

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 RPM 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 ORA management will name a lead coordinator from the affected ORA program or division unit. ORA management will include involved program directors (PDs) or district directors (DDs) or both.

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 is the Home District.

In this chapter, PD/DD means the appropriate director-level official(s) or designee. The PD/DD must consider several factors.

1. Prior Warning

See procedures under RPM [Chapter 10 - Other Procedures](#), 10-2 "Prior Notice," and RPM [Chapter 4 - Advisory Actions](#), 4-1 "Warning Letters" and specific compliance program and policy guides.

2. 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 Chapter 5](#) sections "Administrative Detention of Food" at 5-3 and "Administrative Detention of Devices" at 5-5 contain the specifics of the administrative detention procedures.

3. 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.

4. 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.

5. 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.

6. 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, listed on the FDA Intranet page for “Safety Councils & Committees/EHS Network.”

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.

7. Continuing Violations

When considering a seizure case for which there is evidence (or the likelihood) of repeated or continuing violations, ORA 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.

8. *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.

9. *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.

10. *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 district to another district 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 (DoJ) 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 ORA (PDs and DDs as appropriate) 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, ORA (PDs and DDs as appropriate) 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. ORA 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 ORA (PDs and DDs as appropriate) 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 PD and DD as appropriate, the relevant Center(s), OEIO, OCC Enforcement Advisors and other principals as appropriate. The lead coordinator 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 Senior Enforcement Advisor .

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 ORA attendees (the compliance officer and the investigators would be expected to participate)
3. List of attendees from the Center(s), OEIO, OCC Enforcement Advisors , 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 [Chapter 10 - Other Procedures](#), Section 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 lead coordinator, 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 PD and DD as appropriate, the Center(s), OEIO, and OCC should each assign a contact and a single lead coordinator, who will retain those roles of throughout the case wherever possible. The lead coordinator need not have been a call participant. For OCC, the lead coordinators will be the Designated Enforcement Advisor . 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 lead coordinator 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 6-1 for the 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 [Chapter 10 - Other Procedures](#) section 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 office and the office will submit these documents along with an evidentiary package to the US Attorney's Office/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 lead coordinator in CMS.

For seizure actions, the seizing office 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 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 lead coordinator 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. CIM Submission:

The lead coordinator 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. CIM review:

The concurrent review and submission of the case and all material or significant evidence including the expert opinion to DoJ 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. Division and Program Responsibilities:

Prior to creating a PA work activity in CMS, the compliance officer should consult with the director of the compliance branch (DCB) and other ORA management (PDs and DDs as appropriate) to obtain support for the proposed action. The DCB 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 lead coordinator 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 also [subsection 6-1-5](#) and [Exhibit 6-1](#).

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 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. The seizing office 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 lead coordinator 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.

- c. When it receives notice that a seizure will be executed, the seizing office is responsible for promptly notifying the appropriate Centers, DE, OCC and any other offices or other tribal, state, local and territorial officials that may be involved in the case. The seizing office is also responsible for adding an activity note in CMS and updating the date fields. ORA (PDs and DDs as appropriate), 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.
- d. The seizing office is responsible for ensuring appropriate follow-up on seizure actions until the action is adjudicated, and for promptly notifying ORA offices (PDs and DDs as appropriate, the home district, DE), the appropriate Center, and OCC of the current status of the case. The seizing office should log its activities using the activity notes.
- e. The seizing office 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 ORA 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 ORA (PDs and DDs as appropriate), 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 RPM [Chapter 10](#) subsection 10-10 “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 Media 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 ORA 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 ORA offices 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 program, division, district, 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, ORA staff 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 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 ORA or the 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 lead coordinator'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 office'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, the program, 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 that forfeiture actions should be commenced as soon as possible, particularly where continued distribution of the article may threaten the health of the public.

The 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 ORA. The lead coordinator should forward a copy of the filed complaint to DE.

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

After filing the Complaint for Forfeiture, the lead coordinator may make arrangements with the U.S. Marshal to effect seizure when, in the judgment of ORA, such arrangements are needed to ensure that the seizure is carried out satisfactorily. ORA 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 office will promptly notify the OCC attorney, the center, the lead coordinator, the home district, and DE of the amount and value of each lot seized, and the Marshal's return date. The division 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 Overview*

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 office 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 more specifically below.

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, listed on the FDA Intranet page for "Safety Councils & Committees/EHS Network," 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 "Compliance Officer and OCC Attorney Responsibilities in Default and Consent Decrees" in 6-1-9 item 10 below. 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 "Compliance Officer and OCC Attorney Responsibilities in Default and Consent Decrees" in 6-1-9 item 10 below.

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 ORA, 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 office will make the necessary arrangements for supervision with the claimant to ensure compliance with the decree. Before the reconditioning operation is begun, the lead coordinator 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 ORA 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 ORA 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 ORA'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 office 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 office will forward to the lead coordinator 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 ORA 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 office.

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 office 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 ORA, 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 ORA and OCC. U.S. Attorneys' offices should be made aware that they can call upon the assistance of officers in ORA Divisions and Programs and OCC attorneys at headquarters; both ORA 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 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 ORA 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 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, ORA, 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 office 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 ORA 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 on the FDA Collaboration [webpage](#).

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 [225-75-7001](#), [225-86-2000](#), and [225-09-0008](#).

2. U.S. Department Of Agriculture

After clearance as under NMFS, include a similar statement in the seizure recommendation. See Memorandum of Understanding [225-80-2000](#) and [225-12-0007](#).

3. Federal Trade Commission

See Memorandum of Understanding [225-71-8003](#).

4. Environmental Protection Agency

See Memorandum of Understanding [225-73-8010](#).

5. Department Of Labor

See Memorandum of Understanding [225-74-6008](#)

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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 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 Media 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 ORA units involved in the development, preparation, processing, and follow-up of injunctions.

6-2-2 General Guidelines for Injunctions

Before initiating an injunction case, the compliance officer and ORA management will name a lead coordinator from the affected ORA program or division unit. ORA management will include involved PDs, DDs) or both.

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 is the Home District.

PD/DD means the appropriate director-level official(s) or designee. The PD/DD must consider several factors.

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 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 compliance officer maintains 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 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. Injunctions in Multiple Jurisdictions

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

The Centers, ORA offices, programs, and divisions, 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-jurisdictional injunctions are described in the procedures titled “Injunctions (Multi-jurisdiction).” 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-jurisdiction injunction is identified by ORA or the Center. At its discretion, the recommending ORA office may invoke these procedures for a single federal 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 RPM [Chapter 10 - Other Procedures](#), 10-2 "Prior Notice" and 10-3 "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 through 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 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 an affidavit from the program or division director's (PD/DD) 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 ORA or by 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, ORA 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 ORA'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 [subsection 6-1-5](#) for the steps to be included for Injunction cases.

6-2-9 Responsibilities for Injunction Actions

1. Program and District Responsibilities:

Prior to creating a PA work activity in CMS, the compliance officer should consult with the DCB and other ORA management to obtain support for the proposed action. The compliance officer 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 subsection [6-1-5](#) 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.

ORA, 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 lead coordinator 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 6-1](#).

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 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 and 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 ORA 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 ORA 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 RPM [Chapter 10](#) section 10-10 “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 ORA’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-jurisdictional 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 ORA office where action will be taken, with a copy to the designated OCC contact persons, DoJ/OCL, and FDA's Office of Media Affairs. DE should note in CMS the date that the complaint, transmittal letter and ancillary documents were submitted to the office. The Lead coordinator 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 compliance staff.

6-2-10 Cover Letter to DoJ

The cover letter transmitting the case to DoJ/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 TRO. 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 ORA office 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 PD, DD, or their 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 PD/DD's declaration are derived from a review of documents contained in the ORA files and the declaration should so state. A PD/DD 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 PD/DD 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 CIM titled “Violations,” and additional information provided by the Center.

ORA 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 approval from ORA (the PD or DD as appropriate) on matters requiring ORA 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 (PD/DD, 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 ORA (the PD and DD as appropriate) 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. ORA 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 ORA 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 ORA's follow-up discloses that the firm has met the provisions of the decree and notice has issued, the lead coordinator 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 compliance office will prepare a recommendation. For criminal contempt, see the RPM subsection 6-5-8 "Contempt of Court; Violation of Probation". For prosecution see subsection [6-5-6 "Criminal Prosecution After 305 Notice."](#) Should contempt be the action of choice, the lead coordinator 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 ORA office should be notified of the status of the firm. Notify any such office 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 ORA office(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. ORA and the 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 PD/DD'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 program/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 DoJ 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 compliance officer or OEIO), and the Center's compliance office. The decision to issue a press release is made by FDA's Office of Media 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 [subsection 6-1-13 "Issuing Press Releases."](#) 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.

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

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. Division/District

a. Preliminary Steps

When the criteria for requesting an inspection warrant are not clear, the lead coordinator 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.

When the PD/DD decides to recommend an inspection warrant, the lead coordinator 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 PD/DD 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 PD/DD 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, that the location is a personal residence or ORA 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, 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 lead coordinator 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 lead coordinator should identify all adulteration and/or misbranding charges cited in the subject action under the Act/CFR tab in CMS.

The lead coordinator 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 ORA staff, DE should be notified immediately. The recommending PD/DD 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 OCC) 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 ORA office, 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 program or district, as appropriate. CMS will automatically send an e-mail to the person in the office designated to receive notification when ownership of a case has changed to that office. The office 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, 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 FDA [Office of External Affairs](#) of the strategy and impending action immediately after forwarding a warrant application package to the office 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*

OCC 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 RPM [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. Attorney's Manual](#). 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. ORA management must communicate with its local OCI office, as instructed in [subsection 6-5-10 “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 operational procedures 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 ORA, the Center, or another FDA Headquarters component, must be sent to OCI for initial review in accordance with this section. If OCI declines the referral, the Center or ORA may pursue the matter through the preparation of a Summary and Recommendation in accordance with [subsection 6-5-5 et seq.](#)

6-5-2 Referral of Criminal Matters to 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.

ORA 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 OCC and DoJ 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 [SMG 9111](#), ORA management should notify the local Special Agent in Charge (SAIC), Assistant Special Agent in Charge (ASAIC), or Resident Agent in Charge (RAIC) 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 subsections [6-5-5](#) and [6-5-13](#) 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 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 DoJ. 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 to explain the focus for the procedural steps to be addressed by FDA personnel, and 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 ORA is considering initiating a referral for a *Park* Doctrine prosecution, the lead coordinator 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 ORA offices are also encouraged to consult with OCC and OCI HQ SAIC and/or the ASAIC Investigative Operations Division (IOD) early in the process for guidance and recommendations regarding optimal venue.

If ORA or the 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 ORA refers a *Park* Doctrine prosecution to the appropriate OCI 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 office or the center, should also be sent to the Deputy Chief Counsel and Associate Deputy Chief Counsel for Litigation in OCC, and to 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:

1. [SMG 9111 Sharing of Information Related to Criminal Violations](#). 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 office of its initial assessment. It also addresses information sharing between OCI and other FDA components.
2. [SMG 9110 Enhanced Communications with the Office of Criminal Investigations \(OCI\) and Improved Alignment of Criminal/Regulatory Priorities and Activities](#). 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 Act, or joint investigations with OCI and other law enforcement agencies about violations of the 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 office'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 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 lead coordinator submitted the original referral or where the referral relates to an inspectional process, each recommendation must be accompanied by the written concurrence of the DD and the Director of DE. The DD's approval must state why prosecution is the action of choice, and DE 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 [subsection 6-5-13](#) 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 Act, should follow the procedures described below:

1. When ORA does not have direct reference authority to issue a Section 305 notice, ORA will submit a citation recommendation to the appropriate center(s) for review, after contacting OCI (as described in "Referral of Criminal Matters to the Office of Criminal

Investigations” in [subsection 6-5-2](#) 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 ORA or the center identifies an issue requiring consultation with OEIO/DE, OCI, 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 citation recommendation, the lead coordinator will notify the center, which will promptly forward the citation recommendation package to OEIO/DE. Concurrently, a final S&R will be sent by the lead coordinator to DE with copies to the center.

If there is a significant change in the facts or strength of the proposed case, the lead coordinator 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 ORA 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 “Referral of Criminal Matters to the 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 lead coordinator should promptly submit its prosecution S&R directly to DE for a limited review. The lead coordinator 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 PD/DD 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 "Referral of Criminal Matters to the Office of Criminal Investigations" above.

1. The PD/DD 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 director. The lead coordinator 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 lead coordinator 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 lead coordinator who will then follow the procedure under RPM [subsection 6-5-6, "Criminal 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 lead coordinator 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 lead coordinator 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 subsection 6-5-12, "Grand Jury Investigations and Secrecy".

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 program/division offices.

6-5-10 Referrals for Criminal Investigation

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

1. The initiating unit, division 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 unit 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 lead coordinator 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 ORA'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, ORA will work directly with the lead agency in developing evidence and in assisting in the investigation. In such cases, the lead coordinator will promptly notify the relevant centers, ORA program and district, DE, OCI, and OCC of the investigation, the roles of the units in the investigation, and whether a grand jury investigation is contemplated.

As soon as the lead coordinator 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 ORA 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 subsection [6-5-6 "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 RPM [Chapter 10 - Other Procedures](#) 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, program, 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 [Chapter 10 - Other Procedures](#), subsection 10-2 Prior Notice.

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

If ORA 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 proffered 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 PD/DD 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 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:

Section 402(a)(3) Verification

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 in subsections 6-5-6 "[Criminal Prosecution after Section 305 Notice](#)," 6-5-7 "[Criminal Prosecution Without Section 305 Notice](#)", or 6-5-2 "[Referrals of Criminal Matters to OCI 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 lead coordinator 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 subsection [6-5-13 "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 subsection [6-5-13 "Processing a Summary and Recommendation"](#) should be uploaded into CMS. The lead coordinator 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 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 Section [6-6 Civil Penalties – Electronic Product Radiation Control](#).

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 [Section 6-2](#).

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.
 - ii. A non-compliant product must have been delivered for introduction or introduced into interstate commerce.
 - iii. 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.
 - iv. 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.
 - v. 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 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. It is a prohibited act under Section 538 (a)(5)(A) [21 U.S.C. 360oo(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 [Chapter 10 - Other Procedures](#).

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 Director Responsibilities

1. *The PD or DD, as appropriate for the action, 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 lead coordinator should document as fully as possible who was responsible for the violations*

3. *The lead coordinator 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.
 - vi. 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 lead coordinator 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 ORA electronically for submission to the U.S. Attorney, it will be the responsibility of the lead coordinator 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 lead coordinator 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 lead coordinator 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 lead coordinator will provide the information, or may, if necessary, make a personal visit to CDRH.

CDRH will forward a copy of the lead coordinator'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 ORA unit, 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 ORA 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 ORA. 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 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 ORA lead coordinator 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 lead coordinator, 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 PD/DD 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 PD/DD, 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 compliance officer may request examples of inspection warrants, and other examples not available on ORA's intranet site, from DE, telephone 301-796-8200.

EXHIBIT 6-1

6-1A CMS INSTRUCTIONS (removed)

6-1B CASE INITIATION MEMORANDUM

6-2 SEIZURES - U.S MARSHAL LETTER

6-3 FORM OF DEFAULT DECREE OF CONDEMNATION

6-4 FORM OF CLAIM

6-5 FORM OF CONSENT DECREE OF CONDEMNATION

6-6 FORM OF BOND

6-7 NOTICE TO CLAIMANT

6-8 SECOND NOTICE

6-9 LETTER TO CANCEL BOND

6-10 PROCEDURES & MODELS FOR ISSUING PRESS RELEASES

6-11 INJUNCTIONS (MULTI-JURISDICTION)

6-12 MODEL LETTER ACKNOWLEDGING COMPLIANCE

6-13 DRUG/GMP/ADULTERATION/MISBRANDING CASE – INTRODUCTORY LANGUAGE FROM A COMPLAINT

6-14 FOOD ADULTERATION CASE – INTRODUCTORY LANGUAGE FROM A COMPLAINT

6-15 DRUG GMP CASE – DESCRIPTION OF CHARGE FROM A COMPLAINT

6-16 DIRTY WAREHOUSE CASE – DESCRIPTION OF CHARGES FROM A COMPLAINT

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

6-18 EXAMPLES OF CONSENT DECREE PROVISION

6-19 EXAMPLES OF COMPLAINT PROVISION

6-20 AFFIDAVIT/DECLARATION

6-21 MODEL LETTER BILLING CHARGES

6-22 PETITION FOR ORDER TO SHOW CAUSE

6-23 ORDER TO SHOW CAUSE

6-24 FORMAT FOR PROSECUTION SUMMARY AND RECOMMENDATION

6-25 MODEL PROSECUTION SUMMARY AND RECOMMENDATION MEMORANDUM

6-26 MODEL LETTER REQUEST FOR ARTICLES OF INCORPORATION

6-27 RULE 44 - PROOF OF OFFICIAL RECORD

6-28 RULE 6. THE GRAND JURY

6-29 EXAMPLE OF LETTER TO THE DEPARTMENT OF JUSTICE, RE: INJUNCTION AND CIVIL PENALTY

6-30 EXAMPLE OF COMPLAINT FOR INJUNCTION AND CIVIL PENALTY

Exhibit 6-1

6-1-A CMS INSTRUCTIONS: See the CMS User Guide on the FDA Intranet.

Exhibit 6-1**CASE INITIATION MEMORANDUM OUTLINE**

POINTS OF CONTACT List of Primary Center, District, Program, and OEIO-DE contacts with phone numbers (on the top of the very first page). Identify any OCC attorneys who have been consulted on the case.

****NOTE THAT THE FORMAT MUST BE AS A NOTE/REFERRAL TO OCC TO ASSERT THE APPROPRIATE PRIVILEGES TO PROTECT IT FROM DISCOVERY**

(Attachment A “LEAD “ASSIGNMENT to CIM ELEMENTS)

- **BRIEF EXECUTIVE SUMMARY (DESCRIPTION OF EVIDENCE):** limit to 3 or 4 sentences to identify type of product, conduct and nature of the case. Just need the big picture, for example: “This is a proposed permanent injunction against a cheese manufacturer whose products have been found to be contaminated with listeria in the past and who has a lengthy history of egregious sanitation and cGMP deficiencies” OR “This is a proposed mass seizure of food products stored in a facility infested by rodents.”
- **PRODUCT INFORMATION** (Obtain this information from the Center)
 - Examples: Approvals (IND, NDA, 510(k), PMA, IDE, Licensed, OTC Monograph), if relevant to charges
 - Product Classification or Type e.g., Rx, OTC, Device Class, if relevant
 - Product Labels and Labeling (hyperlink to Photos and Draft Complaint)
- **ORGANIZATIONAL CHART** (hyperlink to EIR and/or Org. Chart)
 - Include a BRIEF description of most responsible person(s)
 - Identify proposed defendants including a hyperlink to evidence used to support that this is most responsible person (hyperlink to affidavit and articles of incorporation)
 - Name of current counsel, if known
 - Corporate Relationships (subsidiaries/parent companies)

- **CURRENT INSPECTION**

- Rather than a “cut and paste” of the FDA 483 observations, list the most significant observations/ violations categorized by the type of violation (e.g., filth, cGMP, labeling violations etc.) with reference or hyperlink to details in the EIR AND to the RELEVANT exhibits (Please do not reference ALL EIR exhibits). <INSERT AUTHOR(s) NAME and DISTRICT/PROGRAM/CENTER/DIVISION.
- FURTHER GUIDANCE: FDA 483 observation would be explained within the context of the larger system to frame its significant impact on production, product safety and public health. Provide critical insight and context for the observations explaining its impact on the product or process. For example, rather than “we observed a hole in the roof of the facility,” explain “we observed water dripping onto the food being processed from a hole in the facility’s roof. When including hyperlinks to the evidence please identify the location of key information supporting the FDA 483 observation. For example, the hyperlink to a 42 page laboratory analysis worksheet would identify the page(s) where key evidence is located.
- All documented evidence should be in finalized form (including signatures, as appropriate) whenever possible.
- If the EIR has not been finalized provide a “separate” document that captures this information. <INSERT AUTHOR(s) NAME, DISTRICT/PROGRAM/CENTER/DIVISION>
- FDA 483 Observation Table (Tables of Evidence/Attachment B) if the firm has offered to correct the violations, explain the impact on the firm’s/product’s state of compliance, the risk to public health risk and the regulatory strategy. <INSERT AUTHOR(s) NAME and DISTRICT/PROGRAM/CENTER/DIVISION>
- Comparison of Firm’s Repeat Observations (Tables of Evidence/Attachment B). When possible, include a table with observations from past inspections to demonstrate recurring violations (rather than a narrative of each inspection). Insert hyperlinks in the table or “list of observations” in the report and the exhibits<INSERT AUTHOR(s)NAME and DISTRICT/PROGRAM/CENTER/DIVISION>

- **CENTER OFFICE OF COMPLIANCE CONCURRENCE AND EXPERT INFORMATION** <INSERT AUTHOR(s) NAME and CENTER/DIVISION>

- Charges that the Center preliminarily supports (to be later confirmed through technical/expert support memorandum) public health significance of violations<INSERT AUTHOR(s) NAME and CENTER/DIVISION>

- Weaknesses- please include Center’s weaknesses in the combined “ANTICIPATED DEFENSES” (Potential Weaknesses)* IN THE SECTION BELOW
- Preliminary Risk Assessment (Counter-arguments to Public Health significance) (to be confirmed through technical/expert support memorandum) <INSERT AUTHOR(s) NAME and CENTER/DIVISION
- The Center’s review of the Firm’s FDA 483 response. If incomplete, the status is indicated in Attachment B table, “Firm’s Stated or Observed Corrective Actions.”

 <INSERT AUTHOR(s) NAME and CENTER/DIVISION.
- List of most similar precedent cases (Seizure or Injunction or CMP)
- The Center’s technical /expert evaluations (e.g., GMP; new drug) (separate) is needed but if incomplete would not delay the issuance of the CIM <INSERT AUTHOR(s) NAME and CENTER/DIVISION
 - Table format (Attachment B) for e.g., GMP violations is VERY useful; effective and efficient way to compare current violations with those seen in the past, Focus on major violations, categories of violations, and link observations to particular locations and dates. If more than one, identify the expert (Attachment B) with the particular charges for which each will testify<INSERT AUTHOR(s) NAME and CENTER/DIVISION>
 - If in-house experts, provide a CV and direct phone number and a summary of the expert’s views, prioritizing the supportable violations in order of severity and explaining the significance of each violation
 - For outside experts, provide a CV, email address, and phone number, and confirmation that the expert has been retained and commitments as to date we can expect expert’s evaluation if not already completed.
 - Results of database search if charge involves filing or registering with FDA or obtaining approval from the agency or literature search (GRAS/E) when new drug charges are included <INSERT AUTHOR(s) NAME and CENTER/DIVISION>
 - HHE if applicable <INSERT AUTHOR(s) NAME and CENTER/DIVISION>
 - Review by drug shortage staff or evaluated as medically necessary (device) when appropriate (Center) <INSERT AUTHOR(s) NAME and CENTER/DIVISION>

- Judicial District
- Interstate commerce, hyperlink the key single documents (not an entire CR e.g., doc. Sample/product label) Specify whether the hyperlinked documents are for finished products or components (and if components, the names of the associated finished products); <INSERT AUTHOR(s) NAME and DISTRICT/PROGRAM/CENTER/DIVISION>
- Complaints-Summary of any consumer complaints and/or injuries or whistleblower reports<INSERT AUTHOR(s) NAME and DISTRICT/PROGRAM/CENTER/DIVISION>
- **REGULATORY HISTORY** (hyperlink to finalized documents, where possible and appropriate)
<INSERT AUTHOR(s) NAME and DISTRICT/PROGRAM/CENTER/DIVISION>
 - BRIEF SUMMARY of inspection history including inspection classification with emphasis on recurring violations (should be no more than one or two paragraphs) (Cross Reference TABLES OF EVIDENCE, Attachment B as needed)
 - Recalls (most recent first and should identify products)
 - Warning or Untitled Letters AND response(s) (Cross Reference TABLES OF EVIDENCE, Attachment B as needed)
 - Regulatory meeting minutes
 - Written responses from firm (to inspections, 483s, warning or untitled letters) (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed)
 - FDA evaluation of firm's responses (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed)
 - Other written correspondence from firm or its counsel re: the violations at issue. Please include a table (Cross Reference TABLES OF EVIDENCE/Attachment B as needed) identifying any correspondence received from the firm
 - Please include a table with the firms corrective actions (Cross Reference TABLES OF EVIDENCE/Attachment B) e.g., stated in the firm's 483 response or other correspondence or during the re-inspection) as well as FDA's evaluation of the correction (whether it was adequate <INSERT AUTHOR(s) NAME and CENTER/DIVISION>

