm Violation of Section 538(a)(4) - 1 count

Employee A Violation of Section 538(a)(4) - 1 count

Manager/President Violation of Section 538(a)(4) - 1 count

Total = 3 counts

This specific example provides for a maximum civil penalty of \$3000 for each occurrence of a failure to file the required report. The key to determining the number of counts is the "act or omission made unlawful by Section 538," (i.e. 3 violation instances (counts) are associated with the 1 product involved in the example cited above. Each additional product involved with the same violation would yield 3 additional counts for each occurrence.)

The assembler firm could also be charged under the same section of the Act (Section 538(a)(4)) when the reports continue to be filed in excess of the 15 day time frame. Reports that are more than 30 days late inhibit FDA's ability to test newly installed systems for compliant assembly by the firm. The firm may be attempting to inhibit compliance testing of their systems. However, for each violative product, the charge must be either failure to file or filing the report late. The same installation cannot receive charges under both categories.

# 6-6-6 District Responsibilities

- 1. The district is responsible for deciding if the circumstances warrant recommendation of a civil penalty. Every effort should be made to determine that all necessary documentation has been obtained, all related samples are included, and the supporting Establishment Inspection Reports (EIRs) are complete.
- 2. The district should document as fully as possible who was responsible for the violations
- 3. The district is responsible for seeing that all violations are documented.
  - a. Documentation for each violative product should consist of the following:
    - i. Sample Collection Report
    - ii. Complete interstate documentation where Section 538(a)(1) of the Act is charged.
    - iii. Appropriate affidavits by dealers, purchasers, users, etc., where applicable
    - iv. Copies of appropriate records of proof of sale or installation of equipment, where applicable.
    - v. Copies of appropriate labeling.
    - vi. Clear and distinct photographs of labels, and the equipment, where applicable
    - vii. Copies of all documents that can be considered prior notice or warning

- b. The recommendation packet should consist of the following:
  - i. Memorandum of recommendation to CDRH explaining the details of the case. This memorandum should contain the reasons why you believe that civil penalty is the action of choice, and should address the size of the business and the gravity of the violation.
  - ii. A draft letter to the United States (U.S.) Attorney, which includes the background of the case, a statement of prior notice/warning, the reasons why we are pursuing this course of action, and the violations alleged.
  - iii. A Proposed Complaint for Civil Penalty. This complaint should specify the legal authority for the action recommended, each specific act committed, or, the manner in which the act was committed, when and by whom committed, and the section of the Act violated. The complaint must reflect the basis of each count for which we seek a civil penalty. Where possible, use a chart to reflect instances where more than one count is being charged under a specific prohibited act. The Complaint should also include the amount of civil penalty sought, and a brief description of how it was computed.
  - iv. Copies of appropriate sample records. v. Copies of EIRs reporting the violation.
  - v. If an injunction is being sought in the same complaint, an affidavit, as referenced in the RPM subchapter for Injunctions, should be prepared and submitted.
- 4. The district shall notify CDRH's Field Programs Branch (HFZ-306) that a recommendation is being submitted, and the recommendation shall be submitted by the most expeditious means. An electronic copy on a diskette should also be attached to the recommendation.
- 5. If the approved letter to the U.S. Attorney and the Complaint for Civil Penalty are returned to the district electronically for submission to the U.S. Attorney, it will be the responsibility of the district to see that they are delivered to the U.S. Attorney's office. (If the Complaint includes an injunction, the documents should be delivered to the U.S. Attorney's office by the most expeditious and practical means.)
- 6. The district shall be in direct contact with the U.S. Attorney's office with regard to timeliness of filing of the complaint, and scheduling of any hearings, etc.
- 7. In the event of any hearings in the action, the district shall be responsible for arranging for the presence of any necessary witnesses, funding, and assuring that all necessary documents are available.

#### 6-6-7 CDRH Responsibilities

1. CDRH is responsible for a timely review of the recommendation and for assuring that all the evidence and supporting documentation are adequate. If additional information is needed, the district will provide the information, or may, if necessary, make a personal visit to CDRH.

