

## 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 Division of Case Management Operations (DCMO), 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 DCMO.

#### **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 DCMO. 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 PA call.

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

- 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 preliminary assessment (PA) call between the district(s) that would be involved in the proposed seizure or injunction, the relevant Center(s), OE, 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 MARCS-CMS (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), OE, 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), OE, 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 Chapter 10-8, 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), OE, 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 district initiating the action should draft a CIM that includes the views of the preliminary assessment call participants. The district 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, DCMO and OCC. The Center, DCMO, 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, DCMO will prepare the final letter and legal pleadings and upload them for OCC review. Upon OCC clearance, DCMO 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. DCMO 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, DCMO, 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 DCMO 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, DCMO, 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 OE 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. *OE, Division of Compliance Management and Operations (DCMO) 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 DCMO created. For seizure actions, DCMO 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, DCMO 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. DCMO 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. DCMO will upload a PDF version of the signed USA letter and the complaint in CMS. The e-mail will acknowledge that DCMO 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 DCMO. 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 DCMO.

#### **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 DCMO) 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, DCMO, and OCC agree that the evidence must be updated for an action to be brought, DCMO should update the inspection assignment and upload the assignment in CMS. DCMO 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 DCMO, 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 DCMO.

#### 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 DCMO.

## ***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 DCMO 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.
  - i. 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 7155a.03 and 7155a.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 OE), 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