- Relief requested (Use drafts from RPM as a starting point and filed cases as models) although we will rely on OCC to draft the consent decrees, there are certain substantive provisions which must be drafted by the centers and ORA districts or programs, as they describe the particular technical and scientific steps that must be taken to bring an operation into compliance. We are including samples in the RPM Chapter 6 of usual requirements for a variety of FDA's more typical types of cases. Please note that these are examples only, not boilerplate, and are intended to set out the level of detail that the centers and ORA will need to contribute to the scientific/technical aspects of the relief, in lieu of preparing a draft consent decree. The assigned center and ORA personnel must adapt these provisions to the particular circumstances of each case. In reviewing these samples, employees are not limited to linking the specific relief to a particular type of case. For example, in these examples, audit requirements are set out in the CGMP sections, but there may be situations in which a food sanitation case will need that type of relief. Similarly, the examples do not encompass every type of violation seen in FDA's cases, but they should provide sufficient guidance to assist in generating the operative portion of the decree in cases involving other types of violations <INSERT AUTHOR(s) NAME and DISTRICT/PROGRAM/CENTER/DIVISION>
 - Proposed charges and consent decree provisions (Reference the RPM) Look at all the CDs to pick and choose what will get them to the goal (take a look at the precedent cases)
- ANTICIPATED DEFENSES [DISTRICT/PROGRAM/CENTER/OCC]: Any potential weaknesses in case including defense's already known or advanced by the firm or its counsel. Both ORA and the Center need to provide input on potential weaknesses for the case including any weaknesses that were discussed during the Preliminary Assessment Call. <INSERT AUTHOR(s) NAME and DISTRICT/PROGRAM/CENTER/DIVISION>
- Other reports submitted (or confirmation that none were filed) such as Field Alert reports, adverse event reports, medical device reports, post marketing reports. <INSERT AUTHOR(s) NAME and DISTRICT/PROGRAM/CENTER/DIVISION>

Attachment A**LEAD ASSIGNMENTS to CIM ELEMENTS**

	<u>ELEMENT</u>	<u>LEAD</u>
1	POINTS OF CONTACT List of Primary Center, District, Program, and OEIO-DE contacts with phone numbers (on the top of the very first page). Identify any OCC attorneys who have been consulted on the case.	
2	BRIEF EXECUTIVE SUMMARY (DESCRIPTION OF EVIDENCE) (limit to 3 or 4 sentences) to identify type of product, conduct and nature of the case. Just need the big picture, for example: “This is a proposed permanent injunction against a cheese manufacturer whose products have been found to be contaminated with listeria in the past and who has a lengthy history of egregious sanitation and cGMP deficiencies” OR “This is a proposed mass seizure of food products stored in a facility infested by rodents .”	
3	PRODUCT INFORMATION (Obtain information from the center)	
	Examples: Approvals [IND, NDA, 510(k), PMA, IDE, Licensed, OTC Monograph], if relevant to charges	
	Product Classification or Type e.g., Rx, OTC, Device Class, if relevant	
	Product Labels and Labeling (hyperlink to Photos and Draft Complaint)	
4	ORGANIZATIONAL CHART (Hyperlink to EIR and/or Org. Chart)	
	Include a BRIEF description of most responsible person(s)	
	Identify proposed defendants including a hyperlink to evidence used to support that this is most responsible person (hyperlink to affidavit and articles of incorporation)	
	Name of current counsel, if known	
	Corporate Relationships (subsidiaries/parent companies)	

5	CURRENT INSPECTION	
	<p>Rather than a “cut and paste” of the FDA 483 observations, list the most significant observations/violations categorized by the type of violation (e.g., filth, cGMP, labeling violations etc.) with reference or hyperlink to details in the EIR AND to the RELEVANT exhibits (Please do not reference ALL EIR exhibits).</p> <p>FURTHER GUIDANCE: FDA 483 observation would be explained within the context of the larger system to frame its significant impact on production, product safety and public health. Provide critical insight and context for the observations explaining its impact on the product or process. For example, rather than “we observed a hole in the roof of the facility,” explain “we observed water dripping onto the food being processed from a hole in the facility’s roof. When including hyperlinks to the evidence please identify the location of key information supporting the FDA 483 observation. For example, the hyperlink to a 42 page laboratory analysis worksheet would identify the page(s) where key evidence is located</p>	
	<p>If the EIR has not been finalized provide a “separate” document that captures this information</p>	
	<p>FDA 483 Observation Table (Tables of Evidence/Attachment B) if the firm has offered to correct the violations, explain the impact on the firm’s/product’s state of compliance, the risk to public health risk and the regulatory strategy.</p>	
	<p>Comparison of Firm’s Repeat Observations (Tables of Evidence/Attachment B). When possible, include a table with observations from past inspections to demonstrate recurring violations (rather than a narrative of each inspection). Insert hyperlinks in the table or “list of observations” in the report and the exhibits</p>	

<p>6.</p>	<p>CENTER OFFICE OF COMPLIANCE CONCURRENCE AND EXPERT INFORMATION</p> <p>Charges that the Center preliminarily supports (to be later confirmed through technical/expert support memorandum) public health significance of violations</p> <p><u>Please include Center’s weaknesses in the combined “CENTER/DIVISION POTENTIAL WEAKNESSES”* section below</u></p> <p>Preliminary Risk Assessment (Counter-arguments to Public Health Significance) (to be confirmed through technical/expert support memorandum)</p> <p>The Center’s review of the Firm’s FDA 483 response. If incomplete, the status is indicated in Attachment B (table), “Firm’s Stated or Observed Corrective Actions.”</p> <p>List of most similar precedent cases (Seizure or Injunction or Civil Money Penalty)</p> <p>The Center’s technical /expert evaluations (e.g., GMP; new drug) (separate) is needed but if incomplete would not delay the issuance of the CIM Expert Evaluations (e.g., GMP; new drug, GRAS/E,) –vary with type of case. If more than one, identify the expert (Attachment B) with the particular charges for which each will testify.</p> <p>If in-house experts, provide a CV and direct phone number and a summary of the expert’s views, prioritizing the supportable violations in order of severity and explaining the significance of each violation</p> <p>For outside experts, provide a CV, email address, and phone number, and confirmation that the expert has been retained and commitments as to date we can expect expert’s evaluation if not already completed.</p> <p>Results of database search if charge involves filing or registering with FDA or obtaining approval from the agency or literature search (GRAS/E) when new drug charges are included</p> <p>HHE if applicable</p> <p>Review by drug shortage staff or evaluated as medically necessary (device) when appropriate (Center)</p>	
<p>7</p>	<p>JUDICIAL DISTRICT</p>	

8	INTERSTATE COMMERCE Hyperlink the key single documents (not an entire CR e.g., doc. Sample/product label) Specify whether the hyperlinked documents are for finished products or components (and if components, the names of the associated finished products)	
	Finished Product Interstate Documentation	
	Component Interstate Documentation	
9	SHORTAGE REVIEW by drug shortage staff or evaluated as medically necessary (device) when appropriate	
10	COMPLAINTS Summary of any consumer complaints and/or injuries or whistleblower reports	
11	REGULATORY HISTORY (hyperlink to finalized documents, where possible and appropriate)	
	Brief Summary of inspection history including inspection classification with emphasis on recurring violations (should be no more than one or two paragraphs) (Cross Reference TABLES OF EVIDENCE, Attachment B as needed)	
	Recalls (most recent first and should identify products)	
	Warning or Untitled Letters AND response(s) (Cross Reference TABLES OF EVIDENCE, Attachment B as needed)	
	Regulatory meeting minutes	
	Written responses from firm (to inspections, 483s, warning or untitled letters) (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed)	
	FDA evaluation of firm's responses (Cross Reference TABLES OF EVIDENCE/ Attachment B as needed)	
	Other written correspondence from firm or its counsel re: the violations at issue. Please include a table (Cross Reference TABLES OF EVIDENCE/Attachment B as needed) identifying any correspondence received from the firm	
	Please include a <u>table</u> with the firms corrective actions (Cross Reference TABLES OF EVIDENCE/Attachment B) e.g., stated in the firm's 483 response or other correspondence or during the re- inspection) as well as FDA's evaluation of the correction (whether it was adequate	

12	RELIEF REQUESTED (Use drafts from RPM as a starting point and filed cases as models) Specific relief the Center and ORA seeks; e.g., stop distribution, initiate a recall, hire consultant. repair facility	
	Proposed Consent Decree Charges AND consent decree provisions	
13	ANTICIPATED DEFENSES [ORA/CENTER/OCC] Any potential weaknesses in case including defense's already known or advanced by the firm or its counsel. Both ORA and the Center need to provide input on potential weaknesses for the case including any weaknesses that were discussed during the Preliminary Assessment Call.	
14	OTHER REPORTS SUBMITTED (or confirmation that none were filed) such as Field Alert reports, adverse event reports, medical device reports, post marketing reports.	

Attachment B**TABLES OF EVIDENCE**

FDA 483 Observation Table (Current Inspection) (Example)

483 Observation	Citation	Supporting Documents (Hyperlink)

Comparison of Firm's Repeat Observations (Regulatory History) (Example)

Observation	Inspection #1 [DATE]	Inspection #2 [DATE]	Inspection #3 [DATE]
	FDA 483 # []	FDA 483 # []	FDA 483# []

Center's Significant FDA 483 Observations and Identified Expert Table

483 Observation (Prioritized by Severity)	Citation	Center Supported/ Not Supported	Expert Identified (if Center Supported)

Correspondence Received from the Firm (Example)

Correspondence by Firm or its Agents	ORA Review	Center Review	Did the FDA Respond (Yes or No)	Date FDA Responded
[DATE] & Hyperlink to Corresponden ce	[DATE] & Hyperlink to review memo or email	[DATE] & Hyperlink to review memo or email		[DATE] & Hyperlink to FDA response

Firm's Stated or Observed Corrective Actions (Example)

FDA 483 Observation # [& Date Observed by FDA]	Firm's Stated Correction	ORA Evaluation of the Correction	Center Evaluation of the Correction

Exhibit 6-2**SEIZURES - U.S MARSHAL LETTER**

Reference: SAMPLE NO.

FDC NO.

PRODUCT:

Dear Sir: Please refer to Complaint for Forfeiture which has been filed in the above referenced matter.

As soon as seizure has been effected, we will appreciate your providing us with the following information, which may be furnished by filling in the captions below, on the extra copy of this letter enclosed for that purpose.

Sincerely yours,

Enclosure

cc this letter

Self-addressed franked envelope

DATE SEIZED:

AMOUNT SEIZED:

RETURN DATE (date after which default will be entered):

SEIZED IN POSSESSION OF:

WHERE STORED AFTER SEIZURE:

SEIZED BY: _____

U.S. Marshal or Deputy Marshal

FORM FDA 487 (6/82)

Exhibit 6-3**FORM OF DEFAULT DECREE OF CONDEMNATION**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

United States of America,)	No. _____
)	
Plaintiff,)	
)	
v.)	
)	
So many cartons, more or less,)	
of an article of food labeled in part:)	
)	
" _____,")	
)	
Defendant.)	

On _____, 20____, a Complaint for Forfeiture against the above described article was filed on behalf of the United States of America. The Complaint alleges that the article proceeded against is a food which was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a)(3), in that it consisted in part of a filthy substance by reason of the presence therein of insects. Pursuant to warrant for arrest in rem issued by this Court, the United States Marshal for this district seized the article on _____, 20____.

It appearing that process was duly issued herein and returned according to law; that notice of the seizure of the above described article was given according to law; and that no persons have appeared or interposed a claim before the return day named in the process;

Now, therefore, on motion of _____, United States Attorney for the District of Maryland, by _____, Assistant United States Attorney, for a Default Decree of Condemnation and Destruction, the Court being fully advised of the premises, it is

ORDERED, ADJUDGED AND DECREED that the default of all persons be and the same are entered herein; and it is further:

ORDERED, ADJUDGED AND DECREED that the seized article is a food (or: device, drug, etc.) which was adulterated (or misbranded) when introduced into interstate commerce (or: while in interstate commerce, or: is adulterated while held for sale after shipment in interstate commerce) within the meaning of 21 U.S.C. 342(a)(3), (or appropriate charge) in that it consists in part of a filthy substance by reason of the presence therein of insects, (or enter appropriate statement) and is therefore hereby condemned and forfeited to the United States pursuant to 21 U.S.C. 334(a); and it is further:

ORDERED, ADJUDGED AND DECREED, pursuant to 21 U.S.C. 334(d), that the United States Marshal in and for the District of Maryland destroy the condemned article and make return to this Court. Destruction shall be in a manner that complies with the requirements of the National Environmental Policy Act.

Dated this _____ day of _____, 20__.

United States District Judge

NOTE:

EXHIBITS: Where exhibits of the seized article are desired for use in displays, to illustrate public speeches, or in subsequent prosecution proceedings, the last paragraph of the above decree should be worded:

(for the entire lot) "*** that the United States Marshal in and for the District of Maryland do forthwith deliver same to a representative of the Food and Drug Administration for official use or uses***."

(for a portion of the lot) "*** do forthwith deliver a portion of same to a representative of the Food and Drug Administration for official use or uses and destroy the remainder of same***."

Exhibit 6-4**FORM OF CLAIM**

In the District Court of the United States for the _____
 District of _____, _____ Division. _____,
 Term, A.D., 20____

UNITED STATES OF AMERICA,)

v)

No. _____, _____
 CLAIM

Now appears before this Honorable Court _____ Company, a
 corporation duly organized and existing under the laws of the State of _____,
 with its principal place of business in the City of _____, State of
 _____, intervening in this proceeding by virtue of its interest as
 _____, and prays to defend the article(s) above described, and makes claim
 to the article(s) as the same is attached by the United States Marshal for this District
 under process of this Court at the instance of the United States of America, libellant;

And the claimant avers that it has a true and bona fide interest in the article;
 wherefore it prays to defend accordingly.

_____ Company

By: _____

 Proctor for Claimant

State of _____)

)

SS:

County of _____)

_____, being duly sworn, deposes and says that he is the
_____ of _____ Company, the corporation which is
described in and which executed the foregoing Claim; that he has authority to act on
behalf of the corporation in this matter and that he signed the Claim pursuant to his
authority; that he has read the Claim and knows the contents thereof, and that the same is
true to the best of his knowledge, information, and belief; and that he knows the seal
affixed to the Claim is the seal of the corporation and was duly affixed as such.

Sworn to before me this _____ day of _____, 20____.

Notary Public

Exhibit 6-5**FORM OF CONSENT DECREE OF CONDEMNATION**

In the District Court of the United States for the _____

District of _____

_____ Term, A.D., 20____.

UNITED STATES OF AMERICA)

)

v.)

No. _____, _____

) Decree of Condemnation

)

On _____, 20 ____, a Complaint for Forfeiture against the above described article was filed in this Court on behalf of the United States of America by the United States Attorney and the Assistant United States Attorney for this District. The Complaint alleges that the article proceeded against is a food which was adulterated when introduced into interstate commerce within the meaning of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 342(a)(3), (or appropriate charge) because it consisted of a filthy substance by reason of the presence therein of insects. Pursuant to a warrant for arrest in rem issued by this Court, the United States Marshal for this District seized the article on _____, 20____. Thereafter, _____ Company of _____, _____ intervened and filed claim to said article. Claimant consents that a decree, as prayed for in the Complaint, be entered condemning the article under seizure.

The Court being fully advised of the premises, it is on motion of the parties hereto:

ORDERED, ADJUDGED AND DECREED that the seized article is a food (or: device, drug, etc.) which was (or is) adulterated (or misbranded) when introduced into interstate commerce (or: while in interstate commerce, or: while held for sale after shipment in interstate commerce) within the meaning of 21 U.S.C. 342(a)(3) (or appropriate charge) because it consists in part of a filthy substance by reason of the presence therein of insects, (or enter appropriate statement) and is therefore hereby

condemned and forfeited to the United States pursuant to 21 U.S.C. 334(a); and it is further:

ORDERED, ADJUDGED, AND DECREED, pursuant to 21 U.S.C 334(e), that the United States of America shall recover from said Claimant court costs and fees, and storage and other proper expenses, as taxed herein, to wit, the sum of \$ _____; and

Claimant having petitioned this Court that the condemned article be delivered to it pursuant to 21 U.S.C. 334(d), it is further

ORDERED, ADJUDGED, AND DECREED that the United States Marshal for this District shall release said article from his custody to the custody of claimant for the purpose of bringing the article into compliance with the Act if claimant, within 20 days from the date of this decree, (a) pays in full the aforementioned court costs and fees, and storage and other proper expenses of this proceeding and (b) executes and files with the clerk of this Court a good and sufficient penal bond with surety in the sum of _____ Dollars (\$ _____), approved by this Court, payable to the United States of America, and conditioned on the claimant's abiding by and performing all the terms and conditions of this decree and such further Orders and Decree as may be entered in this proceeding; and it is further

ORDERED, ADJUDGED, AND DECREED that:

1. After the filing of the bond in this Court, the claimant shall, at its own expense, cause the article to be shipped to its plant at _____. When the article arrives at the _____ plant, claimant shall give written notice to the _____ Division/District, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, Department of Health and Human Services that the article has arrived and that claimant is prepared to bring it into compliance with the law under the supervision of a duly authorized representative of the Department of Health and Human Services (DHHS).

2. The claimant shall at all times, until the article has been released by the DHHS representative, retain intact the entire lot of goods comprising the article for examination or inspection by said representative, and shall maintain the records or other proof necessary to establish the identity of said lot to the satisfaction of said DHHS representative.

*3. The claimant shall not commence bringing said article into compliance until it has received authorization to do so from the DHHS representative.

*NOTE: In mass seizure cases, this item should read as follows:

3. The claimant shall not commence bringing the articles into Compliance until the premises have been rendered clean and suitable for the storage of _____ and it has received authorization to do so from the DHHS representative.

4. The claimant shall at no time, ship, sell, offer for sale, or otherwise dispose of any part of the article until the DHHS representative shall have had free access thereto in order to take any samples or make any tests or examinations that are deemed necessary, and shall in writing have released the article for shipment, sale, or disposition.

5. Within 30 days from the date of the filing of the bond in this Court, claimant shall complete the process of bringing the article into compliance with law under the supervision of the Department of Health and Human Services.

6. The claimant shall abide by the decisions of the DHHS representative which decisions shall be final. If claimant breaches any conditions stated in the decree, or of any subsequent decree or order of this Court in this proceeding, claimant shall return the article immediately to the United States Marshal for this District at Claimant's expense, or shall otherwise dispose of it pursuant to an order of this Court.

7. The claimant shall not sell or dispose of said article or any part thereof in a manner contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, or the laws of any State or Territory.

8. The claimant shall compensate the United States of America for cost of supervision at the rate of \$_____ per hour per person for each day actually employed in the supervision of the reconditioning, as salary or wage; where laboratory work is necessary, at the rate of \$_____ per hour per person for such laboratory work; where subsistence expenses are incurred, at the rate of \$_____ per day per person for such subsistence expenses. Claimant shall also compensate the United States of America for necessary traveling expenses at \$.____ per mile and for any other necessary expenses which may be incurred in connection with the supervisory responsibilities of DHHS.

9. If requested by the DHHS representative claimant shall furnish the representative duplicate copies of invoices of sale of the released article, or shall furnish such other evidence of disposition as said representative may request.

The United States Attorney for this District, on being advised by the DHHS representative that the conditions of this decree have been performed, shall transmit such information to the Clerk of this Court, whereupon the bond given in this proceeding shall be canceled and discharged; and it is further

ORDERED, ADJUDGED, AND DECREED that if the claimant does not avail itself of the opportunity to repossess the condemned article in the manner aforesaid, the United States Marshal for this District shall retain custody of said article pending the issuance of an order by this Court regarding its disposition; and it is further

ORDERED, ADJUDGED, AND DECREED that this Court expressly retains jurisdiction to issue further decrees and orders as may be necessary to the proper disposition of this proceeding, and should the claimant fail to abide by and perform all the terms and conditions of this decree, or of such further order or decree as may be entered in this proceeding, or of said bond, then said bond shall on motion of the United States of America in this proceeding be forfeited and judgment entered thereon.

Dated at _____, this _____ day of _____, 20____.

United States District Judge

We hereby consent to the entry of the foregoing Decree.

United States Attorney

Assistant United States Attorney

Proctor for Claimant

Exhibit 6-6**FORM OF BOND**

In the District Court of the United States for the _____ District of
 _____, _____ Division. _____ Term, A.D.,
 20____

UNITED STATES OF AMERICA,)	
)	
v.)	No. _____, _____.
)	Bond
_____)	

KNOW ALL MEN BY THESE PRESENTS: That _____,
 as Principal, and _____,
 a corporation duly organized under the laws of the State of _____,
 and having a place of business at _____, as Surety, are held and
 firmly bound unto the United States of America in the sum of
 _____ (\$____) Dollars, for the payment of which to the
 United States of America they bind themselves, their representatives, successors, and
 assigns, jointly and severally, firmly by these presents.

WHEREAS, on _____, 20____, a decree was entered in the above-described
 proceeding, a copy of which Decree is hereto annexed, marked Exhibit A, and made a
 part thereof;

NOW, THEREFORE, the condition of this obligation is such that if the said
 Principal shall abide by and perform all the terms and conditions of said Decree and such
 further Orders and Decrees as may be entered by the above-designated Court in this
 proceeding, then this obligation shall become null and void; otherwise it shall remain in
 full force and effect.

And the Principal and Surety covenant and agree that, by entering into and
 furnishing this Bond, they submit themselves, and each of them, to the jurisdiction of the
 above-designated Court and irrevocably appoint the Clerk of Said Court as their agent
 upon whom any papers affecting their liability on said Bond may be served, that their
 liability on and under the Bond may be enforced on motion made in and to the Court

without the necessity of an independent action, and that the motion and notice thereof may be served on the Clerk of the Court.

Signed with our hands and seals this _____ day of _____,
20__.

By: _____

Principal

By: _____

Surety

Attest:

Secretary

Bond approved _____, 20__.

UNITED STATES ATTORNEY

_____ Division _____ District of _____,
20__.

Exhibit 6-7**NOTICE TO CLAIMANT**

(Sample No.)
FDC _____, Civil # _____
Shelled Walnuts

June 17, 20__
U.S. vs. 12 cases ***** and
9 cases ***** Walnuts

Firm Name
Street Address
City, State, Zip

Dear Sir or Madam:

In accordance with the terms of the decree, these lots of walnuts have been satisfactorily reconditioned and the good portion, consisting of 854 lbs., is released for your disposition. The rejects, consisting of 30 lbs., have been destroyed under the supervision of a representative of this office.

The following supervisory charges were incurred during the reconditioning operations:

Investigator's time	6 hrs. at \$**.** per hr	\$XXX.XX
Mileage-Govt. car	18 miles at \$0.** per mile	\$ X.XX
Analyst's time	5 hrs. at \$**.** per hr	<u>\$XXX.XX</u>
	Total Charges	\$XXX.XX

(* Note: Use rates of reimbursement specified in Consent Decree)

Please remit promptly a money order, bank draft, or certified check for \$XXX.XX, made payable to the United States Treasury, attach to the enclosed copy of this letter, and forward to:

U.S. Food and Drug Administration
_____ Office
Compliance Branch
Street Address
City, State Zip

Upon receipt of your remittance, we shall advise the United States Attorney that, insofar as this office is concerned, the bond posted to cover the decree may be canceled.

Sincerely yours,

Director, Compliance Branch
_____ Office

Enc: cc this ltr.
cc: Fiscal Branch

Exhibit 6-8**SECOND NOTICE**

(Sample No.)
FDC _____, Civil # _____
Shelled Walnuts

July 17, 20____
U.S. vs. 12 cases ***** and
9 cases ***** Walnuts

CERTIFIED MAIL - RETURN RECEIPT

Firm Name
Street Address
City, State, Zip

Dear Sir or Madam:

Under date of June 17, 20____, we mailed you "NOTICE TO CLAIMANT" requesting payment for charges incurred in the supervisory operations specified in the terms of the decree entered in the above identified seizure action. You were requested to remit money order, bank draft, or certified check, in the amount of \$XXX.XX, to this office. Remittance has not been received.

This is to inform you that unless payment of the costs specified in our letter of June 17, 20____, is received within two weeks after the date of receipt of this notice, the claim will be referred to the United States Attorney for collection.

Sincerely yours,

Director, Compliance Branch

_____ Office

Enc: cc this ltr.
cc: Smith & Smith Attorneys
XYZ Bonding Co.

(Send one month after first Notice; follow up in 2 weeks)

Exhibit 6-9**LETTER TO CANCEL BOND**

(Sample No.)
FDC _____, Civil #_____
Shelled Walnuts

July 25, 20__
U.S. vs. 12 cases ***** and
9 cases ***** Walnuts

Honorable _____
United States Attorney
Street Address
City, State, Zip

Dear _____:

The terms of the Order of Condemnation entered in the above-identified action, providing for reconditioning, have been complied with under the supervision of a representative of this office.

Costs of supervision have been paid, and insofar as we are concerned the bond may be canceled.

Sincerely yours,

Director, Compliance Branch

_____ Office

Exhibit 6-10**Procedures & Models for Issuing Press Releases**

Procedures for Issuing Press Releases on Enforcement Actions

(Seizures & Injunctions)

OCC – Office of Chief Counsel

ORA – Office of Regulatory Affairs

DE – ORA's Office (Program and District)

OMA – Office of Media Affairs

AUSA – Assistant U.S. Attorney

1. _____ Before Issuing a Press Release

1. Issuance of Press Releases to Publicize Enforcement Actions – Generally speaking, FDA will issue a Press Release when an enforcement action is taken by the Agency. The release should include a description of the enforcement action, i.e., type of action, basis for action, firm, location, product(s) and firm's geographical market area. In the case of seizure actions, the Letter to the U.S. Attorney and Complaint for Forfeiture should be provided by OCC to OMA for the drafting of the release. In the case of injunction actions, the Complaint for Injunction and/or Consent Decree should be provided to OMA by OCC.
2. Decision to Publicize – Typically, the release will be issued at the national level. If, however, OMA determines that the release is more appropriate for the local level, it will notify OCC (attorney assigned to the case), ORA (ORA Headquarters) and the Center (Office of Compliance) of its decision.

Example of what would be publicized at local level – firms with limited geographic distribution of their products

3. Coordinating with AUSA – The OCC attorney assigned to the case contacts the AUSA to inform him/her of FDA's plans to issue press and to obtain concurrence. If the AUSA plans to issue a release, FDA typically will defer issuance of the release to the AUSA and may request that an FDA quote be included in the DoJ release. The OCC attorney notifies OMA whether the AUSA concurs with FDA issuing press or prefers to issue one itself.