CDRH will forward a copy of the district's original recommendation to OEIO/DE, even though it may prepare an amended copy to include any deletions or additions of its own.

- 2. CDRH will prepare a memorandum to DE reflecting the issues considered by CDRH in reviewing the case and providing the scientific assurances which support the case. A copy of CDRH's concurrence memorandum should be sent to the recommending district, at the time that it is forwarded to DE. In case of disapproval, CDRH shall state clearly the reason for such disapproval and include any guidance necessary for the district to present an acceptable case. If follow-up for additional information is indicated, CDRH shall be specific as to what is needed, and so advise the district. If a case is disapproved, a copy of the disapproval memorandum shall be sent to DE.
- 3. CDRH will identify a qualified expert(s) for any court cases.
- 4. CDRH will provide an affidavit from the CDRH/OC Records Manager for any notification and reporting charges under Sections 538(a)(2) and (a)(4).

#### 6-6-8 DE Responsibilities

DE will be responsible for ensuring that the recommendation complies with agency policy. It will review the proposed letter to the U. S. Attorney and Complaint for Civil Penalty. If it finds that these documents, or any other required documents, are not satisfactory, it will be responsible for obtaining the necessary and proper document(s) and submitting them to the Office of the Chief Counsel (OCC).

DE will be responsible for determining that the necessary distribution is made of the final documents, as approved by OCC to the appropriate offices. Approved actions for submission to the U. S. Attorney shall be forwarded to the district by electronic transmission.

# 6-6-9 OCC Responsibilities

OCC will provide the final legal review of all the documents in the case, and will determine the legal sufficiency of the evidence. It will be responsible for any further changes in the Complaint, and/or letter to the U. S. Attorney, if any. Significant changes will be made in consultation with DE, CDRH and the district, as appropriate. OCC shall designate an attorney to be responsible for the case. This attorney will provide legal assistance to the U. S. Attorney's office and the district in the disposition of the case.

#### 6-6-10 Appeals

Appeals of any disapprovals will be handled as prescribed by the Appeal Process in Chapter 10 of the RPM.

# 6-6-11 Consent Decree Of Civil Penalty

The defendant may seek to negotiate a penalty below the maximum for each count. Such negotiated settlement should be in the form of a Consent Decree of Civil Penalty. All proposed settlements will be presented to OCC. All negotiations with the defendant's lawyers will be

conducted by the lawyer representing the agency, in consultation with DE, the district, and CDRH

#### 6-6-12 Case Termination

Upon notification by the Clerk of the Court that the penalty has been assessed by the Court and the defendants have paid the penalty, the case may be closed.

# 6-6-13 Injunction and Civil Penalties

Injunctions under this Act are provided for by Section 539(a).

An injunction recommendation should be included with the civil penalty recommendation if the circumstances warrant it. Criteria to be considered for injunctive relief include, but are not limited to, the following:

- 1. The manufacturer has repeatedly committed the same violation, or same type of violation.
- 2. The violative product could cause significant risk of injury to any person.
- 3. The manufacturer is continuing to commit the same violations (e.g., introduction of noncompliant products into commerce) after being advised of the agency's finding and request to cease and desist.
- 4. The violator refuses to correct previously cited defective or noncompliant products.

Injunction may be recommended to prohibit certain actions such as the introduction of violative products into commerce, or to require the violator to stop violating the Act by taking positive action to correct the existing violations (e.g. correction of noncompliant or defective products, notification of purchasers, submission of reports and information, providing access for inspection, certification of products, etc.).

A recommendation memorandum to CDRH will contain the same information as the recommendation for a civil penalty, but will include a statement recommending an injunction, and giving the reasons for the recommendation.

The letter to the U. S. Attorney and the Complaint will contain the same background information, but will include the additional request for an injunction. The subject of the recommendation will address itself to both the civil penalty and the injunction; and the Complaint will be entitled "Complaint for Injunction and Civil Penalty."