4. Drafting and Clearing the Release – If FDA is issuing the release, the process for drafting and clearing the release starts at OMA.
 - a. OMA creates the first draft of the release using one of the attached model press releases (e.g., injunction or seizure). OMA routes the release for headquarters review and clearance in the following order of offices –
 - i. Center - *Center compliance staff will obtain clearance from appropriate Center officials, including the insertion of a quote, as appropriate, into the release about the action that is being taken.*
 - ii. ORA – *ORA Executive Operations Staff will obtain input from ORA components by circulating the release to the relevant headquarters units and the appropriate ORA offices. Program and District input, when provided, will be routed through the Division of Enforcement (DE) to assure uniformity in enforcement language. Offices will be responsible for coordinating review by State officials if enforcement action involved our state counterparts. When circulating the release for input and comment from ORA components, ORA Executive Operations will attach, if supplied from OMA, the Final Letter to the U.S. Attorney and Complaint for Forfeiture (for seizures) and the File Complaint or Consent Decree (for injunctions). ORA Executive Operations is responsible for coordinating all comments from ORA components. ORA Executive Operations will have the responsibility for obtaining clearance of the proposed quote from the ACRA, ORA Executive Operations staff will obtain final ORA document clearance through the ACRA or his/her designee and send the final ACRA cleared version forward to OMA.*
 - iii. OCC lead case attorney - *OCC will give the AUSA a copy of the release for review.)*
 - b. After the release is cleared through the three offices listed above (Center, ORA, OCC) for technical accuracy, OMA will route it through OMA's standard press release clearance process, which involves top agency officials.
5. Final Copy of Press Release – OMA takes comments, makes final edits to the release and notifies the above offices, concurrently, as appropriate, for last minute edits.

2. Issuance of Press Release

- a. Local press release – OMA returns final copy of release to the appropriate ORA public affairs specialist (PAS) or compliance officer to format the release on ORA's letterhead.

The PAS issues the release to local Associated Press bureau shortly after enforcement action has occurred – no later than 24 hours after the event. OMA sends copy of release to OMA's Website Management Staff for posting to FDA Website.

- b. National press release – OMA will issue and post the release using the same procedures as for other agency releases.
- a. In the case of seizures, press does not issue until the seizure action is completed. If the Complaint for Forfeiture was issued under seal, press can not issue until the seal is lifted. OCC will inform OMA of the appropriate time to release the press statement.

Model Press Release – SEIZURE

(FDA Enforcement Actions)

FDA – Recommended Seizure

Carried out by United States Marshals Under Court Order

At the request of the Food and Drug Administration (FDA), the U.S. District Court for the (name of district) District of (State) issued a seizure warrant for seizure of (various articles of foods/drugs/etc.) at (name of firm) located in (city, state). The U.S. Marshals Office executed the seizure warrant (state when).

The seized (name of product(s)) are (adulterated and/or misbranded) under the Federal Food, Drug, and Cosmetic Act because (state how the products are adulterated and/or misbranded without reference to statute provisions). (Name of firm) distributed the products in (description of geographical area where products were distributed) through (types of consignees).

FDA inspections of (name of company) revealed (state what was revealed), for which (name of firm) was previously issued a Warning Letter(s) outlining unacceptable practices. The company was given an opportunity to correct the violations, but failed to take appropriate action(s).

This product (poses/does not pose) a public health risk because (describe reason why it does not pose a risk/OR describe the health risk involved, i.e., contaminated product can cause).

(possible quote by FDA official – OMA will handle)

The FDA advises consumers to (describe whatever action(s) is/are recommended by the agency – for example, not to purchase the product, stop using the product, discard the product, return to place of purchase, stop using medicine, do not stop using medicine without consulting a physician, consult a physician, etc.).

The FDA has initiated this action to promote and protect the public health by enforcing the Federal Food, Drug, and Cosmetic Act. FDA's mission includes ensuring the safety or safety and effectiveness of a broad spectrum of regulated products, including food, human and animal drugs, vaccines, blood products, medical devices, electronic products that emit radiation, and cosmetics.

Model Press Release – INJUNCTION
(FDA Enforcement Actions)

Food and Drug Administration Seeks Injunction Against (name/type of firm(s))

The Food and Drug Administration (FDA) is seeking a (permanent/preliminary/temporary) injunction against (firm's name and address) to (describe purpose of injunction).

The government's complaint, filed by the U.S. Department of Justice in the U.S. District Court for the (name of district) District of (State) charges (name of firm) with violating the Federal Food, Drug, and Cosmetic Act by (describe the charges in plain English). In addition to (name of firm), the complaint names as defendants (name and title of individual(s)).

The complaint asserts that the defendant(s) has/have carried out (describe the violative action(s)) since (the beginning date) despite the FDA's warning(s) that this/these action(s) is/are illegal.

This/these violative action(s) (poses/does not pose) a public health hazard because (describe the reason(s) why).

The FDA advises consumers to (describe whatever action(s) is/are recommended by the agency – for example, not to purchase the product, stop using the product, discard the product, return to place of purchase, stop using medicine, do not stop using medicine without consulting a physician, consult a physician, etc.).

The FDA has initiated this action to promote and protect the public health by enforcing the Federal Food, Drug, and Cosmetic Act. FDA's mission includes ensuring the safety or safety and effectiveness of a broad spectrum of regulated products, including food, human and animal drugs, vaccines, blood products, medical devices, electronic products that emit radiation, and cosmetics.

Exhibit 6-11**INJUNCTIONS (MULTI-JURISDICTION)****INJUNCTIONS**
(Multi-jurisdiction)**Scope**

These procedures apply to injunction actions where the corporate headquarters and/or the facilities to be enjoined are located in two or more FDA districts. The procedures describe special coordination requirements for this category of injunctions.

Scope

These procedures do not supersede the instructions in section [6-2, INJUNCTIONS](#). They are supplementary for only multi-district injunctions involving 2 or more facilities in the same corporation. These procedures do not apply to Team Biologics.

At its discretion, the recommending district may invoke these procedures for an injunction in a single jurisdiction or involving multiple Centers.

Objectives

Office of Regulatory Affairs (ORA), Centers and other organizations in FDA are involved in the case development activities. A number of case development activities must occur concurrently to ensure high quality work products are generated with adherence to strict timeframes. These procedures are intended to facilitate case processing with respect to:

- Proactive communication with FDA offices that recommend, review, or concur;
- Coordination, organization, and scope;
- Support throughout the case development process;
- Timelines, milestones, deadlines; and
- Quality assurance.

Responsibilities and Roles

Bringing a timely multi-district injunction of high probative value requires a coordinated team effort. To avoid multiple evidence and review updates, redundant edits of work products, and miscommunications, the stakeholders should assume case ownership and be readily available at all critical stages of case development and review.

District/Program Director

The Division Director (DD) or Program Director (PD) will ensure that inspections, investigations, and sample collections that support an injunction action are scheduled and completed with due diligence. In addition, the DD/PD will have an active obligation to expedite the early alert/notification, establishment inspection report, exhibits, collection reports, investigational memos, compliance recommendation, collateral assignments, et al. The DD/PD may delegate these activities as appropriate.

Director of Compliance Branch

The Director of Compliance Branch (DCB) will provide administrative oversight for case management in the unit. The DCB will ensure continued District, Division and Program responsiveness to case support needs until the case is finally adjudicated and follow-up obligations are fulfilled. (S)he has primary responsibility to ensure Early Alert/Notification to the Office of Enforcement.

Director of Investigations Branch

See “ Early Alert/Notification” section in this exhibit under “Procedure,” below.

Director, Office of Enforcement and Import Operations (OEIO), Division of Enforcement

The Director, Division Enforcement (DE) will provide administrative oversight for Compliance Team Coordinator activities. (S)he will ensure continued responsiveness to case support needs until the case is adjudicated.

Compliance Team Leader

The Compliance Team Leader will typically be the Compliance Officer in the recommending unit assigned to the case

The Compliance Team Leader has responsibility for initial review of the evidence, drafting a compelling recommendation, and providing overall direction for ORA case development activities. In addition, the Compliance Team Leader will:

- Develop strategy in collaboration with the Compliance Team Coordinator and other offices, including the appropriate Center and OCC personnel, early in the process, e.g., even at the pre-inspection stage when there is a history of noncompliance;
- Establish deadlines and milestones for meeting timeframes in collaboration with the Compliance Team Coordinator;
- Determine resources, including identification of expertise and division of labor, necessary to meet deadlines, milestones, and timeframes;
- Identify work sharing projects and communicate to the Compliance Team Coordinator the need for research, models, assistance in drafting documents or assignments,

coordinating conference calls, attending meetings, etc. and other needs that will expedite the case and/or contribute to quality;

- Accompany the case to the Center, in appropriate circumstances, unless the DD/PD, Director of OE, or the Center Office of Compliance Director conclude that it would serve no useful purpose; and,
- Provide a copy of the recommendation and all related support documents concurrently to the Center and the Compliance Team Coordinator.

Compliance Team Coordinator

The Compliance Team Coordinator will typically be a Compliance Officer in DE. The Compliance Team Coordinator will act as the ORA headquarters facilitator for the case. In addition, the Compliance Team Coordinator will:

- Collaborate with and provide assistance to the Compliance Team Leader to ensure all case development needs are met;
- Communicate case contact information for each office in the case development chain of command (offices that recommend, review, or concur);
- Serve as a liaison to establish open lines of communication within the case development and review team at each phase of case evaluation;
- Facilitate timeliness of work products;
- Periodically provide a chronology and update of important case events and activities to the case development and review chain of command;
- Identify relevant issues, unexpected events, and other factors impacting the case;
- Conduct a review of the final case recommendation concurrent with the Center's evaluation for the purpose of providing case liaison;
 - Issues identified as part of the Compliance Team Coordinator's review will be deferred to the Compliance Team Leader for resolution.

Procedure

Early Alert/Notification

As soon as the DD, DCB, or Director of Investigations Branch (DIB) identifies a **potential** Multi- jurisdictional injunction, they will provide an early alert to the appropriate Center(s) and the Director, Division of Enforcement (HFC-200). The early alert should include:

- The name, address, and FEI numbers of the target corporate office and facilities;
- Date(s) of the planned, in-process, or completed inspections;
- General nature of the violations, e.g., GMPs, HACCP, sanitation, etc.; and,
- Products involved and any special characteristics, e.g., sterile, LACF, medical necessity, etc.

If a Center or other stakeholder has cause to suspect that a multi-district injunction should be considered, their designee will provide a similar early alert or notification to the Director, Division of Enforcement (HFC-200).

The notification can be made by telephone, email, FAX, or other appropriate electronic communication. Notifications by telephone should be followed up by a written summary that is forwarded to DE (HFC-200) within 2 business days.

The Director, DE will immediately identify a Compliance Team Coordinator and communicate that decision to the appropriate Division, Program, and/or Center contacts.

Organizational Case Management Strategy

Each case presents unique factors and circumstances that if managed properly will mitigate delays and evidence development problems.

The Compliance Team Coordinator and the Compliance Team Leader shall jointly identify the ORA/Center/OCC stakeholders and initiate a conference call with them as soon as practical. The purpose is to front-load the case, facilitate communication among the stakeholders, and expedite the case.

The conference call should:

- Introduce facts and circumstances of the case;
- Provide an overview of previous regulatory actions, e.g., identify which corporations, facilities and products were involved, the types of actions taken, and similarities in the violations;
- Discuss support for the injunction;
- Identify policy implications, e.g., right case, right area;
- Discuss case strategy and scope, e.g., all or specific facilities, all or certain products; and
- Identify roles and partnerships, including those of the Divisions, Districts, the Division of Enforcement, programs, and the relevant Center(s).

The stakeholders will typically include offices that recommend, review, or concur; and those in positions of Compliance Team Leader; Compliance Team Coordinator; DCB; DDs ; Program Director, Division of Enforcement; Director, Office of Enforcement and Import Operations; Center Office Compliance Director, Center Office of Compliance Division Directors, and other Center Compliance personnel; Deputy Chief Counsel for Litigation; and appropriate OCC Senior Enforcement Advisors(s).

Exhibit 6-12**MODEL LETTER ACKNOWLEDGING COMPLIANCE**

Name

Title

Firm Name

Street Address

City, State, Zip

Re: Injunction

Civil # _____

Dear _____:

This is to advise you of the results of an inspection conducted on (Date), at your fish processing plant at (Location).

A comparison of the conditions at the plant and your expert's certification statement submitted under the terms of the injunction showed that your plant was in compliance on that day.

You may, therefore, resume operations at the plant at (Location).

We wish to remind you that the terms of the injunction under which your firm is operating require that you maintain your plant in a sanitary condition in the future. Our approval of the conditions found on (Inspection Date) should not be construed as approval for any conditions that may be found in the future. Should it be determined during any future inspection that you have failed to maintain the plant in a proper sanitary condition, we will not hesitate to request that the court take whatever steps are necessary to ensure compliance.

Very truly yours,

Director

Exhibit 6-13**DRUG/GMP/ADULTERATION/MISBRANDING CASE – INTRODUCTORY
LANGUAGE FROM A COMPLAINT**

An investigation by the Food and Drug Administration (FDA) of (name of firm, city, state) reveals violations of the adulteration and misbranding provisions of the Federal Food, Drug, and Cosmetic Act, resulting in various injectable drugs being produced contrary to current good manufacturing practices, 21 U.S.C. 351(a)(2)(B); failing to have their purported quality because they are not sterile, 21 U.S.C 351(b); and falsely stating that they are sterile when they are not, 21 U.S.C. 352(a). We request that proceedings be instituted pursuant to 21 U.S.C 332(a) to enjoin (name of firm) and (number) of its officers who share responsibility for shipping these adulterated and misbranded drugs in interstate commerce in violation of 21 U.S.C. 331(a) and for adulterating and misbranding these drugs while holding them for sale after shipment in interstate commerce in violation of 21 U.S.C. 331(k). Prior FDA warnings have been unsuccessful in promoting the necessary corrections.

Exhibit 6-14**FOOD ADULTERATION CASE – INTRODUCTORY LANGUAGE FROM A COMPLAINT**

An investigation by the Food and Drug Administration (FDA) of (name of firm, city, state) reveals violations of the adulteration provisions of the Federal Food, Drug, and Cosmetic Act, resulting in human foods becoming adulterated within the meaning of 21 U.S.C. 342(a)(3) and 342(a)(4), in that they have been manufactured under conditions whereby they may have become, and in fact have become, contaminated with filth. We request that proceedings be instituted pursuant to 21 U.S.C. 332(a) to enjoin (name of firm) and (number) of its officers who share responsibility for adulterating food during manufacture in their plant, 21 U.S.C. 331(k), and from shipping adulterated food in interstate commerce, 21 U.S.C. 331(a). Prior FDA warnings have been unsuccessful in promoting the necessary corrections.

Exhibit 6-15**DRUG GMP CASE – DESCRIPTION OF CHARGE FROM A COMPLAINT**

A drug is deemed to be adulterated within the meaning of the Act, 21 U.S.C. 351(a)(2)(B), if the methods used in or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice. Thus, a drug is adulterated regardless of whether it is physically deficient in some respect. The purpose of the good manufacturing practice provision of the Act is to control the process of drug manufacturing and to attack the production of unreliable drugs in its incipency, not after the fact. *United States v. Bel-Mar Laboratories*, 284 F. Supp. 875 (E.D.N.Y. 1968); *United States v. An Article of Drug ... White Quadrisect*, 484 F.2d 748 (7th Cir. 1973). Injunctive relief incorporating the statutory language of the Act, 21 U.S.C. 351(a)(2)(B), has been granted by numerous district courts. See for example the following reported cases: *United States v. Dianovin Pharmaceuticals, Inc.*, 342 F. Supp. 724 (D.P.R. 1972), *aff'd* 475 F.2d 100 (1st Cir. 1973); *United States v. Lit Drug Co.*, 333 F. Supp. 990 (D.N.J. 1971); *United States v. Lanper Co.*, 293 F. Supp. 147 (N.D. Tex. 1968). See also *United States v. Medwick Laboratories*, 416 F. Supp. 832 (N.D. Ill. 1976). The Commissioner of Food and Drugs has published comprehensive regulations specifying good manufacturing practice, 21 CFR Part 211. These regulations, referenced in paragraph ____ of the Complaint for Injunction, are binding and have the full force and effect of law. *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967); *National Nutritional Foods Assoc. v. Weinberger*, 512 F.2d 688 (2nd Cir.), *cert. denied* 423 U.S. 827 (1975).

(Where applicable add) Because the defendants' manufacturing processes are not adequately controlled and are therefore unpredictable, it is not surprising that certain of defendants' drugs have become adulterated by being subpotent (or superpotent, or both). Samples of defendants' drugs analyzed by the Food and Drug Administration establish that such adulteration, within the meaning of 21 U.S.C. 351(b) (or (c)), has in fact occurred.

Exhibit 6-16**DIRTY WAREHOUSE CASE – DESCRIPTION OF CHARGES FROM A COMPLAINT**

The injunction charges defendants with violating the Act, 21 U.S.C. 342(a)(3) and (a)(4). In order to establish adulteration of food within the meaning of 342(a)(4), proof of actual contamination is not required. It is only necessary to prove that the food was held under insanitary conditions whereby it may have become contaminated with filth. *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86 (1964); *Berger v. United States*, 200 F.2d 818 (8th Cir. 1952). The test for determining whether the conditions are sufficiently insanitary to cause food to be deemed to be adulterated is whether such conditions could, with reasonable possibility, result in contamination. See *Berger v. United States*, *supra*, at 821; *United States v. H.B. Gregory Co.*, 502 F.2d 700, 704 (7th Cir. 1974). However, proof of actual contamination may be used to establish that the insanitary conditions could (and did) cause actual contamination. *Golden Grain Macaroni Co. v. United States*, 209 F.2d 166, 167-8 (9th Cir. 1953); *Berger v. United States*, *supra*, at 823. The words "insanitary conditions" and "filth" have been given their usual and ordinary meaning by the Courts; restrictive scientific and medical definitions do not apply. *United States v. Cassaro, Inc.*, 443 F.2d 153, 157 (1st Cir. 1971); *United States v. 44 Cases ... Viviano Spaghetti*, 101 F. Supp. 658 (E.D. Ill. 1951).

A violation of 342 (a)(3) requires a showing that a food actually contained filth within the meaning of the Act. However, the Government need only prove the presence of filth. *United States v. 484 Bags ... Coffee Beans*, 423 F.2d 839 (5th Cir. 1970); it need not establish that the food is unfit, deleterious or dangerous to health. Courts have routinely recognized that insect matter and rodent matter is filth within the meaning of the Act. The presence of any amount of filth is forbidden by the Act, even filth which is capable of being discerned only with the aid of a microscope. *United States v. 484 Bags ... Coffee Beans*, *supra*, at 841; *338 Cartons ... Butter v. United States*, 165 F.2d 728, 730 (4th Cir. 1947).

Exhibit 6-17**MISBRANDING (343(A) AND 352(A)) CASE - DESCRIPTION OF CHARGE FROM A COMPLAINT**

Where, as here, labeling is alleged to be false or misleading under 21 U.S.C. 352(a) (or 343(a)) it is not necessary that the Government prove that all representations are false or misleading. Any one false or misleading representation will support a finding that a product is misbranded. See *United States v. Hoxsey Cancer Clinic*, 198 F.2d 273, 281 (5th Cir. 1952), *cert. denied* 344 U.S. 928 (1953); *United States v. 47 Bottles Jenasol RJ Formula 60*, 320 F.2d 564, 572 (3rd Cir. 1968), *cert. denied* 375 U.S. 953; *United States v. An Article of Device ... Diapulse*, 389 F.2d 612 (2nd Cir. 1968), *cert. denied* 392 U.S. 907; *United States v. One Device ... Colonic Irrigator*, 160 F.2d 194, 200 (10th Cir. 1947); *United States v. 2,000 Plastic Tubular Cases ... Toothbrushes*, 352 F.2d 344 (3rd Cir. 1965), *cert. denied* 383 U.S. 913 (1966); *United States v. An Article of Device ... Ellis Micro-Dynamometer*, 224 F. Supp. 265, 268 (E.D. Pa. 1963). A misleading statement need not be false to violate the Act; it is enough that a statement has the capacity or tendency to deceive, by indirection, ambiguity, or by partial or half-truths. A statement can even be technically true in its entirety and still violate the Act. *United States v. 95 Barrels ... Cider Vinegar*, 265 U.S. 438, 442-3 (1924).

Exhibit 6-18**EXAMPLES OF CONSENT DECREE PROVISIONS**

Note: Although we will rely on OCC to draft the consent decrees, there are certain substantive provisions which must be drafted by the centers and by ORA offices and programs, as they describe the particular technical and scientific steps that must be taken to bring an operation into compliance. We are including samples of usual requirements for a variety of FDA's more typical types of cases. Please note that these are examples only, not boilerplate, and are intended to set out the level of detail that the centers and ORA will need to contribute to the scientific/technical aspects of the relief, in lieu of preparing a draft consent decree. The assigned center and ORA personnel must adapt these provisions to the particular circumstances of each case. In reviewing these samples, employees are not limited to linking the specific relief to a particular type of case. For example, in these examples, audit requirements are set out in the CGMP sections, but there may be situations in which a food sanitation case will need that type of relief. Similarly, the examples do not encompass every type of violation seen in FDA's cases, but they should provide sufficient guidance to assist in generating the operative portion of the decree in cases involving other types of violations.

FOOD SANITATION (LISTERIA)

I. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them each who receive notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a), and the equitable authority of this Court, from directly or indirectly receiving, preparing, packing, labeling, holding, and distributing at or from their plant located at _____ (the "_____ facility"), and any other locations at which Defendants now or in the future receive, prepare, pack, label, hold, or distribute articles of food, any article of food unless and until the following occur:

A. Defendants retain, at their expense, an independent laboratory (the "laboratory") having no personal or financial ties (other than the retention agreement) to Defendants or their families, which is qualified to collect product and environmental samples from within Defendants' plant and analyze those samples for the presence of *Listeria monocytogenes* ("*L. mono*") in a method that is acceptable to the United States Food and Drug Administration ("FDA"). Defendants shall notify FDA in writing immediately upon retaining such laboratory and shall provide FDA a copy of the service contract. Such service contract shall contain certain provisions, acceptable to FDA, for regular environmental and finished product sample collection and analysis, including how and where to sample, the number and frequency of samples to be collected, and

the methods of analysis, in accordance with the Listeria Monitoring Program discussed in paragraph _____ below;

B. Defendants retain, at their expense, an independent expert(s) (the “sanitation expert”) having no personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, education, training, and experience, is qualified to inspect Defendants’ plant and to determine whether the methods, facilities, and controls are operated and administered in conformity with the Act and 21 C.F.R. Part 110. Defendants shall notify FDA in writing of the name(s) and qualifications of the sanitation expert(s) as soon as they retain such expert(s);

C. Defendants’ sanitation expert, in consultation with the laboratory, after review of all FDA observations from _____ to present, develop a written Listeria Monitoring Program, acceptable to FDA, which shall include, at a minimum, the following:

1. An effective written sanitation control program that establishes adequate methods, facilities, and controls for receiving, processing, preparing, packing, holding, and distributing articles of food to minimize the risk of introduction of *L. mono* into Defendants’ food, and to ensure that foods are not adulterated, within the meaning of 21 U.S.C. § 342(a). Such methods, facilities, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants’ plant and all equipment therein suitable for use in receiving, processing, preparing, packing, holding, and distributing articles of food to prevent the articles of food from becoming adulterated, and instituting procedures to ensure that the plant and equipment therein are continuously maintained in a sanitary condition;
2. A written employee training program (in English and Spanish) that includes, at a minimum, instruction on sanitary food handling techniques and documentation that each employee has received such training;
3. An effective program of environmental monitoring and testing of the plant, conducted by the laboratory, to ensure that *Listeria species* (*L. spp.*) are controlled, and *L. mono* is not present, within the plant. Environmental monitoring shall include, but not be limited to, collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the facility (where the raw ingredients, in-process, and finished articles of foods are received, processed, prepared, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analysis of collected samples, in a manner acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) calendar days of receipt by Defendants;

4. A plan for remedial action should *L. spp.*, *L. mono*, or any other pathogenic organism be detected; and
 5. Assigning continuing responsibility for the operation of the Listeria Monitoring Program to a person or persons who, by reason of background, experience, or education, is competent to maintain the plant in a sanitary condition, coordinate with the laboratory, and implement any necessary remedial action(s), and providing such person with the authority to achieve the necessary corrections;
 6. Defendants make English and Spanish versions of the Listeria Monitoring Program available and accessible to all their employees;
- D. The sanitation expert conducts a comprehensive inspection of Defendants' plant and the methods and controls used to receive, process, prepare, pack, hold, and distribute foods to determine whether Defendants have effectively implemented all necessary changes and are operating in compliance with this Decree, the Act, and 21 C.F.R. Part 110. The expert shall submit his/her findings to Defendants and FDA concurrently, within ten (10) business days of completion of the inspection;
- E. Defendants report to FDA in writing the actions they have taken to bring their operations into compliance with the Act and all applicable regulations, including:
1. Documentation that they have cleaned and sanitized their facility and have received laboratory results showing that *L. mono* is no longer present in the facility;
 2. Specific measures that they have taken to address each of the violations documented by FDA since _____; and
 3. A copy of the Listeria Monitoring Program;
- F. Defendants shall destroy, under FDA supervision, all in-process and finished articles of food currently in their custody, control, or possession. For purposes of this subparagraph, raw ingredients will not be deemed to be in-process if they have remained unopened in their original packaging and if Defendants establish to FDA's satisfaction that they have been held under appropriate temperature controls since receipt.
- G. Defendants recall, to the retail level, all foods distributed since _____, at their own expense.
- H. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and all applicable regulations, conducts inspections of Defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

I. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs _____ of this Decree, the Act, and 21 C.F.R. Part 110;

J. Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to paragraphs_____, at the rates set forth in paragraph _____below.

II. Upon resuming operations after completing the requirements of paragraph____, Defendants shall continuously implement the following steps to prevent further *L. mono* contamination of their food products and facility:

A. Effectively implement, on an ongoing basis, the Listeria Monitoring Program developed pursuant to _____, unless Defendants submit, and FDA approves in writing, an alternative *L. mono* control program, consisting of validated methods and controls that are shown to FDA's satisfaction to eliminate *L. mono* in food. In the event that Defendants, their sanitation expert, or laboratory, determines that the Listeria Monitoring Program needs to be revised, Defendants shall provide suggested changes to FDA in writing at least twenty (20) days prior to their implementation.

B. Conduct finished product testing in the following manner:

1. Immediately upon resumption of operations after the completion of the requirements of paragraph____, Defendants shall test for *L. mono* in all lots of each food product for at least five consecutive production days using a testing method acceptable to FDA;

2. After the completion of testing under paragraph_____, Defendants shall test at least one lot of each food product per day for the next twenty (20) production days;

3. After the completion of testing under paragraph_____, Defendants shall test at least one lot of each food product per every five (5) production days for the next three (3) months; and

4. After the completion of testing under paragraph_____, Defendants shall test at least one lot of each food product per quarter thereafter.

If any laboratory test completed pursuant to paragraphs _____shows the presence of *L. mono* in any article of food, then Defendants must immediately cease production until they have determined and corrected the cause of the microbial contamination. Once the cause of the contamination has been corrected, Defendants shall reinstate the complete sequence of testing under this paragraph anew

III. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, or other information, that Defendants have failed to comply with

any provision of this Decree, have violated the Act or applicable regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act or applicable regulations, FDA may, as and when it deems necessary, issue a directive notifying Defendants in writing of the noncompliance and ordering Defendants to take appropriate action, including but not limited to ordering them to take one or more of the following actions immediately:

- A. Cease receiving, preparing, packing, labeling, holding, or distributing articles of food until Defendants receive written notification from FDA that they appear to be in compliance with the Decree, the Act, and applicable regulations, and that Defendants may resume operations;
- B. Recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, customers, or consumers;
- C. Submit samples of articles of food to a qualified laboratory to determine whether it is contaminated with chemicals, toxins, microorganisms, or filth;
- D. Take any other corrective actions as FDA deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, and applicable regulations, including, but not limited to, requiring that Defendants re-implement or re-institute any of the requirements of this Decree.

FOOD SANITATION

I. Upon entry of this Decree, the defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly receiving, manufacturing, preparing, packing, labeling, and distributing at their plant located at _____ (and any new locations at which the defendants receive, manufacture, prepare, pack, label, hold, or distribute articles of food), of any soft-shell flour tortilla unless and until the following occur:

- A. The defendants select an expert or experts (the "sanitation expert") having no personal or financial ties (other than a consulting agreement) to the defendants or the defendants' manufacturing operations and who, by reason of background, education, training, and experience, is qualified to develop, and ensure adequate implementation of, a written sanitation control program, covering the defendants' manufacturing processes, cleaning and sanitizing operations, pest control, employee health and hygiene precautions, and plant construction and maintenance (including the plant's buildings and sanitation-related systems (plumbing, sewage disposal), equipment, and utensils contained therein), to protect against contamination of food, food-contact

surfaces, and food-packaging materials with chemicals, toxins, microorganisms, and filth, and:

1. The defendants inform the United States Food and Drug Administration (FDA) in writing of the name and qualifications of the sanitation expert(s) as soon as they retain such expert;
2. The sanitation expert(s) develops a written sanitation control program for preparing, packing, holding, and distributing the defendants' articles of food, as described in subparagraph____;
3. FDA approves, in writing, the sanitation control program developed by the sanitation expert(s);
4. The defendants make English and Spanish versions of the sanitation control program available and accessible to all their employees;
5. The defendants develop a written employee training program (in English and Spanish) that includes, at a minimum, instruction in sanitation control requirements for food-handling and manufacturing, and the defendants document that each employee has received such training;
6. The defendants assign the responsibility and authority for implementing and monitoring the sanitation control program on a continuing basis to an employee who is trained in sanitation control requirements;
7. The sanitation expert(s) inspects the defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein, to determine whether the defendants have adequately established and implemented the FDA-approved sanitation control program, whether the defendants have adequately addressed the FDA investigators' inspectional observations listed on each Form FDA-483 issued to the defendants since_____, and whether the defendants comply with Current Good Manufacturing Practice (CGMP) requirements set forth in 21 C.F.R. Part 110; and
8. The sanitation expert certifies, in writing, to FDA that the defendants: (i) have adequately established and implemented the FDA-approved sanitation control program; (ii) have adequately addressed the Form FDA-483 observations; and (iii) comply with the CGMP requirements in 21 C.F.R. Part 110.

B. The defendants select an expert (the "food processing expert") having no personal or financial ties (other than a consulting agreement) to the defendants or the defendants' manufacturing operations and who, by reason of background, education, training, and experience, is qualified to develop, and ensure adequate implementation

of, a food processing quality control program, covering the defendants' processes for preparing, packing, and holding soft-shell flour tortillas, to prevent ingredient mix-ups and ensure that the soft-shell flour tortillas manufactured by the defendants consistently contain the type and amount of ingredients that they are intended to contain, based on pre-established written batch formulations, and:

1. The defendants inform FDA in writing of the name and qualifications of the food processing expert as soon as they retain such expert;

2. The food processing expert develops a food processing quality control program, as described in subparagraph_____, and such food processing quality control program, at a minimum, requires: (i) applying and maintaining identification of raw ingredients in English and Spanish on raw ingredient containers; (ii) using appropriate proportions of raw ingredients in the soft-shell flour tortillas manufactured by the defendants; (iii) for each size of soft-shell flour tortillas manufactured by the defendants, establishing written batch formulations, which include the name and amount of the raw ingredients and the complete manufacturing instructions; (iv) for each batch of soft-shell flour tortillas manufactured by the defendants, preparing a batch production record, which documents that each step in the established written batch formulation for the product was followed, and lists the lot numbers of each raw ingredient used in the batch production; and (v) for each retail and bulk package of soft-shell flour tortillas manufactured by the defendants, placing an indelible manufacturing date and time code in a conspicuous location on the back panel of the package where it is easily readable;

3. FDA approves, in writing, the food processing quality control program developed by the food processing expert;

4. The defendants make English and Spanish versions of the food processing quality control program – including the established written batch formulation for each size of soft-shell flour tortillas manufactured by the defendants – available and accessible to all their employees;

5. The defendants develop a written employee training program (in English and Spanish) that includes, in addition to the requirements in subparagraph_____, instruction in proper food processing techniques and food processing quality control, and the defendants document that each employee has received such training;

6. The defendants assign the responsibility and authority for implementing and monitoring the food processing quality control program on a continuing basis to an employee who is trained in food processing quality control requirements;

7. The food processing expert inspects the defendants' plant, equipment, utensils, articles of food, and relevant records contained therein, to determine whether the defendants have adequately established and implemented the FDA-approved food processing quality control program; and

8. The food processing expert certifies, in writing, to FDA that the defendants have adequately established and implemented the FDA-approved food processing quality control program;

C. The defendants, under FDA supervision, examine raw ingredients and in-process and finished articles of foods at the defendants' plant, and the conditions under which they have been stored or held, and the defendants destroy, under FDA supervision, all raw ingredients and in-process and finished articles of food as and when FDA deems necessary;

D. FDA, as it deems necessary to evaluate the defendants' compliance with the terms of paragraph____, conducts inspections of the defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

E. The defendants pay the costs of any supervision, inspection, analyses, examination, and review that FDA deems necessary to evaluate the defendants' compliance with the terms of paragraph____; and

F. FDA notifies the defendants in writing that the defendants appear to be in compliance with the requirements set forth in subparagraphs_____, 21 C.F.R. Part 110, and the Act.

II. Upon resuming operations after completing the requirements of paragraph____, the defendants shall notify FDA in writing of any change in the type or amount of raw ingredients in any batch formulation for soft-shell flour tortillas (including, but not limited to, switching from an ingredient pre-mix to individually packaged ingredients) or any change in manufacturing instructions for any soft-shell flour tortilla, at least ten (10) calendar days before implementing any such change.

III. The defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. violates the Act, 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce; or

C. failing to implement and continuously maintain the requirements of this Decree.

IV. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, or other information, that the defendants have failed to comply with any provision of this Decree, have violated 21 C.F.R. Part 110 or the Act, or that additional corrective actions are necessary to achieve compliance with this Decree, 21 C.F.R. Part 110 or the Act, FDA may, as and when it deems necessary, issue a directive notifying the defendants in writing of the noncompliance and ordering the defendants to take appropriate action, including but not limited to ordering the defendants immediately to take one or more of the following actions:

A. Cease receiving, manufacturing, preparing, packing, labeling, holding, or distributing articles of food until the defendants receive written notification from FDA that the defendants appear to be in compliance with the Decree, 21 C.F.R. Part 110, and the Act, and that the defendants may resume operations;

B. Recall all articles of food that have been distributed or are under the custody and control of the defendants' agents, customers, or consumers;

C. Submit samples of articles of food to a qualified laboratory to determine whether the food contains the type and amount of ingredients that it is intended to contain and whether it is contaminated with chemicals, toxins, microorganisms, or filth;

D. Take any other corrective actions as FDA deems necessary to protect the public health or bring the defendants into compliance with this Decree, 21 C.F.R. Part 110, and the Act, including but not limited to requiring that the defendants re-implement or re-institute any of the requirements of this Decree.

The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA. The defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in paragraph _____ of this Decree.

JUICE HACCP

I. Defendants and each and all of their agents, employees, attorneys, successors, assigns, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of

this Decree, are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from receiving, processing, preparing, packing, holding, or distributing juice, at or from Defendants' juice processing plant located at _____ and at or from any other locations at which Defendants may receive, process, prepare, pack, hold, or distribute juice, unless and until:

A. Defendants retain, at Defendants' expense, an independent person or persons ("expert"), who by reason of background, education, training, and experience, is qualified to develop and implement a Hazard Analysis Critical Control Point ("HACCP") plan for juice. The expert shall be without personal or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity of the expert as soon as they retain such expert;

B. The expert develops written HACCP plans for each type of juice processed by Defendants, consistent with 21 C.F.R. § 120.8(a) - (c);

C. FDA has approved, in writing, the HACCP plan developed by the expert;

D. Defendants establish and implement to FDA's satisfaction the written HACCP plan, developed by the expert and approved in writing by FDA, that is adequate to control food safety hazards likely to occur in the processing of juice, as required by 21 C.F.R. §§ 120.7 and 120.8;

E. Defendants have the expert validate and certify in writing to FDA that the control measures in Defendants' HACCP plan are adequate to consistently produce, at a minimum, a 5-log reduction in the most resistant organism of public health significance that is likely to occur in each juice, as required by 21 C.F.R. § 120.24;

F. To the extent Defendants utilize in their production of citrus juice a surface treatment process to achieve a 5-log reduction of the most resistant organism of public significance, Defendants ensure that their unpasteurized, finished juice products containing citrus juice are analyzed for biotype I *Escherichia coli* ("*E. coli*") in accordance with the frequency and methods of analysis proscribed in 21 C.F.R. § 120.25;

G. Defendants, under FDA supervision, according to procedures approved by FDA, and as and when directed by FDA, destroy or bring into compliance with the Act all food in the plant at the time this Decree is signed;

H. FDA has inspected the plant, including all records relating to the receipt, processing, preparation, packing, holding, and distribution of juice; and

I. FDA has notified Defendants, in writing, that the processes and controls used for the receipt, processing, preparation, packing, holding, and distribution of juice appear to be in compliance with all of the requirements specified in Paragraph ____ of

this Decree, the Act, and 21 C.F.R. Part 120. And, if such notification is based upon one or more FDA inspections, Defendants have paid for such inspection(s) and other work at the rates specified in Paragraph ____.

II. Defendants shall immediately provide any information or records to FDA, upon request, regarding the receipt, processing, preparation, packing, holding, or distribution of juice. Defendants shall maintain a copy of their HACCP plan and all records required by their HACCP plan and 21 C.F.R. Part 120 at the plant in a location where they are readily available for reference and inspection by FDA representatives. All records required to be kept by the HACCP plan and by regulation shall be retained for at least three (3) years after the date they are prepared and shall be presented immediately to FDA investigators upon request.

III. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data submitted by Defendants or the expert, or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to immediately cease receiving, processing, preparing, packing, holding, and distributing juice, and Defendants shall immediately comply with any such written orders. In addition, Defendants shall, as and when FDA deems necessary, recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers. All costs of such recall(s) and corrective actions shall be borne by Defendants. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph shall be borne by Defendants at the rates specified in Paragraph ____.

IV. After Defendants receive written notification from FDA pursuant to Paragraph ____ that they appear to be in compliance with Paragraphs _____ of this Decree, Defendants and each and all of their agents, employees, attorneys, successors, assigns and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree, are permanently restrained and enjoined from:

A. directly or indirectly doing or causing any article of food, within the meaning of 21 U.S.C. § 321(f), to become adulterated, within the meaning of 21 U.S.C. § 342(a)(4), while such food is held for sale after shipment in interstate commerce; and

B. failing to implement and continuously maintain the requirements of this Decree.

SEAFOOD HACCP

I. Defendants and each and all of their officers, agents, employees, successors, assigns, attorneys, and those persons in active concert or participation with any of them, are perpetually restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from receiving, processing, preparing, packing, holding, or distributing, at or from their facility located at _____, and any other locations at or from which defendants process, prepare, pack, hold, or distribute food, including any brined, cold-smoked, and hot-smoked fish and fishery products, unless and until:

A. Defendants have thoroughly cleaned and sanitized the facility and equipment therein and made improvements, thereby rendering the facility and equipment suitable for processing, preparing, packing, holding, and distributing articles of food;

B. Defendants have selected a person or persons ("*Listeria* expert"), other than an employee of _____, who by reason of background, experience and education, is qualified to develop a raw ingredient testing program, a Sanitation Standard Operation Procedure ("SSOP"), an employee training program on sanitary food handling techniques and personal hygiene practices, and an environmental microbial monitoring program for the genus *Listeria* ("*L. spp.*") for the processing of brined, cold-smoked, and hot-smoked fish and fishery products;

C. The *Listeria* expert has developed a written raw ingredient testing and treatment program for *Listeria monocytogenes* ("*L. monocytogenes*"), an SSOP, an employee training program, and an environmental microbial monitoring program for *L. spp.* for the processing of brined, cold-smoked, and hot-smoked fish and fishery products;

D. The United States Food and Drug Administration ("FDA") has approved in writing the raw ingredient testing and treatment program, SSOP, training program, and environmental microbial monitoring program developed by the *Listeria* expert;

E. Defendants, under the supervision of and in accordance with methods acceptable to FDA, have examined all lots of brined, cold-smoked, and hot-smoked fish and fishery products on hand at the facility for *L. monocytogenes*, in the following manner:

1. Defendants shall select a competent, independent laboratory to perform the testing;

2. The name of the laboratory shall be submitted to FDA before the testing begins;

3. All written reports of such examinations shall be submitted to FDA within two (2) calendar days after receipt by defendants;

4. FDA is authorized to conduct additional analyses and examine the articles of food, as it deems necessary, to evaluate whether the articles are adulterated; and

5. All brined, cold-smoked, and hot-smoked fish and fishery products that contain *L. monocytogenes* shall be destroyed by defendants under FDA's supervision, or reconditioned under FDA's supervision pursuant to a reconditioning plan approved in writing by FDA prior to its implementation;

F. Defendants have conducted appropriate hazard analyses and have prepared Hazard Analysis Critical Control Point ("HACCP") plans as required by 21 C.F.R. § 123.6(b) for all foods, including all brined, cold-smoked, and hot-smoked fish and fishery products, received, processed, prepared, packed, held, or distributed at the _____ facility and any other facility, at which defendants conduct their food operations. These analyses must be performed and these plans must be designed to the satisfaction of FDA;

G. Defendants develop and implement an ongoing program of adequate measures to control *L. monocytogenes* ("*Listeria* program"), as described in paragraph__.

H. FDA, as it deems necessary to evaluate defendants' compliance with the terms of paragraph____, conducts inspections of the facility;

I. Defendants pay the costs of inspections, supervision, analyses, and examination by FDA at the rates specified in paragraph__; and

J. FDA has notified defendants in writing that defendants appear to be in compliance with the requirements set forth in paragraphs _____ and with all requirements of 21 C.F.R. Parts 110 and 123.

II. Defendants shall have and implement an ongoing program of adequate measures to control *L. monocytogenes* ("*Listeria* program"). The *Listeria* program shall include the following procedures, unless defendants submit for and receive FDA's written approval for an alternate *L. monocytogenes* control program, consisting of validated methods and controls, that is shown to FDA's satisfaction to eliminate *L. monocytogenes* in both the finished product and in the facility:

A. Treatment or testing of susceptible raw ingredients. Raw material testing for *L. monocytogenes* shall be performed in accordance with timetables and methods submitted to and approved in writing by FDA before testing begins. Defendants shall select a competent, independent laboratory to perform the testing. The name of the laboratory shall be submitted to FDA before testing begins. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) calendar days after receipt by defendants. Where a sample analysis

shows the presence of *L. monocytogenes* in any raw ingredient, the finished product lot made in whole or in part from that raw ingredient shall be placed on hold or recalled, as FDA deems appropriate, and shall, as FDA deems appropriate, be destroyed by defendants under FDA's supervision, or reconditioned under FDA's supervision pursuant to a reconditioning plan approved by FDA. All expenses of such supervision, analyses, and examination by FDA shall be paid by defendants at the rates specified in paragraph__;

B. Effective and diligent sanitation procedures for cleaning and sanitizing manufacturing equipment and environment to minimize the risk of reintroducing *L. monocytogenes*. These procedures shall consist of the SSOP and the training program developed by the *Listeria* expert pursuant to the provisions of paragraph ____ and shall be implemented on a continuous basis;

C. An effective program for environmental monitoring and testing of manufacturing and storage environment to ensure that *L. spp.* are controlled within the facility and *L. monocytogenes* does not occur in the finished product. The ongoing environmental microbial monitoring program shall ensure that the SSOP continues to eliminate the *L. monocytogenes* hazard and that the SSOP is consistently being followed. Environmental monitoring shall include collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the facility (where the fish or fishery products are received, prepared, packed, and held, up to and including final packaging, and common areas that could be reservoirs for cross-contamination), and analyzing such samples for the presence of *L. spp.* Environmental testing for *L. spp.* shall be performed in accordance with timetables and methods submitted to and approved in writing by FDA before testing begins. Defendants shall select a competent, independent laboratory to perform the testing and submit the name of the laboratory to FDA before testing begins. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) calendar days after receipt by defendants;

D. Additional finished product control measures. Defendants shall implement additional control measures to prevent growth of *L. monocytogenes* in finished products. Defendants shall notify FDA regarding the control measures they select. These control measures shall continue until, as in the finished product testing described in paragraph____, the laboratory test results show no presence of *L. monocytogenes* for a period of six consecutive months. If, after such six month period, a laboratory test result shows the presence of *L. monocytogenes*, defendants shall reinstitute the additional finished product control measures under this paragraph and continue to implement them until the laboratory test results show no presence of *L. monocytogenes* for a period of six consecutive months; and

E. Finished product testing. To demonstrate compliance with the requirements described in _____, finished product testing shall include the following:

1. immediately upon resumption of operations and after completion of the requirements in paragraph____, defendants shall test for *L. monocytogenes* in each lot of finished product for at least five consecutive production days;
2. immediately after the completion of testing under paragraph____, defendants shall test at least one lot per day for at least the next 20 production days;
3. immediately after the completion of testing under paragraph _____, defendants shall test at least one lot per every five production days for the next three months; and
4. immediately after the completion of testing under paragraph_____, defendants shall test at least one lot during each three month period thereafter.

If any laboratory test listed in subparagraphs _____ show the presence of *L. monocytogenes* in any product, defendants must stop production and, before resuming any production, determine and correct the cause of the microbial contamination and start the complete sequence of testing again.

III. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analysis of a sample or samples, or other information, that the defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the regulations, or the Act, FDA may, as and when it deems necessary, notify the defendants in writing of the noncompliance and order the defendants to take appropriate action, including, but not limited to, ordering the defendants to immediately take one or more of the following actions:

- A. Cease receiving, processing, preparing, packing, holding, or distributing any article of food;
- B. Recall all articles of food that have been distributed or are under the custody and control of defendants' agents, distributors, customers, or consumers; or
- C. Take any other corrective actions as FDA deems necessary to bring the defendants into compliance with this Decree, FDA regulations, and the Act.

Defendants shall pay all costs of such recalls and corrective actions, including the costs of FDA supervision, inspections, analyses, examinations, review, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in paragraph ____ of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

IV. Any cessation of operations as described in paragraph ____ shall continue until defendants receive written notification from FDA that defendants appear to be in compliance with the

Decree, the Act, and its implementing regulations. After a cessation of operations, and while determining whether defendants are in compliance with the Decree, the Act, and its regulations, FDA may require that defendants re-institute or re-implement any of the requirements of this Decree.

DIETARY SUPPLEMENT

- I. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any product unless and until:
 - A. An approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355(a) or (j) is effective with respect to the product; or
 - B. An effective investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or
 - C. The product's claims comport with an authorized health claim set forth in 21 C.F.R. § 101.72-101.83; or
 - D. Defendants have received a letter of enforcement discretion for a qualified health claim from FDA for that product; or
 - E. Defendants have removed all claims from Defendants' product labels, labeling, promotional materials, websites owned or controlled by or related to Defendants, and in any other media that cause that product to be a drug and/or contain health claims within the meaning of the Act.
- II. Within ten (10) calendar days of FDA's request for any labels, labeling, promotional materials, and/or downloaded copies (on CD-Rom) of any internet websites owned and controlled by or related to Defendants, Defendants shall submit a copy of the requested materials to FDA at the address specified in paragraph ____.
- III. Within twenty(20) calendar days of entry of this Decree, Defendants shall submit to FDA a certification of compliance, signed by each of the individually-named Defendants in this matter, each Defendant stating that he: (a) has personally reviewed all of Defendants' product labels, labeling, promotional materials, and the internet websites referred to in paragraph ____ above; and (b) personally certifies that the product labels, labeling, promotional materials, and internet websites strictly comply with the requirements of the Act and its regulations and do not include claims that the products cure, mitigate, treat, prevent and/or reduce the risk of disease.

Thereafter, Defendants shall submit certifications of compliance every three (3) months for a period of two (2) years.

IV. Within fourteen (14) calendar day of entry of this Decree, Defendants shall retain an independent person or persons (the "expert"), without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their immediate families, who by reason of background, experience, education, and training is qualified to assess Defendants' compliance with the Act, to review the claims Defendants make for all of their products on their product labels, labeling, promotional material, and any internet websites owned or controlled by or related to Defendants including, but not limited to, the websites referred to in paragraph ____ above. At the conclusion of the expert's review, the expert shall prepare a written report analyzing whether Defendants are operating in compliance with the Act and in particular, certify whether Defendants have omitted all claims from their product labels, labeling, promotional materials, websites owned or controlled by or related to Defendants and in any other media, that make any of their products drugs and/or constitute health claims within the meaning of the Act. The expert shall submit this report to FDA and Defendants within thirty-five (35) calendar days of the entry of this Decree. If the expert reports any violations of the Act, Defendants shall, within seven (7) calendar days of receipt of the report, correct those deviations, unless FDA notifies Defendants that a shorter time period is necessary.

V. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of Defendants' product labels, labeling, promotional materials, or websites owned or controlled by or related to Defendants, a report prepared by Defendants' expert, or any other information, that additional corrective actions are necessary to achieve compliance with the Act, applicable regulations, or this Decree, FDA may, as and when it deems necessary, direct Defendants, in writing, to take one or more of the actions:

- A. Cease manufacturing, processing, packing, labeling, holding, and/or distributing any article(s);
- B. Submit additional reports or information to FDA;
- C. Recall any article(s) at Defendants' expense; or
- D. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with the Act, applicable regulations, and this Decree.

DRUG CGMP

I. Except as provided in this paragraph, within fifteen (15) calendar days of entry of this Decree, Defendants shall, under the United States Food and Drug Administration's ("FDA") supervision destroy: (1) all drugs in Defendants' possession, custody, and/or control that are

the subject of recalls announced by _____ from _____ through _____; and (2) in addition to destroying all recalled drugs, all other drugs in Defendant's possession, custody, and/or control, including all in-process drugs and drug components, as well as finished drugs. With respect to any additional recalled drugs that subsequently come into Defendants' possession, custody, and/or control, Defendants shall quarantine any such products, notify FDA in writing of their receipt, and destroy any such products, under FDA's supervision, no later than thirty (30) calendar days after their receipt. Within thirty (30) calendar days of receipt of a reasonable detailed bill of costs, Defendant shall reimburse FDA for the supervision of any destruction under this paragraph, at the rates set forth in paragraph ___ of this Decree. Defendants shall not dispose of any drugs in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969.