Whenever the civil penalty recommendation includes an injunction request, the recommendation will contain the information requested by this chapter, but will be processed according to the RPM subchapter on "Injunctions." The counts involved in the action will be the same as described in this chapter.

#### **EXHIBITS**

These exhibits include a number of models and examples. They should be used only as guides and, with the possible exception of legal citations, should not automatically be used verbatim in any case. Examples from recent cases may be found on ORA's intranet site. The district compliance officer may request examples of inspection warrants, and other examples not available on ORA's intranet site, from DE, telephone 301-796-8200.

## **EXHIBITS**

6-1A CMS INSTRUCTIONS (PDF - 129KB)

6-1B CASE INITIATION MEMORANDUM (PDF - 265KB)

6-2 SEIZURES - U.S MARSHAL LETTER (PDF - 124KB)

6-3 FORM OF DEFAULT DECREE OF CONDEMNATION (PDF - 130KB)

6-4 FORM OF CLAIM (PDF - 131KB)

6-5 FORM OF CONSENT DECREE OF CONDEMNATION (PDF - 140KB)

6-6 FORM OF BOND (PDF - 130KB)

6-7 NOTICE TO CLAIMANT (PDF - 125KB)

6-8 SECOND NOTICE (PDF - 124KB)

6-9 LETTER TO CANCEL BOND (PDF - 125KB)

6-10 PROCEDURES & MODELS FOR ISSUING PRESS RELEASES (PDF - 149KB)

6-11 INJUNCTIONS (MULTI-DISTRICT) (PDF - 167KB)

6-12 MODEL LETTER ACKNOWLEDGING COMPLIANCE (PDF - 124KB)

6-13 DRUG/GMP/ADULTERATION/MISBRANDING CASE – INTRODUCTORY LANGUAGE FROM A COMPLAINT (PDF - 122KB)

6-14 FOOD ADULTERATION CASE – INTRODUCTORY LANGUAGE FROM A COMPLAINT (PDF - 123KB)

<u>6-15 DRUG GMP CASE – DESCRIPTION OF CHARGE FROM A COMPLAINT (PDF - 119KB)</u>

# 6-16 DIRTY WAREHOUSE CASE – DESCRIPTION OF CHARGES FROM A COMPLAINT (PDF - 120KB)

6-17 MISBRANDING (343(A) AND 352(A)) CASE - DESCRIPTION OF CHARGE FROM A COMPLAINT (PDF - 122KB)

6-18 EXAMPLES OF CONSENT DECREE PROVISIONS (PDF - 340KB)

6-19 EXAMPLES OF COMPLAINT PROVISIONS (PDF - 169KB)

6-20 AFFIDAVIT/DECLARATION (PDF - 144KB)

6-21 MODEL LETTER BILLING CHARGES (PDF - 122KB)

6-22 PETITION FOR ORDER TO SHOW CAUSE (PDF - 178KB)

6-23 ORDER TO SHOW CAUSE (PDF - 131KB)

<u>6-24 FORMAT FOR PROSECUTION SUMMARY AND RECOMMENDATION (PDF - 141KB)</u>

6-25 MODEL PROSECUTION SUMMARY AND RECOMMENDATION MEMORANDUM (PDF - 178KB)

6-26 MODEL LETTER REQUEST FOR ARTICLES OF INCORPORATION (PDF - 122KB)

6-27 RULE 44 - PROOF OF OFFICIAL RECORD (PDF - 133KB)

6-28 RULE 6. THE GRAND JURY (PDF - 180KB)

6-29 EXAMPLE OF LETTER TO THE DEPARTMENT OF JUSTICE, RE: INJUNCTION AND CIVIL PENALTY (PDF - 184KB)

6-30 EXAMPLE OF COMPLAINT FOR INJUNCTION AND CIVIL PENALTY (PDF - 727KB)