II. Upon entry of this Decree, Defendants and each and all of their subsidiaries, directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly, doing or causing the manufacture, processing, packing, labeling, holding, or distributing, or introducing or delivering for introduction into interstate commerce at or from any of the _____ facilities, any drug, as defined by 21 U.S.C. § 321(g)(1), unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in conformity with CGMP. 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

B. Defendants retain, at Defendant's expense, an independent person or persons (the "CGMP expert"), who is without any personal or financial (other than the consulting agreement between the parties), or familial ties to Defendants or their immediate families, who by reason of background, training, education, or experience, is qualified to inspect Defendants' drug manufacturing facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP expert as soon as they retain such expert;

C. The CGMP expert shall perform a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs. The CGMP expert shall determine whether Defendants' facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs are in compliance with CGMP.

D. The CGMP expert certifies in writing to FDA that:

1. He or she has inspected Defendants' facilities, methods, processes, and controls;
2. All CGMP deviations brought to Defendants' attention since _____ by FDA, the CGMP expert, or any other source, including but not limited to any experts hired prior to the entry of this Decree, have been corrected; and
3. Such facilities, methods, processes, and controls are in compliance with the requirements of CGMP. As part of this certification, the CGMP expert shall include a full and complete detailed report of the results of his or her inspection;

E. Defendants report to FDA in writing the actions they have taken to:

1. Correct the CGMP deviations brought to Defendants' attention by FDA, the CGMP expert, and any other source, including but not limited to any experts hired prior to the entry of this Decree;
2. Ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP;
3. Defendants may submit two (2) interim reports under this subparagraph, which shall include the CGMP drug expert certification described in subparagraph_____, in support of the immediate marketing of a priority product(s);

F. FDA representatives inspect Defendants' facilities to determine whether the requirements of this Decree have been met, and whether Defendants' facilities are operating in conformity with CGMP, the Act, and its implementing regulations; and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs_____. In no circumstance will FDA's silence be construed as a substitute for written notification.

III. After Defendants have complied with paragraphs _____ and FDA has notified them pursuant to paragraph ____, Defendants shall retain an independent person or persons (the "auditor") to conduct audit inspections of _____'s drug manufacturing operations not less than once every six (6) months for a period of no less than five (5) years. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to any of _____'s officers or employees or their immediate families and may, if _____chooses, be the same person or persons described as the CGMP expert and/or unapproved new drug expert, as set forth in paragraphs ____.

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations therefrom ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) calendar days after the date the audit inspection(s) is completed. If audit reports identify deviations from the Act, its implementing regulations, and/or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any adverse observations, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the audit report observations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) business days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule") and provide justification describing why the additional time is necessary. The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance will FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

New Drug

I. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons or entities in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, processing, packing, labeling, holding, or distributing the drugs identified in Appendix A (attached hereto) **(*Appendix A – list to be supplied by Center)** or any drug that is a new drug within the meaning of 21 U.S.C. § 321(p), unless and until:

1. an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug;
2. an investigational new drug application filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect for such drug and the drug is distributed and used solely for the purpose of conducting clinical investigations in strict accordance with the investigational new drug application; or
3. Defendants retain, at Defendant's expense, an independent person or persons (the "unapproved new drug expert"), without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their immediate families, who by reason of background, experience, education, and training, is qualified to inspect Defendants' facilities, product labeling, including promotional material and internet site information, adverse event reports, and complaints for all drugs and dietary supplements stored, processed, labeled, packed, or distributed by Defendants. Defendants shall notify FDA in writing of the identity of the unapproved new drug expert as soon as they retain such person.

(a) The unapproved new drug expert shall perform a comprehensive inspection of Defendants' facilities, product labeling, including promotional material and internet site information, adverse event reports, and complaints. The unapproved new drug expert shall determine whether Defendants have eliminated drug claims from their labeling, including promotional materials and internet information, so the products are no longer misbranded or unapproved new drugs;

(b) Defendants' expert shall certify in writing to FDA that he or she has inspected Defendants' facilities, product labeling, including promotional material and internet site information, adverse event reports and complaints, and that Defendants are not making drug claims for their products and that such products constitute dietary supplements, within the meaning of 21 U.S.C. § 321(ff). As a part of this certification, the unapproved new drug expert shall include a full and complete detailed report of the results of his or her inspection;

(c) Defendants shall report to FDA in writing the actions they have taken to eliminate drug claims from their labeling, including any

promotional materials and internet site information. Defendants may submit two (2) interim reports under this subparagraph, which shall include the unapproved new drug expert certification described in subparagraph_____, in support of the immediate marketing of a priority product(s);

(d) Within forty-five (45) calendar days after receiving a report under subparagraph_____, FDA shall either notify Defendants in writing that, with respect to the products identified in the report as being reviewed, (1) they appear to be compliance with the requirement of this Decree and the Act, or (2) they do not appear to be in compliance with the requirements of this Decree and the Act, along with the reasons for such appearance of noncompliance.

B. Introducing or delivering for introduction into interstate commerce any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Causing the adulteration of any drug within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drug is held for sale after shipment of one or more components in interstate commerce; and

D. Introducing or delivering for introduction into interstate commerce any drug that is misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B).

II. After Defendants have complied with paragraphs _____ and FDA has notified them pursuant to paragraph ____, Defendants shall retain an independent person or persons (the "auditor") to conduct audit inspections of ___'s drug manufacturing operations not less than once every six (6) months for a period of no less than five (5) years. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to any of ___'s officers or employees or their immediate families and may, if _____chooses, be the same person or persons described as the CGMP expert and/or unapproved new drug expert, as set forth in paragraphs ____.

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations therefrom ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) calendar days after the date the audit inspection(s) is completed. If audit reports identify deviations from the Act, its implementing regulations, and/or this Decree, FDA may, in its discretion, require

that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any adverse observations, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the audit report observations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) business days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule") and provide justification describing why the additional time is necessary. The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance will FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

NEW DRUG/MONOGRAPH

I. Before Defendants may commence manufacturing or distributing any new drug product or continue the manufacture or distribution of any previously distributed drug that is a new drug within the meaning of 21 U.S.C. § 321(p), Defendants shall first notify FDA in writing of their intention to do so, and shall also do the following:

A. For any drug that is an OTC drug and is not manufactured and labeled in strict conformance with an applicable OTC monograph under the terms of subparagraph_____, Defendants shall demonstrate to FDA that the drug is the subject of either (1) an approved application filed under 21 U.S.C. § 355(a) or § 355(j), or (2) an effective investigational new drug application filed under 21 U.S.C. § 355(i). In no event may Defendants distribute a drug product that is not the subject of an approved application under 21 U.S.C. §§ 355(a) or (j), or the subject of an effective investigational new drug application under 21 U.S.C. § 355(i), which must explicitly authorize manufacture of the drug at Defendants' facility;

B. If the product purports to be an OTC monograph drug as described in paragraph _____, Defendants may not distribute such drug unless and until:

1. Defendants retain, at Defendants' expense, an independent person or persons (the "drug monograph expert"), who is without any personal or financial ties (other than the agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to review the labeling of Defendants' OTC drug(s) to determine whether such product complies with the applicable OTC drug monograph and other labeling requirements of the Act and FDA regulations. Defendants shall notify FDA in writing of the identity and qualifications of the drug monograph expert as soon as they obtain such expert;
 2. The drug monograph expert performs a comprehensive review of the OTC drug and the drug's proposed labeling to determine whether the product strictly conforms to an applicable FDA OTC monograph and all labeling requirements, including 21 C.F.R. Part 201, and that the OTC drug is not otherwise misbranded;
 3. The drug monograph expert certifies in writing to FDA that: (a) he or she has reviewed the OTC drug and its labeling; (b) the OTC drug and its labeling conform to the requirements of an OTC drug monograph and all applicable labeling requirements, including 21 C.F.R. Part 201; and (c) the OTC drug is not otherwise adulterated or misbranded. As part of this certification, the drug monograph expert shall attach the labeling he or she has received to a full and complete detailed report of the results of his or her review, including, but not limited to, identifying the labeling he or she reviewed and references to the OTC monograph and labeling regulations addressed in the process of conducting the labeling review;
 4. Defendants have provided to FDA any additional information requested by FDA after FDA's review of the drug monograph expert's certification pursuant to subparagraph _____; and
 5. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs _____, the Act, and the applicable regulations related to OTC drug products. In no circumstance may FDA's silence be construed as a substitute for written notification. If FDA finds, after issuance of this notification, that Defendants are not in compliance with subparagraphs _____, the Act, or applicable regulations related to OTC drug products, Defendants, upon notification from FDA, shall immediately take whatever action that FDA specifies.
- II. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data prepared or submitted by defendants, the expert, the auditor, or any other information, that defendants have failed to comply with any provision of this Decree, or have

violated the Act, its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree or the Act, FDA may, as and when it deems necessary, order defendants in writing to take appropriate action, including, but not limited to, one or more of the following actions:

- A. Cease manufacturing, processing, packing, labeling, holding, and distributing any or all drug(s);
- B. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;
- C. Submit additional reports or information to FDA;
- D. Recall specified drug products released or distributed by defendants or that are under the custody and control of defendants' agents, distributors, customers, or consumers. Defendants shall bear the costs of such recall(s); and/or
- E. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring defendants into compliance with the Act, its implementing regulations or this Decree.

DEVICE APPROVAL/CLASSIFICATION/CGMP

I. Upon entry of this Decree, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of the contents of this Decree by personal service or otherwise, are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly designing, manufacturing, processing, packing, repacking, labeling, holding, distributing, importing into or exporting from the United States of America, any device, unless and until:

- A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute devices are established, operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the Quality System regulation prescribed in 21 C.F.R. Part 820.
- B. Defendants select and retain at their expense an independent person or persons (the "Expert"), to conduct inspections of Defendants' operations and to review Defendants' procedures and methods for designing, manufacturing, processing, packing, repacking, labeling, holding, and distributing devices, to determine whether their methods, facilities, and controls are operated and administered in conformity with the Act, its implementing regulations, and this Decree. The Expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without

personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or their immediate families. Defendants shall notify FDA in writing of the identity of the Expert within ten (10) calendar days of retaining such Expert.

C. The Expert shall perform a comprehensive inspection of Defendants' operations and certify in writing to FDA: (1) that he or she has inspected Defendants' facilities, processes, and controls; (2) whether Defendants have corrected all violations set forth in FDA's Inspectional Observations (Forms FDA 483) from all prior FDA inspections since _____; and (3) based upon this comprehensive inspection, whether Defendants' operations are operated in conformity with the Act, its implementing regulations, and this Decree. The Expert's certification report shall encompass, but not be limited to, an evaluation of the following:

1. Defendants' compliance with 21 U.S.C. §§ 351(h), 360j(f)(1), 352(t)(2), and 352(o), and 21 C.F.R. Parts 803 and 820;
2. Defendants' procedures for its Corrective and Preventive Action ("CAPA") system including, but not limited to: analyzing quality data to identify existing and potential causes of nonconforming product and other quality problems; investigating the causes of nonconformities relating to product, processes, and the quality system; identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; verifying or validating corrective and preventative actions to ensure such actions are effective and do not adversely affect the finished device; implementing and recording changes in methods and procedures as needed to correct and prevent quality problems; conducting and documenting adequate failure investigations; and implementing an effective complaint handling system;
3. Defendants' design control system, including the design change control process; and
4. Defendants procedures to adequately control received or purchased products to verify conformance to product specifications.

D. Defendants report to FDA in writing the actions that they have taken to: (1) correct all violations brought to Defendants' attention by the Expert and/or set forth in FDA's Inspectional Observations from all prior FDA inspections since _____; and (2) ensure that the methods used in, and the facilities and controls used for designing, manufacturing, processing, packing, repacking, labeling, holding, and distributing devices are operated and administered and will be continuously operated and administered in conformity with the Act, its implementing regulations, and this Decree.

E. FDA representatives inspect Defendants' operations to determine whether the requirements of this Decree have been met, and whether Defendants' operations

are otherwise operated in conformity with current good manufacturing practice, the Act, and its implementing regulations.

F. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs _____ of this Decree.

II. Before Defendants may commence designing, manufacturing, or distributing any device, they shall first notify FDA in writing of their intent to do so, and shall demonstrate to FDA that the device is either (a) the subject an approved application for premarket approval pursuant to 21 U.S.C. § 360e(a); (b) the subject of a cleared premarket notification pursuant to 21 U.S.C. § 360(k); or (c) is exempt from the premarket approval/clearance requirements. Defendants shall not commence distributing any device prior to receiving written notification from FDA that the device appears to be in compliance with this paragraph. In no circumstances may FDA's silence be construed as a substitute for written notification.

III. After Defendants have complied with paragraphs _____ and FDA has notified Defendants in writing pursuant to paragraph _____, Defendants shall retain an independent person or persons (the "Auditor") at Defendants' expense to conduct audit inspections of Defendants' operations not less than once every six (6) months for a period of one (1) year and not less than once every twelve (12) months for a period of four (4) years thereafter, for a total of five (5) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to Defendants' officers or employees or their immediate families. The Auditor may be the same person or persons described as the Expert in paragraph ____.

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants' operations are conducted and administered in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than twenty (20) calendar days after the date the audit inspections are completed. If any Audit Reports identify any deviations from the Act, its implementing regulations, and/or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at their facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty (30) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is

necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. That Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved Correction Schedule. Within thirty (30) calendar days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observation(s). Within five (5) calendar days of the beginning of that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected.

IV. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analysis of samples, a report or data prepared or submitted by Defendants, the Expert, or the Auditor pursuant to this Decree, or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions. Such actions may include, but are not limited to, the following:

- A. Cease designing, manufacturing, processing, packing, repacking, labeling, holding, storing, distributing, installing, servicing, importing, and/or exporting devices;
- B. Revise, modify, or expand any report(s) prepared pursuant to the Decree;
- C. Submit additional notifications, reports, or any other materials or information to FDA;
- D. Recall, at Defendants' sole expense, adulterated or misbranded devices or components therein manufactured, distributed, and/or sold by Defendants or that are under the custody and control of Defendants' agents, distributors, customers, or consumers;
- E. Issue a safety alert, public health advisory and/or press release; and/or
- F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with Act, its implementing regulations, and this Decree.

NO PMA/NO 510K

I. Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or

otherwise, are enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, introducing or delivering for introduction into interstate commerce (including foreign commerce) the ____ or any other device that is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), unless and until:

A. An approved investigational device exemption ("IDE") by FDA, filed under 21 U.S.C. § 360j(g) and 21 C.F.R. § 812, for such device is in effect, and the use and distribution of the device conforms strictly to those requirements; or

B. There is an FDA approved application for premarket approval (PMA) filed under 21 U.S.C. § 360e; or

C. FDA has received a premarket notification as required by 21 U.S.C. § 360(k) (also referred to as 510(k) submission) for the device and has advised Defendants in writing pursuant to 21 U.S.C. § 360c(i)(1)(A) that the device is substantially equivalent to a predicate device.

II. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate corrective actions, including, but not limited to, the following:

A. Cease all manufacturing, processing, packing, repacking, labeling, holding, and/or distributing any or all device(s);

B. Recall, at Defendant's expense, any device that is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Submit any application or any supplement to an existing device application to FDA;

F. Issue a safety alert; and/or

G. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

EVICE CGMP

I. Upon entry of this Decree, Defendants and each of their officers, directors, agents, employees, representatives, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise, are enjoined from manufacturing, processing, packing, labeling, and distributing any device (including components) unless and until Defendants:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and distribute devices are established, operated, and administered in compliance with the requirements of CGMP and the QS regulation, 21 C.F.R. Part 820, including but not limited to the following:

1) Establishing and implementing adequate written procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria;

2) Establishing and implementing adequate written procedures to control product that does not conform to specified requirements;

3) Establishing and implementing adequate quality requirements that must be met by suppliers, contractors, and suppliers, and adequate written procedures to ensure that all purchased or otherwise received products and services conform to specified requirements;

4) Developing, conducting, controlling, and monitoring production processes to ensure that device conform to their specifications;

5) Adequately validating processes whose results cannot be fully verified by subsequent inspection and testing, and establishing and implementing adequate written procedures for monitoring and controlling process parameters for validated processes to ensure that specified requirements continue to be met;

6) Establishing and implementing adequate written procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality;

7) Establishing and implementing adequate written procedures to control environmental conditions that could reasonably be expected to have an adverse effect on product quality;

8) Establishing and implementing adequate requirements for the health, cleanliness, personal practices, and clothing of personnel;

9) Establishing and implementing adequate written procedures for identifying, documenting, validating or verifying, reviewing, and approving design changes prior to their implementation;

10) Establishing and implementing adequate design validation requirements to ensure that devices conform to defined user needs and intended uses; and

11) Establishing and implementing adequate written procedures for identifying employee training needs and for ensuring that all personnel are trained to adequately perform their assigned responsibilities.

B. Defendants develop and implement adequate written Medical Device Reporting (MDR) procedures in compliance with 21 C.F.R. Part 803.

C. Defendants recall at their own expense _____ [which devices from which time frame?]

D. Defendants select and retain, at Defendants' expense, an independent person or persons (the "expert(s)"), who is qualified by education, training, and experience to evaluate whether Defendants are in compliance with CGMP/QS regulation requirements as set forth at 21 C.F.R. Part 820 and the MDR reporting requirements set forth at 21 C.F.R. Part 803. The expert(s) shall be without personal or financial ties (other than the consulting agreement between the parties) to any officer or employee of Defendants or their immediate families. Defendants shall notify FDA in writing of the identity of the expert(s) as soon as they retain such expert(s), and the expert(s) shall:

1) Determine whether Defendants are in compliance with the CGMP/QS regulation requirements as set forth at 21 C.F.R. Part 820 and the MDR requirements set forth at 21 C.F.R. Part 803; and

2) Provide FDA with a complete and adequate written evaluation of Defendants' compliance with CGMP and 21 C.F.R. Parts 820 and 803.

E. Defendants submit an adequate written report of all corrections Defendants have made to come in to compliance with the requirements of the Act and 21 C.F.R. Parts 820 and 803.

F. Defendants submit a written report to FDA documenting what steps have been taken to ensure that Defendants' employees and managers are adequately trained in the CGMP/QS regulation and MDR requirements applicable to their assigned responsibilities and positions.

G. The expert(s) has certified to FDA in writing that Defendants are in compliance with the Act, CGMP, and 21 C.F.R. Parts 820 and 803.

H. Duly authorized FDA representatives have made inspections, as and when FDA deems necessary and without prior notice, of Defendants' facilities, including buildings, equipment, personnel, finished and unfinished materials, containers and

labeling, and all records relating to the manufacturing, packing, labeling and distributing of devices to determine whether the requirements of paragraph _____ of this Decree have been met. Such inspection shall commence no later than _____ days after receipt of the reports and certifications pursuant to paragraph _____ above; and

I. FDA notifies Defendants in writing that they may commence manufacturing, packing, labeling, and distributing medical devices.

DRUG (OR DEVICE) CGMP

I. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any articles of drug unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in compliance with CGMP. 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to inspect Defendants' drug manufacturing facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the CGMP expert as soon as they retain such expert;

C. The CGMP expert performs a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, pack, label, hold, and distribute drugs to determine whether they are in compliance with CGMP. This inspection shall include, at a minimum, the following:

(1) An evaluation as to whether the Defendants have established a comprehensive written quality assurance (QA) and quality control (QC) program (QA/QC program) that is adequate to ensure continuous compliance with applicable laws and regulations.

(2) The CGMP expert shall determine whether the QA/QC program, at a minimum:

- a. Addresses all facets of compliance monitoring and trend analyses, and internal audit procedures, and confirms that Defendants' Quality Unit is adequately trained and staffed to evaluate CGMP compliance and prevent and correct future deviations from CGMP;
- b. Includes procedures to ensure that the Defendants, in a timely manner, thoroughly investigate any unexplained discrepancy or the failure of a batch of drug or its components to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy, and to take required and timely corrective actions for all products that fail to meet their specifications;
- c. Establishes mechanisms to ensure that written standard operating procedures (SOPs) specifying the responsibilities and procedures applicable to QA or QC personnel are updated, followed, and periodically reviewed by the Quality Unit to ensure that they reflect current and CGMP compliant-practices;
- d. Includes written SOPs necessary to ensure that all facets of compliance monitoring are reviewed and controlled by QA personnel; and
- e. Includes written SOPs to ensure that the Defendants' QA personnel participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations and/or problems and there are systems to ensure that such written SOPs are continuously followed;

D. The CGMP expert certifies in writing to FDA that:

- (1) He or she has inspected Defendants' facilities, methods, processes, and controls;
- (2) All CGMP deviations brought to Defendants' attention since _____ by FDA, the CGMP expert, or any other source, including but not limited to any experts hired prior to the entry of this Decree, have been corrected; and
- (3) Such facilities, methods, processes, and controls are in compliance with the requirements of CGMP. As part of this certification, the CGMP expert shall include a full and complete detailed report of the results of his or her inspection;

E. Defendants report to FDA in writing the actions they have taken to:

(1) Correct the CGMP deviations brought to Defendants' attention by FDA, the CGMP expert, and any other source, including but not limited to any experts hired prior to the entry of this Decree; and

(2) Ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP.

F. Defendants recall and destroy in accordance with the procedures provided in paragraph ____ all drugs that they manufactured, processed, packed, labeled, held, or distributed prior to _____;

G. FDA representatives inspect Defendants' facilities to determine whether the requirements of this Decree have been met, and whether Defendants' facilities are operating in conformity with CGMP, the Act, and its implementing regulations; and

H. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs _____. In no circumstance will FDA's silence be construed as a substitute for written notification.

II. Within fifteen (15) calendar days of entry of this Decree, Defendants shall, under FDA supervision, destroy all drugs in Defendants' possession, custody, and/or control that are adulterated because they were not manufactured, processed, packed, labeled, held, and/or distributed in accordance with CGMP. Defendants shall reimburse FDA for the supervision of the destruction, including Defendants' destruction of products since _____, and prior to entry of this Decree, at the rates set forth in paragraph ____ of this Decree. Defendants shall not dispose of any drugs in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969.

III. After Defendants have complied with paragraphs _____ and FDA has notified them pursuant to paragraph _____, Defendants shall retain an independent person or persons who shall meet the criteria described in paragraph _____ to conduct audit inspections of their drug manufacturing operations no less frequently than once every six (6) months for a period of no less than five (5) years (hereinafter, "auditor"). If Defendants choose, the auditor may be the same person or persons retained as the CGMP expert in paragraph _____.

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with CGMP and identifying any deviations from CGMP ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered

contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the audit inspection(s) is completed. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendants are not in compliance with CGMP, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance will FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

IV. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, the CGMP expert, the auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated CGMP, the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, CGMP, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease all manufacturing, processing, packing, labeling, holding, and/or distributing any or all drug(s);

B. Recall, at Defendants' own expense, any drug that is adulterated or otherwise in violation of this Decree, CGMP, the Act, or its implementing regulations;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Issue a safety alert; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with this Decree, CGMP, the Act, or its implementing regulations.

TISSUE RESIDUE

I. Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who have received notice of this Decree, are hereby permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly: introducing and causing to be introduced into interstate commerce, and delivering and causing to be delivered for introduction into interstate commerce, any article of food, within the meaning of 21 U.S.C. § 321(f), consisting of animals and their edible tissues; and, subject to paragraph____, administering any new animal drug, within the meaning of 21 U.S.C. § 321(v), to any animal while such drug is held for sale after shipment in interstate commerce, unless and until the following occur:

A. Defendants have established and implemented a system that ensures that each of the animals that they acquire, purchase, hold, transport, sell, consign, or distribute is individually and permanently identified by tag number;

B. Defendants have established and implemented a written record-keeping system that prevents them from selling, consigning, or distributing animals whose edible tissue contains new animal drugs in amounts above the levels permitted by law. This system shall include, but not be limited to, keeping written records on every animal to which Defendants administer drugs. These records shall include, at a minimum: (1) the identity of each animal that Defendants medicate; (2) the date of each administration of each drug to each animal; (3) the name of each drug administered; (4) the dosage of each drug administered; (5) the route of administration of each drug; (6) the written order of a licensed veterinarian for each drug used, if applicable; (7) the name of the person administering each drug; (8) the established withdrawal period for each drug administered; (9) the date the withdrawal period will terminate for each drug; (10) the date each medicated animal is shipped for slaughter or leaves Defendants' control; and (11) the name and address of the purchaser, consignee, or recipient of each medicated animal that is shipped for slaughter or leaves Defendants' control;

C. Defendants have established and implemented a system that ensures that their use of new animal drugs conforms to the uses approved by the United States Food and Drug Administration ("FDA") as set forth in the drugs' approved labeling or, for new animal drugs used in an extra-label manner, to the lawful written orders of a licensed veterinarian and in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21 C.F.R. Part 530.

This system shall include, at a minimum, measures to prevent: (1) the use of drugs in Defendants' animals that are not approved for use in that species or not approved for the disease or other condition for which the animal is being medicated, unless such use is in accordance with the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and is in compliance with 21 C.F.R. Part 530; (2) the administration of drugs in excess of the approved dosage, unless such administration is in accordance with the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and is in compliance with 21 C.F.R. Part 530; (3) the administration of drugs by a non-approved route unless such administration is in accordance with the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and is in compliance with 21 C.F.R. Part 530; and (4) the sale and delivery for slaughter of medicated animals before the expiration of the withdrawal period, as specified in the approved labeling or, for new animal drugs used in an extra-label manner, in the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in compliance with 21 C.F.R. Part 530);

D. Defendants have established and implemented a drug inventory and accountability system that prevents them from selling, consigning, or distributing animals with illegal new animal drug residues. This system shall include a written record for each drug that Defendants purchase or receive for medicating their animals, which record shall include, at a minimum: (1) the name of the drug; (2) the date of purchase or receipt of the drug; (3) the quantity, strength, and form of the drug; (4) the expiration date of the drug; (5) the name and address of the seller or supplier of the drug; (6) the date each drug is administered; and (7) the amount and method of each administration of each drug. In addition, the inventory and accountability system shall include periodic checks of inventory and records, no less frequently than once every fourteen (14) calendar days, to ensure that records accurately document the drugs currently on hand and the disposition of all drugs purchased or received;

E. Defendants have established and implemented a quarantine or segregation system that ensures ready distinction between medicated and unmedicated animals and that prevents Defendants from selling, consigning, or delivering for slaughter for use as food any animal with illegal new animal drug residues;

F. Defendants have established and implemented a system that ensures that each animal that has been medicated is not directly or indirectly sold, consigned, or delivered for immediate or ultimate slaughter before expiration of the withdrawal period (specified in the approved labeling or, for new animal drugs used in an extra-label manner, in the lawful written order of a licensed veterinarian and in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21 C.F.R. Part 530). This system shall also ensure that each purchaser, consignee, or recipient receives, prior to accepting any animal, a written statement from Defendants certifying either that any animal that has been

medicated has also been withdrawn for the appropriate time period or that the animal has not been medicated. This written statement shall also include the date(s) on which the animal was medicated, each drug with which the animal was medicated, the required withdrawal period for each drug, and the date(s) on which the withdrawal period(s) expired. Defendants shall, prior to selling any animal, obtain the signature of the purchaser, consignee, or recipient documenting date of receipt of the statement from Defendants. Defendants shall keep, as part of their records, a copy of the signed written statement described in this paragraph;

G. Defendants have established and implemented a system to identify the source of each animal that they purchase or transport and to document whether the animal has been medicated, the date of medication, the drug used, and the withdrawal period for the drug;

H. Defendants have reported to FDA in writing the steps they have taken to comply with paragraphs _____;

I. FDA has inspected Defendants' operations, including all records relating to the medication, purchase, sale, consignment, and distribution of food-producing animals;

J. Defendants have paid for the costs of the inspections, as described in paragraph _____; and

K. FDA has notified Defendants in writing that they appear to be in compliance with the requirements of paragraphs _____ of this Decree

II. Prior to obtaining written notification from FDA as specified in paragraph _____, Defendants may administer drugs to an ill food-producing animal that they own, but only after the animal has been examined by a licensed veterinarian and the veterinarian has diagnosed the animal and prescribed that drug for that animal. Within ten (10) calendar days after the drug is administered to Defendants' animals pursuant to this paragraph, Defendants shall provide FDA with copies of the veterinarian's diagnosis, prescription, and receipts for treatment (or the equivalent)

III. Defendants shall maintain all records described in paragraph _____ for each animal for a period of at least two (2) years after the date that the animal is sold, consigned, or delivered for slaughter. These records shall be made available immediately to FDA upon request for purposes of inspection and copying.

IV. After Defendants receive written notification from FDA as specified in paragraph _____, Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, are permanently restrained and enjoined from directly or indirectly doing and causing to be done any of the following acts:

A. Introducing and delivering for introduction into interstate commerce any article of food, within the meaning of 21 U.S.C. § 321(f), that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii) or 342(a)(4);

B. Administering any article of drug, within the meaning of 21 U.S.C. 321(g), to any food-producing animal unless the administration conforms to the drug's labeled conditions for use or to the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in compliance with 21 C.F.R. Part 530;

C. Doing any act with respect to any article of drug, within the meaning of 21 U.S.C. § 321(g), if the act is done while such drug is held for sale after shipment in interstate commerce and results in the drug being adulterated within the meaning of 21 U.S.C. § 351(a)(5); and

D. Failing to implement and continuously maintain the requirements of this Decree.

V. Upon request, Defendants shall promptly provide any information and records to FDA regarding the sale, consignment, distribution, or medication of any animal.

VI. If, based on the results of any inspection or analysis conducted after the inspection described in paragraph _____ or any other information, FDA finds that any Defendant is not in compliance with the requirements of this Decree, the Act, and FDA regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the non-compliance and may require that Defendants immediately take one or more of the following actions:

A. Cease selling and delivering, and causing to be sold and delivered, any article of food within the meaning of 21 U.S.C. § 321(f);

B. Cease administering to animals any new animal drug, within the meaning of 21 U.S.C. § 321(v), except under the terms specified in paragraph ____; and

C. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the Act, and FDA regulations, including, but not limited to, requiring that Defendants re-institute or re-implement any of the requirements in paragraph ____ of this Decree.

Upon receipt of such notification, Defendants shall immediately and fully comply with the terms of the notice. Any cessation of operations or other action ordered by FDA as described above shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the terms of this Decree and that they may resume operations.

Animal Drug CGMP

I. Upon entry of this Decree, the defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and all persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly and indirectly manufacturing, processing, packing, labeling, holding, and distributing any animal drug at their facilities located at _____ (and any other location or any new location at which the defendants manufacture, process, pack, label, hold, or distribute animal drugs), unless and until all the following occur:

A. The defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute animal drugs are established, operated, and administered in compliance with CGMP requirements within the meaning of 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

B. The defendants establish and implement a quality assurance and quality control program to ensure that the methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute animal drugs are established, operated, and administered in continuous compliance with CGMP. The defendants shall assign responsibility and authority for monitoring quality assurance and quality control at the defendants' facilities on a continuous basis to an individual who is appropriately qualified;

C. The defendants retain, at their expense, an independent person or persons (the "expert"), to make inspections of their animal drug manufacturing operations to determine whether their methods, facilities, and controls are operated and administered in conformity with CGMP. The expert shall be qualified by education, training, and experience to conduct the inspections, and shall be without personal or financial ties (other than a consulting agreement) to the defendants or their immediate families. The defendants shall notify the United States Food and Drug Administration (FDA) in writing of the identity and qualifications of the expert as soon as the defendants retain the expert;

D. The expert performs a comprehensive inspection of the defendants' animal drug manufacturing operations. The expert shall determine whether the defendants' facilities and the methods and controls used to manufacture, process, pack, label, hold, and distribute animal drugs are in compliance with CGMP. The expert shall also evaluate whether the defendants have established and implemented adequate quality assurance and quality control measures to ensure continuous compliance with CGMP;

E. The expert certifies in writing to FDA that: (1) he or she has inspected the defendants' animal drug manufacturing operations; (2) all CGMP deviations brought to the defendants' attention by FDA since _____, or by the expert, or through any other source have been corrected; and (3) the defendants' facilities, methods, and

controls are in compliance with CGMP. Among others, the CGMP deviations previously brought to the defendants' attention by FDA relate to the requirements in: 21 C.F.R. §§ 211.22, 211.25(a), 211.42(c)(10)(v), 211.67(a), 211.67(b), 211.100(a), 211.100(b), 211.110(a), 211.113(b), 211.160(b), 211.160(b)(4), 211.165(d), 211.165(e), 211.165(f), 211.166(a)(3), 211.170(b), and 211.192. As part of the expert's certification, the expert shall include a complete and detailed written report with the results of his or her inspection;

F. The defendants report to FDA in writing the actions they have taken to (1) correct the CGMP deviations brought to their attention by FDA, the expert, and any other source, and (2) ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing animal drugs at their facilities will remain in continuous compliance with CGMP;

G. The defendants recall, as FDA deems necessary, all animal drugs that are within the possession, custody, or control of the defendants and their distributors;

H. The defendants destroy, under FDA supervision, such in-process materials and finished animal drug products as FDA shall designate that were manufactured, processed, packed, held, labeled, or distributed at the defendants' facilities, and are within the defendants' possession, custody, or control, including all animal drugs to be recalled pursuant to Paragraph _____. The defendants shall not dispose of animal drugs in a manner contrary to any federal, state, or local laws, including the National Environmental Protection Act of 1969;

I. FDA, in its discretion and without prior notice, inspects the defendants' facilities to determine whether the defendants are operating their facilities in conformity with the Act, CGMP, and this Decree;

J. The defendants pay the costs of any supervision, inspections, analyses, examinations, and reviews that FDA deems necessary to evaluate the defendants' compliance with the terms of Paragraph ____; and

K. FDA notifies the defendants in writing that they appear to be in compliance with the requirements set forth in Paragraphs _____ and that they are authorized to resume manufacturing, processing, packing, labeling, holding, and distributing animal drugs

II. Upon resuming operations after completing the requirements in Paragraph ____, the defendants shall meet the following requirements:

A. The defendants shall retain an independent person or persons (the "auditor") to conduct audit inspections of their animal drug manufacturing operations not less than once every six (6) months for a period of five (5) years. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without

personal or financial ties (other than the consulting agreement) to the defendants or their immediate families. If the defendants choose, the auditor may be the same person or persons retained as the expert in Paragraph ____.

B. At the conclusion of each audit inspection, the auditor shall prepare a written audit report (the “audit report”) analyzing whether the defendants are in compliance with the Act, CGMP, and this Decree, and identifying any deviations from CGMP (“audit report observations”). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by the defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to the defendants and FDA by courier service or overnight delivery service, no later than ten (10) business days after the date the audit inspections are completed. If any audit report identifies CGMP deviations, FDA may, in its discretion, require that the five (5)-year auditing cycle be extended or begin anew. In addition, the defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

C. If an audit report contains any audit report observations indicating that the defendants are not in compliance with the Act, CGMP, and this Decree, the defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies the defendants that a shorter time period is necessary. If, after receiving the audit report, the defendants believe that correction of the deviations will take longer than thirty (30) calendar days, the defendants shall, within five (5) business days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections (“correction schedule”) and provide justification describing why the additional time is needed. The correction schedule must be reviewed and approved by FDA in writing prior to implementation by the defendants. The defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of the defendants’ receipt of an audit report, unless FDA notifies the defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by the defendants to correct the audit report observations. Within ten (10) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

III. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, report, or other information, that the defendants have failed to comply with any provision of this Decree, have violated CGMP or the Act, or that additional corrective actions are necessary to achieve compliance with this Decree, CGMP, or the Act, FDA may, as and when it deems necessary, issue a directive notifying the defendants in writing of the noncompliance and ordering the defendants to take appropriate action, including

but not limited to ordering the defendants immediately to take one or more of the following actions:

- A. Cease manufacturing, processing, packing, labeling, holding, and distributing animal drugs unless and until the defendants receive written notification from FDA that the defendants appear to be in compliance with the Decree, CGMP, and the Act, and that the defendants may resume operations;
- B. Recall any and all animal drugs;
- C. Submit additional reports or information to FDA; and
- D. Take any other corrective actions as FDA deems necessary to bring the defendants into compliance with this Decree, CGMP, and the Act, including but not limited to requiring that the defendants re-implement or re-institute any of the requirements of this Decree. The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA. The defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in Paragraph _____ of this Decree.

MEDICATED FEEDS

I. The defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive actual notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing the manufacture, processing, packing, labeling, holding, and distribution at their facilities located at _____ (and any new locations at which the defendants manufacture, process, pack, label, hold, or distribute medicated feeds), of any article of medicated feed unless and until:

- A. The defendants establish, operate, and administer their feed manufacturing methods, facilities, and controls in conformity with the current good manufacturing practice ("CGMP") regulations for medicated feeds, 21 C.F.R. Part 225, and in a manner that ensures that all medicated feeds manufactured by the defendants are in accord with their label specifications and meet the assay limits set forth at 21 C.F.R. § 558.4(d);
- B. The defendants retain a person ("qualified person") who is without any personal or financial ties other than the consulting agreement to the defendants and their families and who, by reason of background, training, and experience, is qualified to

make inspections of medicated feed manufacturing mills to determine whether the established methods, facilities, and controls are operated and administered in conformity with CGMP requirements, as specified in 21 C.F.R. Part 225; the defendants notify the United States Food and Drug Administration ("FDA") in writing of the person's identity and qualifications as soon as they retain the person; the qualified person inspects _____ and the manner of operating_____, and any new locations at which the defendants manufacture medicated feeds; and the qualified person certifies in writing to FDA that the requirements set forth in paragraph ____of this Decree have been met;

C. The defendants retain a laboratory other than one affiliated with _____ that, by reason of background, staff training, and experience, is qualified to analyze medicated feeds to determine whether the medicated feeds contain each drug that they purport or are represented to contain and said drug(s) meet(s) the assay limits set forth at 21 C.F.R. § 558.4(d); the defendants notify FDA in writing of the laboratory's identity as soon as they retain the laboratory; the defendants provide the laboratory with samples of each medicated feed, and the corresponding labels, manufactured at _____ that is still in the possession or under the custody or control of the defendants at the time this Decree is filed; and the laboratory analyzes all samples and simultaneously provides FDA and the defendants the results of all tests performed on the samples, along with the labels, and certifies in writing whether the samples contain each drug that they purport or are represented to contain and whether such drug(s) meet(s) the assay limits set forth at 21 C.F.R. § 558.4(d);

D. The defendants, under the supervision of and in accordance with methods acceptable to FDA, recall, destroy, or otherwise bring into compliance with FDA regulations and the Act all adulterated lots of medicated feed identified by the laboratory analyses described in the preceding paragraph, including, when FDA deems necessary, medicated feed distributed to the defendants' agents, distributors, customers, or consumers;

E. The defendants report in writing to FDA all actions they have taken to ensure that the requirements in paragraph _____ of this Decree have been met;

F. FDA, as it deems necessary to evaluate the defendants' compliance with the terms of this Decree, conducts inspections of the defendants' facilities;

G. The defendants pay the costs of any supervision, inspection, analyses, examination, and review that FDA deems necessary to evaluate the defendants' compliance with the terms of this Decree; and

H. FDA notifies the defendants in writing that the defendants appear to be in compliance with the requirements in paragraphs_____, FDA regulations, and the Act.

II. Upon resuming operations after completing the requirements of paragraph____, the defendants shall have the laboratory retained pursuant to paragraph _____ (or a similarly qualified laboratory) conduct the following analyses:

A. During the first six months of such operation, the defendants shall – for each drug and drug combination the defendants use to manufacture medicated feeds – collect and have tested at least three representative samples of medicated feed to determine whether the drug(s) meet(s) the assay limits set forth at 21 C.F.R. § 558.4(d). The sample collection and testing for each drug and drug combination the defendants use to manufacture medicated feeds shall be conducted under the following conditions:

1. The representative samples of medicated feed shall be collected and tested at periodic intervals throughout the six-month period;

2. One of the representative samples of medicated feed shall be collected from the batch that contains the first use of the drug or drug combination during the six-month period;

3. The defendants shall have the laboratory simultaneously provide FDA and the defendants all results of the analyses; and

4. The defendants shall investigate and take corrective action for all medicated feeds determined by laboratory analyses to be outside the assay limits set forth at 21 C.F.R. § 558.4(d). All investigation and corrective action regarding medicated feeds found to be outside the assay limits set forth at 21 C.F.R. § 558.4(d) shall be conducted pursuant to 21 C.F.R. § 225.58(d) and (e);

B. During the subsequent six-month period, the defendants shall repeat all of the requirements set forth at paragraph _____; and

C. After the first year, the defendants shall follow the medicated feed sampling and testing requirements set forth at 21 C.F.R. § 225.58

III. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analysis of a sample or samples, or other information, that the defendants have failed to comply with any provision of this Decree, have violated FDA regulations or the Act, or that additional corrective actions are necessary to achieve compliance with this Decree, FDA regulations, or the Act, FDA may, as and when it deems necessary, notify the defendants in writing of the noncompliance and order the defendants to take appropriate action, including, but not limited to, ordering the defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, or distributing any medicated feeds;

B. Recall all articles of medicated feed distributed at _____ (or any new location), including feed distributed to the defendants' agents, distributors, customers, or consumers; or

C. Take any other corrective actions as FDA deems necessary to bring the defendants into compliance with this Decree, FDA regulations, and the Act, including, but not limited to, requiring that the defendants re-institute or re-implement any of the requirements in paragraphs _____ of this Decree. Upon receipt of such notification, the defendants shall immediately and fully comply with the terms of the notice. In the event that the defendants disagree with the terms of the notice, the defendants may appeal to this Court but shall continue to immediately and fully comply with the terms of the notice unless and until the Court modifies or overturns the notice. The defendants shall pay all costs of such recalls and corrective actions, including the costs of FDA supervision, inspections, analyses, examinations, review, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in paragraph _____ of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

Exhibit 6-19**EXAMPLES OF COMPLAINT PROVISIONS****(Jurisdiction Model)**

In this action, plaintiff, the United States of America, seeks a statutory injunction to restrain defendants, (Firm Name), and (Individual) , from manufacturing and distributing in interstate commerce an adulterated drug in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 301 et seq. Jurisdiction to restrain such violations is granted to the district courts of the United States pursuant to 21 U.S.C. 332(a). This Court also has jurisdiction over this action pursuant to 28 U.S.C. 1331, 1337, and 1345. Venue is proper in this District pursuant to 28 U.S.C. 1391(b) and 1391(c).

(Models of Defendants' Responsibility/Authority--Drug Manufacturer)

Defendant (Firm) is a corporation incorporated under the laws of the Commonwealth of Pennsylvania with its principal place of business at (street address, City, State), within the jurisdiction of this Court

Defendant (Individual), an individual, is the president of (firm), and has overall responsibility for, and authority over, all operations of the corporation, including the manufacture and distribution of drug products

(Individual) performs his duties as president of (firm) at (street address, city, State).

The defendant, _____, an individual, is the Chief Executive Officer of _____. He is responsible for personnel and pharmaceutical operations of the firm. He performs those duties at _____.

The defendant, _____, an individual, is the Treasurer of _____. He is also a principal stockholder in _____. _____ is responsible for deciding whether the firm will market particular drugs. He shares final responsibility with _____ for authorizing financial expenditures. He performs those duties at _____.

(Model of Defendant Responsibility/Authority--Food Warehouse)

The defendant, _____, an individual, is secretary, treasurer, and manager of the corporation, performing his duties at _____. He has responsibility for and authority over the day-to-day operations at the warehouse, including the expenditure of funds for the proper operation and maintenance of the facility.

(Model of Defendants' Business Activities and Related Violations-- Unapproved New Drug)

The defendants have been and are now engaged, at the _____ facility at (Street address, City, State), in repacking, labeling, storing, promoting, and distributing in interstate commerce, the drug " _____, " which defendants promote through the use of literature accompanying (the drug) shipments to be used in the treatment, mitigation, cure, and prevention of various human diseases, including AIDS, lupus, and Parkinson's disease.

(Drug name) is a drug within the meaning of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because, based on the therapeutic claims made by the defendant, it is intended for use in the cure, mitigation, treatment, or prevention of disease in humans.

_____ is a new drug within the meaning of the FD&C Act, 21 U.S.C. 321(p), because it is not generally recognized by qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. There is not now nor has there ever been in effect an approval by the United States Food and Drug Administration (FDA) of an application, filed pursuant to 21 U.S.C. 355(i). _____ is, therefore, an unapproved new drug pursuant to 21 U.S.C. 355(a).

(Model of Defendant's Business Activities and Related Adulterations--Medicated Feeds)

The defendants have been and are now engaged at their plant at Street address, City, State, in manufacturing, processing, packing, labeling, storing, and holding for sale various articles of medicated feed, which articles of medicated feed are drugs within the meaning of 21 U.S.C. 321(g)(1) and new animal drugs within the meaning of 21 U.S.C. 321(w) after shipment of one or more of the components of the feeds have moved in interstate commerce, and in distributing said articles of medicated feed in interstate and intrastate commerce.

Medicated feeds manufactured by defendants are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of 21 U.S.C. 351(a)(2)(B) in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with current good manufacturing practice, 21 CFR 225, to assure that such drugs meet the safety requirements of the Act and have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

Certain medicated feeds manufactured by defendants, including those containing amprolium, lincomycin, and monensin in combination, and monensin, chlortetracycline, and sulfamethazine in

combination, are also adulterated within the meaning of 21 U.S.C. 351(a)(6) while held for sale after shipment of one or more of their components in interstate commerce, in that such feeds bear or contain new animal drugs, 21 U.S.C. 321(w), which are unsafe within the meaning of 21 U.S.C. 360b(a)(2) since no approvals of applications filed pursuant to 21 U.S.C. 360b(b) and 21 U.S.C. 360b(m) are in effect with respect to the use and intended use of such drugs.

Certain medicated feeds manufactured by defendants, including _____ and _____, are also adulterated within the meaning of 21 U.S.C. 351(c) while held for sale after shipment of one or more of their components in interstate commerce, in that their quality and purity fall below or their strength differs from that which they purport and are represented to possess because they do not contain the amount of drug declared on their label.

(Model of Defendants' Business Activities & Related Adulteration--Food Processor)

The defendants have been and are now engaged in processing in-shell pecans into shelled pecan nut meats, a food within the meaning of 21 U.S.C. 321(f). The defendants routinely ship finished shelled nut meats to customers outside the State of _____.

The shelled pecan nut meats being produced by defendants are adulterated within the meaning of 21 U.S.C. 342(a)(4) in that they have been prepared and packed under insanitary conditions whereby they may have become contaminated with filth.

(Another Model; Food Adulteration)

The wheat, when introduced or delivered for introduction into interstate commerce, is adulterated within the meaning of 21 U.S.C. 342(a)(2)(B), in that it bears and contains a pesticide chemical, malathion, which is unsafe within the meaning of 21 U.S.C. 346a in that the malathion is present in excess of the tolerance prescribed for the pesticide chemical on the raw agricultural commodity under 21 U.S.C. 346a(a).

(Another Model; Device Adulteration/Misbranding)

All of the defendants' devices are adulterated within the meaning of 21 U.S.C. 351(h) because the methods used in, and the facilities and controls used for, their manufacture, packing, and storage do not conform to FDA regulations establishing good manufacturing practice requirements, 21 CFR Part 820, promulgated under authority of 21 U.S.C. 360j(f)(1).

Certain of the defendants' in vitro diagnostic devices are misbranded within the meaning of 21 U.S.C. 352(f)(1) in that their labeling lacks adequate directions for use because the data required by regulation, 21 CFR 809.10(a)(5), to support the expiration dates appearing on the labeling of the devices either does not exist or has not been analyzed to verify the expiration period represented.

(Model for Inspectional Evidence--Food Processor)

Two recent inspections of _____ facility by FDA found insect infestation and other insanitary conditions that could cause the flour produced there to become contaminated with filth. During an inspection on April 23 and 24, 2003, moth cocoons and insect webbing were observed on each of the firm's three milling machines, and live insects were seen on walls in the milling room and on floors and walls of the packaging room. Similar insanitary conditions had been observed at a previous inspection on February 9, 2002.

Inspections by the State of _____ have also found continuing insect and rodent activity within _____'s facility. The _____ State Department of Agriculture ("_SDA") has inspected _____ at least five times since 2001 under a federal/state contract with FDA. _SDA investigators observed evidence of insect and/or rodent activity on three of these inspections.

Inspections conducted by FDA on _____, and _____, 20__, at the defendants' facility revealed insanitary conditions substantially similar to those found during the most recent inspection.

(Model for Previous Inspectional Evidence--Drug GMP)

Previous inspections of _____ establish that it has a consistent history of failure to comply with GMP. Inspections conducted by FDA from _____ to _____, 20__, and from _____ to _____, 20__, at the defendants' plant revealed substantially similar, and equally serious, deviations from the GMP regulations as revealed during the _____, 20__, inspection. (Also identify other written notifications given by FDA to the defendants about their violative conduct.)

(Model for Inspectional Evidence--Illegal Sale of Animal Drugs)

On _____, 20__, an FDA investigator inspected the defendants' facility to determine their activities with respect to the sale of prescription veterinary drugs and new animal drugs. A review of sales invoices and other records revealed that the defendants routinely sold prescription veterinary drugs without valid prescriptions, and sold new animal drug Type A medicated articles without having an unrevoked written statement that the purchasers held approved medicated feed applications for the use

of such Type A medicated articles in animal feed. The inspection disclosed that the defendants had made numerous sales of prescription veterinary drugs, including oxytocin, dexamethasone, and Liqueamycin, without a valid prescription or an order from a licensed veterinarian reduced to writing. The defendants had also made four sales of the new animal drug Type A medicated article Mecadox (carbadox) to three consignees for use in animal feed. At the time of these sales, the defendants did not have valid written statements from the purchasers that they were holders of approved medicated feed applications.

(Model for Charging 301(k))

Defendants violate 21 U.S.C. 331(k) by their acts of manufacturing, processing, packing, and holding, and by their acts of causing to be manufactured, processed, packed, and held, articles of food and drug, after one or more of the components of such foods and drugs have been shipped in interstate commerce, all of which acts result in the articles being adulterated as set out in paragraph _____ above, and being misbranded as set out in paragraph _____ above.

(Model for Charging 301(a))

Defendants violate 21 U.S.C. 331(a) by introducing and causing the introduction in interstate commerce of articles of device that are adulterated and misbranded as set forth in paragraph _____.

(Model for Charging 301(d))

The defendant, by introducing or delivering for introduction into interstate commerce _____, an unapproved new drug, has been and is in violation of 21 U.S.C. 331(d).

(Affirming Need for Injunction)

Despite having been warned by FDA that the distribution of _____ violates the Act, the defendants continue to repackage, label, store, distribute, and promote this product in the manner described (in the complaint) above.

(Another Model)

The defendants' history of sanitation control problems demonstrates their unwillingness and/or inability to maintain a sanitary food manufacturing facility. Both FDA and _SDA have warned defendants that the insanitary conditions at their facility might subject them to regulatory action.

Notwithstanding these warnings, and notwithstanding assurances from defendants that the sanitation problems would be remedied, the problems persist.

Based on the defendants' repeated course of conduct, it is evident that unless restrained by order of this Court, defendants may well continue to manufacture and distribute _____ in violation of the Act, 21 U.S.C. 331(a) and 331(k).

(Model Prayers)

WHEREFORE, PLAINTIFF PRAYS:

I. That the defendants, _____, a corporation, and _____, and _____, individuals, and each and all of their officers, agents, representatives, employees, successors or assigns, attorneys, and those persons in active concert or participation with them or any of them, be perpetually restrained and enjoined pursuant to 21 U.S.C. 332(a) from directly or indirectly doing or causing the introduction or delivery for introduction into interstate commerce of any drug that is a new drug within the meaning of 21 U.S.C. 321(p); and from directly or indirectly manufacturing, processing, packing, labeling, or holding for sale, after shipment of one or more of its components in interstate commerce, any drug that is a new drug within the meaning of 21 U.S.C. 321(p), unless and until:

A. An approved application filed pursuant to 21 U.S.C. 355(b) is effective with respect to said drug;

B. An acceptable notice of claimed investigational exemption filed pursuant to 21 U.S.C. 355(i) and regulation 21 CFR 312.1 is on file for such drug; or

C. FDA has advised defendants that the drug is not a "new drug."

II. That the plaintiff be granted judgment for its costs herein, and that the Court grant such other and further relief as the Court deems just and proper.

(Another Model)

WHEREFORE PLAINTIFF PRAYS:

I. That the defendants _____, a corporation, _____, and _____, individuals, and all of their officers, agents, representatives, employees, successors or assigns, attorneys, and all persons in active concert or participation with them or any of them, be preliminarily and perpetually restrained and enjoined from directly or indirectly introducing or causing the introduction into interstate commerce of any device, or

holding for sale any device after shipment of one or more of its components in interstate commerce, unless and until defendants satisfy FDA that:

A. The labeling for the devices is not false or misleading; and

B. The methods, facilities, and controls for manufacturing, processing, packing, and labeling the devices are established, operated, and administered in conformity with FDA's GMP regulations for devices, 21 CFR Part 820.

II. That recalls of devices manufactured by the defendants shall be made as the FDA deems necessary.

III. That the Court award plaintiff its costs herein, and such other and further relief as the Court deems just and proper.

(Another Model)

WHEREFORE PLAINTIFF respectfully requests that this Court:

I. Preliminarily and permanently enjoin the defendants, _____, a corporation, and _____, an individual, and each and all of their directors, officers, agents, representatives, employees, successors or assigns, attorneys, and any and all persons in active concert or participation with them or any of them, from directly or indirectly doing or causing the introduction or delivery for introduction into interstate commerce of any adulterated food which has been received, prepared, packed, or held at the defendants' facility.

II. Order the defendants to recondition or destroy all food under their control, and render their warehouse facility suitable for handling foods, in the manner and to the extent FDA deems necessary.

III. Grant plaintiff its costs and such other further relief as the Court deems just and proper.

(Model Signature Page)

Respectfully submitted,

NAME IN CAPS
Assistant Attorney General
Civil Division

NAME IN CAPS
United States Attorney

NAME IN CAPS
Assistant U.S. Attorney
Mail Address
City, State Zip

OF COUNSEL:

NAME IN CAPS
Chief Counsel
Food and Drug Administration

NAME IN CAPS
Trial Attorney
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

NAME IN CAPS
Attorney
Office of Consumer Litigation
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
(202) 307-0047

Exhibit 6-20**AFFIDAVIT/DECLARATION**

(NOTE: FOR AFFIDAVIT FORM, SEE END OF THIS MODEL)

IN THE UNITED STATES DISTRICT COURT

FOR THE _____ DISTRICT OF _____

UNITED STATES OF AMERICA)

) Civil Action No.

Plaintiff,

v.

_____, INC., a corporation,
NAME IN CAPS, and
NAME IN CAPS, individualsSTATEMENT OF
NAME IN CAPS

Defendants.

State of _____

County of _____

1. I am District/Division/Program Director, _____ Division, _____ Program, Food and Drug Administration, Department of Health and Human Services, Street Address, City, State.

2. I direct and supervise the day-to-day enforcement of the Federal Food, Drug, and Cosmetic Act for the United States Food and Drug Administration, _____ Division/Program, _____ Office of Enforcement and Import Operations (OEIO)/Program which includes the States/Program of _____, _____, _____ and _____.

3. I am familiar with the investigation of Firm, Inc. performed by the _____ Division/Program, and the laboratory at the _____ Office, Food and Drug Administration. The official records of the Food and Drug Administration, contained in the files located in the _____ Division/Program, establish the facts in this statement.

4. Firm, Inc. was incorporated in 1954 under the laws of the State of _____, and is now engaged in the manufacture of prescription and non-prescription drug products (tablets) primarily on the special order of customers who specify the formulation.

5. Firm, Inc., is presently doing business at street address, City, State Zip.
6. Individual A, President of Firm, Inc., presently resides at Street address, City, State.
7. Individual B, Production Manager for Firm, Inc. presently resides at Street address, City, State.
8. Inspection of Firm, Inc. during July 1999 revealed deviations from good manufacturing practices, including improper batch production records. A list of Observations was presented to and discussed with Individual A, who promised that corrections would be made.
9. Inspection of Firm, Inc. during March-April 2000, revealed a continuation of the deviations previously brought to the attention of Individual A. A written List of Observations was presented to Mr. _____, Production Manager, who promised corrections on most of the observations.
10. On July 14, 2000, an Untitled Letter was issued to Individual A informing him that two lots of ascorbic acid tablets, 20214-4 and 20214-5, manufactured by Firm for private label distribution by a consignee in City, State, failed content uniformity testing. Lot 20214-4 contained only 92.2% of the declared ascorbic acid and was therefore also subpotent.
11. Inspection of Firm, Inc. on November 2 through 11, 2001, revealed serious deviations from current good manufacturing practice regulations as they appear in Title 21, Code of Federal Regulations, Parts 210 and 211. At the conclusion of that inspection, a List of Observations, consisting of 54 deviations from good manufacturing practice regulations, a copy of which is appended as Exhibit A, was issued to Individual A and discussed with him and Individual B, Assistant Production Manager. Individual A stated during the discussion that Individual B was hired to assist the firm in complying with current good manufacturing practice regulations. The investigator informed Individual A and Individual B of their responsibilities under the Federal Food, Drug, and Cosmetic Act when manufacturing drug products and the penalties that can be invoked for violating said Act. Individual A stated that he intended to bring Firm, Inc. into compliance with current good manufacturing practice regulations.
12. A sample of sugar coated yellow oval tablets of conjugated estrogen 1.25 mg manufactured by Firm was collected by _____ ORA investigator _____ on November 3, 2001, during the course of his inspection of the firm. Analyses of the drug at the FDA _____ Laboratory and a headquarters laboratory revealed that the product was not only subpotent with respect to total conjugated estrogens (51.7% and 46.6%) but also failed to meet compendial standards for the relative amounts of two constituent estrogens.
13. As a result of the violative inspection November 2 through 11, 2001, a sample of Nitroglycerin tablets, among others, was collected at a consignee in City, State, by the Food

and Drug Administration. Analysis of the sample revealed that seven of thirty tablets failed to meet prescribed potency requirements and on a check analysis three of thirty tablets were not within compendial limits. The article therefore did not conform to United States Pharmacopeia requirements for content uniformity. Furthermore, seventeen of eighteen tablets on original analysis and eighteen tablets on check analysis failed to comply with compendial disintegration requirements. Firm, Inc. was advised of these results and recalled and destroyed the lot.

14. A sample of lot 21244-1 of Potassium Sulfate tablets manufactured by Firm was collected by FDA in November 2001. Analysis revealed that this drug did not meet the requirements for disintegration of an enteric coated tablet as prescribed in the United States Pharmacopeia. Upon the firm's failure to recall this drug, seizure was accomplished on January 27, 2002, in the United States District Court for the _____ District of _____ (Docket #CA _____; FDC _____).

15. On December 23, 2001, a Warning Letter, a copy of which is appended as Exhibit B, was issued to Individual A. This letter outlined deviations from current good manufacturing practice regulations observed during the November 1998 inspection.

16. Inspection of February 1 through 9, 2002, made as a follow-up to the November 1998 inspection, revealed a continued lack of compliance with good manufacturing practice regulations. Numerous deviations from current good manufacturing practice regulations were observed. A List of Observations, a copy of which is appended as Exhibit C, consisting of 79 items was presented to Individual A and discussed with him and Individual B, who was now Production Manager, and four other Firm, Inc. personnel. Individual A stated that he was aware of the seriousness of the situation. Individual A and Individual B agreed to make some corrections, many of them deviations previously called to their attention which they had failed to correct.

17. As a result of the violative inspection of February 1 - 9, 2002, a sample of _____ tablets manufactured by Firm was collected at a consignee in City, State, by FDA. Analysis revealed that the drug was subpotent in declared opium (67.2% original analysis and 64.8% by check analysis) and atropine sulfate (58% original analysis and 69.4% by check analysis). When notified of these results, Individual A stated he would not remove this lot from sale. Upon the firm's failure to recall this drug, seizure was recommended to the United States Attorney for the _____ District of _____.

18. A limited inspection was instituted March 11, 2002, to determine what corrections had been made in the firm's operation based upon the observations called to management's attention in February. Inspection revealed that while a few improvements had been made, there was a continuing lack of compliance with current good manufacturing practice regulations. A List of Observations consisting of 47 items, attached as Exhibit D, was presented to Individual A and discussed with him, with Individual B, and with Dr. _____, President of _____ Associates, Inc., a consultant to Firm, Inc.

19. During the course of the inspection instituted March 11, 2002, the investigators noted that two lots of _____ tablets had been returned by the consignee in City, State, because of visible deterioration.

I declare under penalty of perjury that the forgoing is true and correct.

Executed on _____.

NAME IN CAPS

District/Division/Program Director

If an affidavit, rather than a statement, is to be used, make the following changes:

1. Change the word STATEMENT to AFFIDAVIT.
2. Before item 1. add: " Before me, _____, a Notary Public, personally appeared _____, who, first being duly sworn, deposes and says:"
3. At the end, delete the last sentence and, under the signature add: "Subscribed and sworn to before me in the City and District aforesaid this day of _____ 20__.

Notary Public

The end of the affidavit will then appear as follows:

19. During the course of the inspection instituted March 11, 2002, the investigators noted that two lots of _____ tablets had been returned by the consignee in City, State, because of visible deterioration.

NAME IN CAPS

District/Division/Program Director

Subscribed and sworn to before me in the City and District aforesaid this ____ day of _____ 20__.

Notary Public

Exhibit 6-21**MODEL LETTER BILLING CHARGES**

Sample Number
INJ ____, FDC _____

Date

Firm
Street Address
City, State Zip

Sir/Madam:

The following costs have been incurred by your firm as a result of the Decree of Preliminary Injunction entered by the Court on _____.

Under the terms of that Decree, your firm is required to pay the costs of inspection and analytical work performed by FDA to insure compliance with the terms of the injunction.

Investigator's time	6 hrs. at \$**. ** per hr	\$XXX.XX
Mileage-Gov't car	18 miles at \$0.*** per mile	\$ X.XX
Analyst's time	5 hrs. at \$**. ** per hr	<u>\$XXX.XX</u>
	Total Charges	\$XXX.XX

(* Note: Use rates of reimbursement specified in Consent Decree)

Please remit promptly a money order, bank draft, or certified check for \$XXX.XX, made payable to the United States Treasury, attach to the enclosed copy of this letter, and return to this office.

Sincerely yours,

Director, Compliance Branch
_____ District/Division

Enc: cc this letter

Exhibit 6-22**PETITION FOR ORDER TO SHOW CAUSE**

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF _____

UNITED STATES OF AMERICA,))	
Plaintiff,)	
)	
v.))	Criminal Action No. _____
NAME IN CAPS,)	
and)	
NAME IN CAPS,)	
Corporations,)	
)	
and)	
)	
NAME IN CAPS,)	
NAME IN CAPS,)	
NAME IN CAPS,)	
NAME IN CAPS, and)	
NAME IN CAPS,)	
Individuals,)	
Defendants)	

PETITION FOR ORDER TO SHOW CAUSE WHY DEFENDANTS
SHOULD NOT BE HELD IN CRIMINAL CONTEMPT

Plaintiff, United States of America, hereby moves this Court for an Order to Show Cause why Firm A, Inc. (Firm A), and Firm B, Inc. (Firm B), corporations, and Individual A, Individual B, Individual C, Individual D, and Individual E, individuals (hereafter, collectively, the defendants) should not be adjudged in criminal contempt of a Consent Decree of Permanent Injunction (Decree) entered by this Court on April 25, 1999. In support of this Petition, the United States of America states as follows.

BACKGROUND

1. On April 7, 1999, the United States filed a Complaint for Injunction (1999 Complaint) against named defendants Firm A, Individual A, and another individual not named in this

action, Ex. 1, along with a signed Consent Decree of Permanent Injunction (Decree). Ex. 2. Judge _____ entered the Consent Decree on April 25, 1999. *Id.* Firm A was and is a manufacturer of devices within the meaning of the Federal Food, Drug, and Cosmetic Act (FDCA). 21 U.S.C. § 321(h). The FDCA defines a device as an "instrument, apparatus, implement, machine, ... or other similar or related article, including any component, part, or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man" 21 U.S.C. § 321(h).

2. The 1999 Complaint alleged that Firm A and Individual A were violating the FDCA by introducing or delivering for introduction into interstate commerce devices adulterated within the meaning of 21 U.S.C. § 351(h), and by manufacturing, packing, and storing devices after shipment of one or more of their components in interstate commerce under conditions that resulted in the devices becoming adulterated. 21 U.S.C. §§ 331(a) and (k). At that time, defendants manufactured several devices including, but not limited to, an electrosurgical device (the Electro Probe) and a silicone chin implant (the Axis Implant). See Ex. 1 ¶¶ 6-8. The Electro Probe is used by doctors to control bleeding during various types of surgery; the Axis Implant is used to augment or reconstruct the chin. *Id.* Inspections performed by the Food and Drug Administration (FDA) prior to the filing of the 1999 Complaint revealed that defendants had failed, over a period of several years, to assure that the Electro Probe and Axis Implant were manufactured in conformity with FDA's current good manufacturing practice (CGMP) regulations -- regulations promulgated to assure that devices are safe and effective. See 21 U.S.C. § 360j(f) (1) and 21 C.F.R. Part 820.

3. The Decree permanently enjoined defendants Firm A and Individual A and any and all of their representatives, agents, employees, successors, and those persons in active concert or participation with any of them who received actual notice of the contents of the Decree from "directly or indirectly"

(1) introducing or causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, *any article of device* within the meaning of 21 U.S.C. § 321(h); and

(2) manufacturing, packing, or storing *any article of device* held for sale ... unless and until:

A. The methods used in, and the facilities and controls used for and by defendants for manufacturing, packing, or storing devices comply with the Food and Drug Administration's (FDA) good manufacturing practice (GMP) regulations for devices.

Ex. 2 ¶ I11 (emphasis added).

4. The Decree set forth conditions under which the defendants could resume operations. See Ex. 2 ¶ I11 B-E. Those bound by the Decree could begin shipment of devices in interstate commerce only after:

a. defendants hired an expert consultant to inspect Firm A's manufacturing, packing, and storing systems;

b. defendants certified to FDA that, based upon such inspection, the consultant had concluded that Firm A could in the future manufacture devices in conformity with FDA's CGMP regulations;

c. FDA made such inspections as it deems necessary; and

d. FDA gave defendants written authorization to begin manufacturing and distributing devices. Ex. 2 ¶ III B - E.

5. Approximately one year after the Decree was entered, Firm A certified to FDA that it could manufacture and distribute the Axis Implant in conformity with the law, and FDA provided Firm A written authorization to so do. Ex. 3. FDA did not authorize, and to date has not authorized, the manufacture and delivery of any other Firm A devices, including the Electro Probe.

DEFENDANTS HAD ACTUAL NOTICE OF THE DECREE

6. At the time the 1999 Complaint was filed, defendant Individual A was the President of Firm A and signed the Decree both on behalf of Firm A as its president as well as in his capacity as an individual defendant. Ex. 2 at 10. Upon the Decree's entry, defendant Individual B became Firm A's President, Ex. 4, and he signed a statement dated May 19, 1999, acknowledging receipt of the Decree. Ex. 5.

7. Defendant Individual C was a Firm A employee when the Decree was entered. *Id.* Firm A sent a copy to her by certified mail pursuant to Paragraph IX of the Decree, which

required that Firm A provide copies of the Decree to all its officers and employees. Ex. 2 ¶ IX. She signed for receipt of the Decree on May 25, 1999. Ex. 5.

8. Individual D was also a Firm A employee when the Decree was entered. Id. He signed a statement dated May 19, 1999, stating that he had received a copy of the Decree from Firm A. See Ex. 5.

9. Soon after agreeing to and receiving notice of the Decree, Firm A and Individual B entered into negotiations with FDA to allow Firm A to export at least some of its inventory of pre-Decree devices to Europe under a provision in the Decree that allowed defendants to attempt to bring the devices into compliance with the law. Ex. 6. FDA worked with Firm A and Individual B to assure that any such export complied with the FDCA. Id. and Ex. 7. On October 19, 1999, this effort culminated in Firm A exporting its pre-Decree inventory to Med Dev Europe, an affiliate of Firm A's located in the Netherlands, which later distributed the devices to a company called Device Workshop, also in the Netherlands. Ex. 8.

10. Defendant Individual E was the director of Device Workshop and, therefore, a customer of Firm A's. To lawfully ship adulterated devices to Device Workshop, Firm A had to establish, among other things, that the devices accorded to Device Workshop's specifications. See 21 U.S.C. § 381(e) (1) (A). To do so, FDA suggested that Firm A inform Individual E that the devices he would receive had not been manufactured in conformity with CGMP. See Ex. 6, June 26, 1999, letter to Mark Able from FDA, at 3. Firm A did so and, on October 2, 2000, Individual E sent a letter to Firm A stating that he had read and understood the Decree. Ex. 9.

11. During the negotiations between Firm A and FDA over the circumstances of export of its inventory, Firm A requested permission to distribute in the United States components of some of its devices, including the Electro Probe. Ex. 7, July 24, 1999, letter to FDA from Michael Smith. FDA advised Firm A in writing that manufacturing, holding for sale, or selling in interstate commerce components of its devices would constitute a violation of the Decree because the components were devices that had not been brought into compliance with CGMP, as required by the Decree. Ex. 7; see also 21 U.S.C. § 321(h).

THE DEFENDANTS' VIOLATIONS OF THE DECREE

12. Despite FDA's efforts to work closely with Firm A to effect a lawful export of its inventory, Firm A's certification to FDA that the Axis Implant could be manufactured and

distributed in compliance with the CGMP regulations, and FDA's notice to Firm A that the unauthorized manufacture and distribution of device components would be a violation of the Decree, defendants flagrantly violated the Decree's requirements with respect to the Electro Probe. As shown below, the individual defendants violated the requirements of the Decree by establishing a successor corporation to Firm A called Firm B, transferring assets and employees to Firm B, and manufacturing and distributing components of the Electro Probe to Med Dev Europe. These components could be easily assembled by purchasers to form a finished Electro Probe device.

Defendant Firm A

13. Between entry of the decree on April 25, 1999, and at least until the beginning of an FDA inspection of Firm B on September 3, 2000, defendant Firm A caused the manufacture and distribution of the Electro Probe through defendants Firm B, Individual B, Individual C, and Individual D despite the fact that FDA had not authorized the manufacture and distribution in interstate commerce of the Electro Probe, as is required by the Decree. Ex. 2 ¶ 111. Firm A provided to Firm B critical business assets -- the plans and specifications for the Electro Probe, Ex. 10, and a list of its suppliers. Ex. 11. Firm B labeled the Electro Probes it manufactured to state that they had been manufactured by Firm A. Ex. 12. Firm A employees Individual C and Individual D worked for Firm B for several months while also on the Firm A payroll. Ex. 13 ¶¶ 4 and 5. And, Firm A's president directed Individual C and Individual D in the performance of their duties while they were employed by Firm B. Id. In short, Firm A knowingly and deliberately violated the terms of the Decree by causing Firm B to manufacture and introduce into interstate commerce components for the Electro Probe, even though FDA had not authorized such activities.

Defendant Firm B

14. On or about November 13, 1999, six months after entry of the Decree, defendants Individual A, Individual B, and Individual E filed papers incorporating Firm B in the Commonwealth of Virginia for the stated purpose of "servicing of electrosurgical or related medical devices" and "any activity reasonably incidental or reasonably necessary thereto." Ex. 14, Articles of Incorporation, 1. Defendant Individual E is the president of Firm B and defendants Individual A and Individual B serve as directors of that firm. Id. at 6 Defendant

Individual A, a named defendant in the Decree, owns eighty percent of Firm B's stock. Id. at 8-10. Individual B and Individual E own the remainder of the stock. Id. at 8- 10.

15. Between November of 1999 and September of 2000, Firm B manufactured and distributed devices intended for reconstruction of the nose and chin. Specifically, defendant Firm B:

a. Employed former Firm A employees Individual C and Individual D as vice presidents. Ex. 13 ¶¶ 4 and 5.

b. Received from defendants Individual B and Firm A specifications and plans to manufacture Firm A's devices, including the Electro Probe. These plans were labeled "Medical Device Research Partners" or "Firm A, Inc.," indicating that they were developed for use by Firm A and were the business assets of Firm A. See Ex. 10. As a result, Firm B received a significant business asset from Firm A and is a successor corporation to Firm A. As a successor corporation, Firm B is bound by the Decree. Ex. 2 ¶ 111.

c. Ordered Electro Probe parts identical to those previously ordered by Firm A from the same companies that had supplied Firm A. Some of these parts were ordered from companies outside of Virginia. Id. As a result, Firm B stored devices after shipment of one or more of their components in interstate commerce.

d. Used these parts to manufacture device components which could be assembled into devices identical to those manufactured by Firm A, including the Electro Probe. Ex. 13 ¶ 5. Such manufacture is expressly prohibited by the Decree. Ex. 2 ¶ III (2).

e. Labeled at least some of the finished device components "Firm A, Inc. Richmond, VA USA," although they had been manufactured by Firm B. Ex. 12. Such manufacture and distribution in interstate commerce are in direct contravention of the Decree's prohibitions. Ex. 2 ¶ III(1) and (2).

f. Stored the device components in Firm B's facility at Richmond, Virginia. Such storing is expressly prohibited by the Decree until such time as FDA authorizes storing devices by Firm A or others bound by the Decree. Id.

g. Delivered these device components to Highland International Forwarders for shipment to Med Dev Europe in the Netherlands, and then submitted invoices to Med Dev Europe for the device components. Ex. 15. Such distribution is expressly prohibited by the Decree until such time as FDA authorizes distribution in interstate commerce. Compare Ex. 2 ¶ III(1) with ¶ III E.

16. Firm B only manufactured and distributed device components that were previously manufactured and distributed by Firm A; it did not manufacture any other products.

17. During FDA's inspection, Firm B employees claimed that they were merely manufacturing components of devices. Ex. 13 ¶¶ 4 and 5. By law, components of devices are also devices, 21 U.S.C. § 321(h). Moreover, records indicate that Firm B shipped to customers the same number of components in each shipment that could easily be assembled to complete finished devices identical to Firm A's Electro Probe. Ex. 13 ¶¶ 5 and 9; Ex. 15. These components were ordered by "Individual B" at Med Dev Europe. See Ex. 15 at 2. FDA collected records at Firm B which show that Firm B shipped components for the assembly of at least 59 finished devices. Ex. 13 ¶ 6.

Defendant Individual A

18. Defendant Individual A signed the Decree both in his capacity as the president of Firm A and as an individual defendant. Ex. 2 at 10. He had direct and actual knowledge of the Decree's contents. See. Nevertheless, just seven months after signing the Decree, he agreed to serve as a member of the Board of directors of Firm B and purchased eighty percent of Firm B's stock, see Ex. 14, and while so serving, he manufactured device components consisting of one or more components that had been shipped in interstate commerce and, later, introduced the device components into interstate commerce. Such actions were in direct violation of the Decree because the Decree specifically prohibited Individual A's manufacture and distribution in interstate commerce of the Electro Probe unless and until FDA authorized such work. Ex. 2 ¶ III (I), (2), and E. To date, FDA has not so authorized.

Defendant Individual B

19. Defendant Individual B was the vice president of Firm A in 1998 and became its president in March 1999. Ex. 4. He signed a statement on May 19, 1999, acknowledging receipt of a copy of the Decree from Firm A. Ex. 5. Individual B also corresponded extensively

with FDA after entry of the Decree, see Ex. 6, and certified to FDA that Firm A's Axis Implant manufacturing line was operating in compliance with the CGMP regulations. Ex. 3. In short, Individual B continually demonstrated that he understood the provisions of the Decree and Firm A's obligations under that Decree.

20. Despite the Decree's restrictions and Individual B's understanding of them, Individual B violated the Decree in several ways. First, Individual B served as a member of Firm B's Board of Directors. Ex. 14. Second, Individual B directed the contumacious activities of defendants Individual C and Individual D while they were employees at Firm A and, later, at Firm B. Ex. 13 ¶¶ 4 and 5. Third, Individual B delivered to Firm B the plans and specifications for Firm A's Electro Probe so that Firm B could manufacture the device components and ship sets of them to Med Dev Europe. *Id.* ¶ 4. Fourth, after FDA's inspection revealed to FDA that defendants were manufacturing and distributing components for Firm A's Electro Probe, Individual B wrote to defendant Individual C and stated that Med Dev Europe would not provide the money necessary to bring Firm B into compliance with CGMP, Ex. 16, as is expressly required by the Decree. Ex. 2 ¶ 111 A - E. Individual B resigned as president of Firm A soon after FDA's inspection of Firm B. Ex. 17.

21. Defendant Individual B's activities were in direct contravention of the Decree because he actively participated in a scheme to circumvent the requirements of the Decree through the manufacture and distribution of Firm A's Electro Probe despite the fact that the defendants had not certified to FDA that they could manufacture and distribute the Electro Probe in compliance with CGMP regulations and FDA had not authorized such activities.

Defendant Individual C

22. Defendant Individual C was an employee of Firm A at the time the Decree was entered by this Court. Ex. 18. She received notification of the Decree through certified mail by Firm A, Ex. 5, and was bound by its terms. Ex. 2 ¶ 111.

23. Despite the provisions of the Decree, while she was employed at Firm A, Individual C also worked for Firm B during evenings and weekends to help establish the company. Ex. 13 ¶ 4. She admitted doing so in order to assist defendant Individual B in his effort to supply Med Dev Europe with device components so that at least some of Firm A's

devices could be sold overseas. Id. On March 29, 2000, Individual C began working full time for Firm B. Ex. 13 ¶ 4 and Ex. 18.

24. At Firm B, defendant Individual B was a vice president in charge of administrative matters. Ex. 13 ¶ 4. She was responsible for ordering and receiving parts, preparing invoices, and shipping devices to Med Dev Europe. See Ex. 15. She told FDA investigators that, while defendant Individual B was responsible for some managerial decisions at Firm B, she also made managerial decisions for the company. Ex. 13 ¶ 4. Individual C also carried out Individual B's instructions when necessary. Id.

25. Once FDA's inspection of Firm B was completed, Individual C requested financial support from Individual B to enable Firm B to come into compliance with CGMP, Ex. 16, revealing Individual C's understanding that Firm B was required to comply with CGMP regulations.

Individual D

26. Defendant Individual D was an employee of Firm A at the time the Decree was entered by this Court. Ex. 18. He was notified of it by Firm A, Ex. 5, and was bound by its terms. Ex. 2 ¶ 111. Like Individual C, while employed at Firm A, he worked evenings and weekends to set up Firm B and later went to work for Firm B full time. Ex. 13 ¶ 5.

27. Individual D was Firm B's vice president for production. Id. He was responsible for producing all device components that Firm B manufactured, packed, and stored. Id. Individual D told FDA investigators that he produced approximately 100 to 200 subassemblies, or components, of devices according to training and device specifications that he received from defendant Individual B. Id. When questioned by FDA investigators about the similarity in the names for Firm B's and Firm A's electrosurgical devices (Firm A's Electro Probe is called the ER-8100 and Firm B's is called the ESU- 8100), Individual D acknowledged that they were the same device. Id.

28. The Decree prohibited Firm A, its employees, and all persons in active concert or participation with either of them, which language clearly includes Individual D, from manufacturing, packing, storing, and distributing all devices, including the Electro Probe, until FDA authorized such activities. Despite this clear prohibition, Individual C continued to

oversee manufacture, packing, storage, and distribution of a device that had changed in name only. This is a clear violation of the Decree.

Individual E

29. By letter dated October 2, 1999, Individual E acknowledged that he knew of and understood the terms of the Decree. Ex. 6. Yet, in November of 1999, he began serving as the president of Firm B. With the help of Individual C and Individual D in 2000, he manufactured the Electro Probe, stored it, and introduced it into interstate commerce. All of these acts were in direct violation of the Decree's prohibitions of the manufacture and distribution in interstate commerce of devices that FDA had not, and has not, authorized in writing.

WHEREFORE, pursuant to Rule 42(b) of the Federal Rules of Criminal Procedure, the United States of America respectfully requests that this Court:

1. Issue an Order to Show Cause requiring defendants Firm A and Firm B, corporations, and Individual A, Individual B, Individual C, Individual D, and Individual E, individuals, to appear before this Court and to show cause why they should not be adjudged in criminal contempt of the Decree entered by this Court on April 25, 1999;
2. Following the issuance of the Order to Show Cause and an appropriate hearing, enter a judgment of criminal contempt against defendants Firm A and Firm B, corporations, and Individual A, Individual B, Individual C, Individual D, and Individual E, individuals, for violating the April 25, 1999 Decree;
3. Impose an appropriate fine against the defendant Firm B;
4. Impose an appropriate fine against the defendant Firm A.;
5. Impose an appropriate fine or term of imprisonment against the individual defendant Individual A;
6. Impose an appropriate fine or term of imprisonment against the individual defendant Individual B;
7. Impose an appropriate fine or term of imprisonment against the individual defendant Individual C;

8. Impose an appropriate fine or term of imprisonment against the individual defendant Individual D;

9. Impose an appropriate fine or term of imprisonment against the individual defendant Individual E; and

10. Grant such other relief as the Court deems just and proper.

Dated:_____

NAME IN CAPS
Chief Counsel

NAME IN CAPS
Associate Chief Counsel
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
301-827- _____

Respectfully submitted:
NAME IN CAPS
Assistant Attorney General

NAME IN CAPS
United States Attorney

Assistant U.S. Attorney
Address
City, State Zip
Phone number

Office of Consumer Litigation
Department of Justice
P.O. Box 386
Washington, D.C. 20044

Exhibit 6-23**ORDER TO SHOW CAUSE**

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF _____

UNITED STATES OF AMERICA,)

Plaintiff,)

)

v.)

Criminal Action No. _____

NAME IN CAPS)

and)

NAME IN CAPS.)

Corporations)

and)

NAME IN CAPS,)

NAME IN CAPS,)

NAME IN CAPS,)

NAME IN CAPS,)

and)

NAME IN CAPS,)

Individuals,)

Defendants)

ORDER TO SHOW CAUSE

Upon consideration of the government's Petition for an Order to Show Cause why the defendants Firm A, Inc. (Firm A), Firm B, Inc. (Firm B), corporations, and, Individual A, Individual B, Individual C, Individual D, and Individual E, individuals, should not be held in criminal contempt, and it appearing to the Court from the allegations contained therein that the defendants have violated the terms of the Consent Decree of Permanent Injunction entered on April 25, 1999, it is therefore:

ORDERED, pursuant to Rule 42(b) of the Federal Rules of Criminal Procedure, that defendants Individual A, Individual B, Individual C, Individual D, and Individual E, and duly authorized representatives of defendants Firm A and Firm B shall appear before this Court in

Room No.____, _____ (address), City, State on_____(date) at __ (time), and show cause why they should not be held in criminal contempt of the permanent

injunction entered in the above-captioned case on April 25, 1999.

SO ORDERED:

Dated: _____, 2001.

Judge _____

United States District Judge

Exhibit 6-24**FORMAT FOR PROSECUTION SUMMARY AND RECOMMENDATION**Memorandum

FROM: _____ District/Division/Program _____

SUBJECT: PROSECUTION

Lead Sample Number, et al.

TO: Division of Enforcement, Office of Enforcement and Import Operations or
Center for Drug Evaluation and Research, Office of Compliance (HFD-300) or
Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-600) or
Center for Veterinary Medicine, Office of Surveillance and Compliance (HFV-200) or
Center for Devices and Radiological Health, Office of Compliance (HFZ-300) or
Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality
(HFM-600)

SAMPLE NO., PRODUCT, DATE SHIPPED, AND RELATED INFORMATION

In a case where an element of the offense does not involve samples, outline the elements which describe the offense.

CITATIONLEGAL STATUSALLEGED VIOLATIONHISTORYPRIOR NOTICEOTHER CORRESPONDENCEWITNESSES FOR INSPECTIONAL AND ANALYTICAL FINDINGSOTHER WITNESSESRECOMMENDATION

PERMANENT ABEYANCE OF SAMPLES AND/OR INDIVIDUALSSAMPLE DATA

1. Date Lot Shipped/Received
2. Date Lot Sampled/By
3. Description of Lot and Sample Size
4. Analysts
5. Analytical Method(s)
6. Number of Subs Analyzed
7. Analytical Findings verifying that part of offense based on laboratory analysis
8. 702(b) portion
9. Seizure(s)
10. Recall(s)
11. Documentation of Interstate Commerce

REMARKS

Signature of Compliance Officer

Signature of Director, Compliance Branch

Concurrence by: District/Division/Program Director(s)

Enclosures:

Case files

Exhibit 6-25**MODEL PROSECUTION SUMMARY AND RECOMMENDATION MEMORANDUM**

DATE:

FROM: _____ District/Division/Program_____

SUBJECT: PROSECUTION

Lead Sample Number, et al.

TO: Division of Enforcement, Office of Enforcement and Import Operations

SAMPLE NO.	PRODUCT	DATE SHIPPED	RELATED INFORMATION
Sample No. (Count I)	Lima Beans	12/18/01	Seized
Sample No. (Count II)	Lima Beans	11/20/01	Seized
Sample No. (Count III)	Peas	11/31/02	Vol. destroyed
Sample No. (Count IV)	Lima Beans	11/30/02	Seized

CITATION

Issued to: Firm
Street Address
City, State Zip
a corporation

and
Individual A, President
Street Address
City, State Zip

and
Individual B
Street Address
City, State Zip
Individuals

There has been no new evidence developed since the Recommendation for Citation was submitted or at the 305 meeting on [date]. Therefore, the case was sent directly to the Division of Enforcement, Office of Enforcement and Import Operations (OEIO).

LEGAL STATUS

Firm, Inc. was incorporated under the laws of the State of _____ in 1978. Certified copies of the Articles of Incorporation have been obtained. The officers of the corporation are Individual A, President and Chief Executive Officer, and Individual B, Warehouse Distribution Manager. The responsible individuals at the Irving warehouse are the same now as at the times of violations.

ALLEGED VIOLATIONS

This storage warehouse has been storing peas and beans which have become rodent contaminated after receipt in interstate commerce. 21 U.S.C. 331(k), 342(a)(3), and (4). Lima beans represented by samples collected during the inspection of _____, are adulterated within the meaning of 21 U.S.C. 342(a)(3) in that the products contained rodent excreta pellets and live insects (Count I) and rodent hairs (Count II). Peas and lima beans are represented by samples collected during the inspection of _____, and are adulterated within the meaning of 21 U.S.C. 342(a)(3) in that the peas contained rodent excreta and rodent hairs (Count III) and the beans contained live insects (Count IV).

In addition, the products were adulterated within the meaning of 21 U.S.C. 342(a)(4) because they were held under conditions which could have resulted in their becoming contaminated with filth (Counts I-IV).

HISTORY

The proposed defendants have a long history of noncompliance with the Food, Drug, and Cosmetic Act. FDA first inspected the firm in February 1993. That inspection revealed widespread rodent and insect infestation. Products found in violation were voluntarily destroyed. Inspection in 1994 revealed continuing problems and two lots of rice were seized, No. _____, N.D. Texas (FDA reference FDC _____). Between 1995 and 2000, FDA and State of Texas, under contract with the FDA, inspected the Corporation on several occasions. Those inspections revealed some minor insanitary conditions and resulted in the voluntary destruction of some foods.

In June 2001, a joint inspection by FDA and the state again revealed extensive rodent infestation. No food was seized as Individual A voluntarily destroyed the contaminated lots. Follow-up inspections in May 2002 and December 2002 are the subject inspections upon which this recommendation is based.

PRIOR NOTICE

After each of the referenced inspections management at the Irving warehouse received a Form FDA 483 Inspectional Observations (FDA 483). Seizures of food products were accomplished in 1994, 2001, and 2002. A Warning Letter was issued to the Corporation and Individual A on October 25, 2001.

Sample No. - Lima Beans

Description of Lot
and Sample Size:

Lot - 42 bales (12/2 lb. bags); 13 bales were examined, 6 had rodent excreta and 3 had rodent urine on their surfaces, 8 were rodent gnawed and in 5 bales the gnawing penetrated cello bags inside the bales. Cello bags in one bale contained insects and one cello bag was almost completely empty and contained rodent excreta. A nest containing three dead rodents was found between bales in the lot. An 11 sub selective sample consisting of 7 rodent gnawed cello bags collected from 5 different bales and 4 subs from the exterior of bales was collected

Analyst:

Name (____ - ORA District/Division/Program)

Analytical Methods:

Macroscopic, Microscopic, and Xanthidrol

Number of Subs Analyzed:

All

Analytical Findings:

402(a)(3) Verification

Subs IB, 3, 3A, 4, 5, and 5A. poly bags of beans bearing rodent incisor marks penetrating bagging material. Sub 3A contained a fly. Sub 3 contained an insect pupa case. Subs 3A and 5 contained insect pupae. Subs 4 and 5A contained rodent excreta pellets.

402(a)(4) Verification

Other subs collected from exterior of lot revealed gnawed bagging material, urine stained paper, and rodent hairs.

702(b) Portion:

Yes

Seizure:

Yes

Documentation of Interstate Commerce:

1. Dealer's Statement dated 5-09-2002 signed by Mr. _____, as General Foreman (Assistant Distribution Manager), Firm, Inc., City, State covering receipt of the lot on or about 1-27-2002 from Food Products, Inc., Dallas, Texas, and sampling.

Mr.____furnished copies of the following documents:

a. Firm, Inc. Purchase Order No. 0123 dated 1-18-2002 stamped "Hauled on Rogers truck" and marked "Date Received 1-27-2002."

b. Invoice No. 76543 dated 1/27/2002 issued by Food Products, Inc.

2. Affidavit dated 5/19/2002 signed by Mr._____, Quality Assurance Manager, Food Products, Inc., Dallas, Texas, stating that the shipment of lima beans to Firm, Inc., City, State,

under Invoice No. 7653 dated 1/27/2002, was packed by his firm from beans received from Downs Warehouse Company, Crows Landing, California. Mr. _____ furnished copies of the following documents:

- a. Invoice No. 010305 dated 12/28/2001 issued by Downs Warehouse Co.
- b. Bill of Lading (Shipper's No. 5520 and Agent's No. 43218) dated 12/28/2001 issued by Southern Pacific Transportation Company, covering the shipment of 194,000 pounds of dry beans from Downs Warehouse Company, Crows Landing, California, to Food Products, Inc., Dallas, Texas.

(Counts II through IV of this example would be listed with the factual information as in Count I above.)

REMARKS

We are not aware of any potential problem areas or weaknesses in the case. Individual A is in his mid-40's, while Individual B is reportedly 38.

OCI was contacted regarding the case and declined it.

Prosecution is the action of choice in this case. The evidence shows that this firm, under current management, had serious rodent and insect infestations as early as 1993, and despite repeated warnings, has allowed these grossly filthy conditions to persist.

Signature of Compliance Officer

Signature of Director, Compliance Branch

Concurrence by: District/Division/Program Director(s)

Enclosures:

cc: Notice of Hearing and Charge Sheet

cc: Record of Hearing and Hearing Exhibits

cc: Legal Status Sheet

cc: Articles of Incorporation

cc: Collection Reports, Labels, Worksheets, and state correspondence (5)

In separate envelope:

3 cys. Notice of Hearing and Charge Sheet

1 cy. Articles of Incorporation

3 cys. letter to firm dated 10-25-87

cc: HFS-605

HFA-224

Exhibit 6-26**MODEL LETTER REQUEST FOR ARTICLES OF INCORPORATION**

Dear Sir:

Re: Name of Firm
Address of Firm

Please furnish us with copies of the Articles of Incorporation and Certificate of Existence for the referenced firm. As these documents may be introduced as evidence in a court proceeding in accordance with Rule 44 of the Federal Rules of Civil Procedure (copy enclosed), it will be necessary for them to be authenticated by the officer having legal custody of these records, or by his deputy, and accompanied by a certificate that the individual is legal custodian of these records.

The documents should cover the existence of the firm for the period from on or about (earliest shipment date contained in the Information or Indictment) to the present time.

Sincerely,

Exhibit 6-27**RULE 44 – PROVING AN OFFICIAL RECORD**

To establish that a document, or an entry in it, to be used as evidence is an official record that is otherwise admissible:

See the Federal Rules of Civil Procedure at 28 USC § 44 – Proving an Official Record on www.gpo.gov ([link](#)).

(From the Federal Rules of Civil Procedure. Incorporates the revisions that took effect January 7, 2001.)

Exhibit 6-28**Rule 6. THE GRAND JURY**

See the Federal Rules of Criminal Procedure at 28 USC § 44 – Proving an Official Record at www.uscourts.gov > [Rules of Criminal Procedure](#).

(From the Federal Rules of Criminal Procedure. Includes text from 2011, 2014 amendments.)

Exhibit 6-29**EXAMPLE OF LETTER TO THE DEPARTMENT OF JUSTICE, RE: INJUNCTION AND CIVIL PENALTY**

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
Our Ref: INJ [insert number] [insert date]
[insert name], Director
Office of Consumer Litigation
Civil Division
Department of Justice
Post Office Box 386
Washington, D.C. 20044

Dear [insert name]:

Investigations conducted by the Food and Drug Administration (FDA) indicate that ABC Company, Inc. (ABC) and Alan R. Smith, its president, have violated the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 301, et seq. Specifically, ABC and Alan R. Smith have: (1) manufactured and distributed into commerce 149 diagnostic x-ray systems which did not comply with the applicable performance standards prescribed in the Act, in violation of 21 U.S.C. 360oo(a)(1); (2) issued 22 certifications that 22 x-ray systems complied with the applicable performance standards, when they had knowledge that the certifications were false or misleading in a material respect, in violation of 21 U.S.C. 360oo(a)(5)(B); and (3) failed to notify the purchasers of 270 x-ray units that the units did not comply with the applicable performance standards, and failed to bring the 270 x-ray units into compliance with the standards, without charge, or to replace the x-ray units with like or equivalent x-ray units, or to refund the cost of the units, all in violation of 21 U.S.C. 360oo(a)(2). Therefore, we request the initiation of an action for permanent injunction and civil penalties against both the corporate and individual defendants.

A. BACKGROUND

ABC is a corporation organized under the laws of the State of Illinois, with headquarters in Peoria, Illinois, and trading and doing business in the State of Illinois. The firm became incorporated on March 23, 1967. Alan R. Smith has been President and Chief Executive Officer of the firm since 1989. He also holds the position of Corporate Treasurer. Prior to 1989, Alan R. Smith was the firm's Vice President. In his current position, Alan R. Smith is responsible for ABC's importation, production, sales, and complaint handling operations. ABC

is engaged in the importation and manufacture of diagnostic x-ray systems. Since 1976, ABC has imported two basic x-ray units, models 11 and 12, from X-Ray Company in Japan. ABC manufactures these x-ray units for use as portable, general purpose systems or as mobile, wall-mounted, or stationary podiatry systems.¹

Models 13, 14, 15, and 16 (mobile and wall-mounted podiatry x-ray systems), and models 17, and 18 (portable, general purpose x-ray systems), are the products at issue in the proposed injunction and civil penalties action.

B. APPLICABLE LAW

The Electronic Product Radiation Control Program (the Program), 21 U.S.C. 360hh - 360ss, is part of the Federal Food, Drug, and Cosmetic Act. Congress intended the Program to protect the public from the hazard of unnecessary exposure to radiation emitted by electronic products such as diagnostic x-ray systems. To achieve this end, the Program proscribes a manufacturer from introducing into commerce any electronic product that does not comply with the applicable standards promulgated by the Commissioner of Food and Drugs under authority delegated to him by the Secretary of Health and Human Services ("Secretary") under 21 CFR 5.10(a)(3). 21 U.S.C. 360oo(a)(1).

The standards promulgated by the Commissioner include a light localizer illuminance requirement, 21 CFR 1020.31(d)(2)(ii), and a contrast ratio requirement, 21 CFR 1020.31(d)(2)(iii). X-ray systems use a light localizer to define the light field so the operator of the equipment can adjust the x-ray field to the proper image receptor size. The contrast ratio requirement exists to permit the operator to align the film with the edges of the x-ray field. Failure of a system to meet these two requirements could cause the operator to visualize inaccurately the x-ray field, and could result in an x-ray field that is larger than necessary for the examination. An x-ray field that is too large or misaligned could overexpose the patient to radiation, and could unnecessarily expose sensitive body organs to radiation. If critical organs are exposed to radiation, there is an increased risk to the patient of cell damage and cancer.

ABC and Alan R. Smith, as importers of diagnostic x-ray equipment and manufacturers of complete diagnostic x-ray systems, are "manufacturers" within the meaning of 21 U.S.C. 360hh(3) and 21 CFR 1000.3(n).

¹ ABC's models 11 and 12 x-ray systems are each made up of two different components. One component is comprised of a tube housing assembly, a high voltage generator, and an x-ray control. The second component, a collimator, is a beam-limiting device that provides a means to restrict the dimensions of the x-ray field. ABC has equipped both the models 11 and 12 x-ray systems with model 19 collimators. The only difference between the model 11 and 12 systems is that model 11 has a fixed output tubehead and model 12 has a variable output tubehead. The components of the systems are otherwise identical.

ABC's podiatry x-ray systems are designated as follows: stationary: models 20 and 21; mobile: models 13 and 14; and wall-mounted: models 15 and 16. ABC's portable, general purpose x-ray systems are designated as models 17 and 18.

In addition to prohibiting manufacturers from placing noncompliant products into commerce, the Program also requires that manufacturers certify that their products meet the applicable standards. 21 U.S.C. 360kk(h). The Program prohibits a manufacturer from certifying that a product complies with the applicable performance standards when the manufacturer, in the exercise of due care, would have reason to know that the certification is false or misleading in a material respect. 21 U.S.C. 360oo(a)(5)(B). Furthermore, the Program requires that manufacturers notify the users of equipment that it does not meet the performance standards and correct those systems that are violative. 21 U.S.C. 360oo(a)(2). Specifically, the manufacturers must notify promptly the Secretary and the dealers, distributors, and/or first purchasers of any electronic products that have a defect or that do not comply with any applicable performance standard. 21 U.S.C. 360ll(f). Manufacturers must also bring the violative product into compliance with the standards, without charge, or replace the product with a like or equivalent product that meets the standards, or refund the cost of the product. 21 U.S.C. 360ll(f).

A manufacturer who violates any of the provisions described above is subject to civil penalties of not more than \$1,000 per violation, up to a total of \$300,000 for any related series of violations. 21 U.S.C. 360pp(b)(1).

C. CHARGES AND SUPPORTING EVIDENCE

The attached complaint charges each defendant with 149 violations of 21 U.S.C. 360oo(a)(l), introducing into commerce electronic products that do not comply with the applicable standards. The complaint also charges each defendant with 22 violations of section 360oo(a)(5)(B), issuing 22 certifications that 22 x-ray products complied with the applicable performance standards, when, in the exercise of due care, they should have known that the certifications were false or misleading in a material respect. Finally, the complaint charges each defendant with 270 violations of 21 U.S.C. 360oo(a)(2), failing to notify users that the equipment was violative and failing to bring the equipment into compliance, without charge, or replace the violative equipment, or refund the cost of the equipment.

The employee from FDA's Winchester Engineering and Analytical Center (WEAC) who tested the defendants' x-ray system will testify that the defendants' mobile and wall-mounted podiatry x-ray systems and their portable, general purpose x-ray systems do not comply with the light illuminance, contrast ratio, and labeling and certification requirements, 21 CFR 1020.31(d)(2)(ii) and (iii) and 21 CFR 1010.2, respectively. A witness from the Center for Devices and Radiological Health (CDRH) will be available to provide expert testimony concerning the diagnostic x-ray standards and the health risks associated with x-ray systems that fail to meet the performance standards.

FDA investigators who conducted the inspections at ABC will testify that the defendants placed into commerce a total of 149 violative x-ray units between January 18, 1991 and August 8, 1995. The investigators will also testify that defendants sold 22 of these units, with certification, after they had knowledge that the units did not comply with the regulations. In addition, the

investigators will produce evidence documenting that the defendants sold a total of 270 noncompliant units from January 21, 1988 through August 8, 1995. The defendants did not notify the users of the 270 x-ray systems about the violations, nor did the defendants take action to correct the violations.

D. DEFENDANTS' VIOLATIVE CONDUCT

1. The Initial Warning Letter and Follow-Up Correspondence

On August 9, 1993, CDRH issued a Warning Letter to the defendants, advising them that WEAC had tested their model 12 x-ray system and found that it did not comply with the required standards. Specifically, the unit did not comply with: (1) the x-ray tube current accuracy requirement, 21 CFR 1020.31(a)(4); (2) the light localizer illuminance and contrast ratio requirements, 21 CFR 1020.31(d)(2)(ii) and (iii); and (3) the labeling and certification requirements, 21 CFR 1010.2. The letter advised defendants that they could refute the findings made by WEAC, request an exemption from the standards, or submit a corrective action plan that included notifying the purchasers of the violative equipment.

Following a meeting between CDRH and Alan R. Smith on September 24, 1993, CDRH sent a letter to the defendants, reiterating that defendants' mobile and wall-mounted podiatry x-ray systems and portable, general purpose x-ray systems did not comply with the above-referenced requirements. The letter also clarified an issue raised in the meeting concerning the meaning of the term "maximum SID [source to image receptor distance]." ² The letter stated that the "maximum SID," as used in 21 CFR 1020.31(d)(2)(ii) and (iii), is determined by equipment design and not by a label statement.

2. Defendants' Request for a Variance from the Applicable Standards

Defendants, in a letter to CDRH dated November 4, 1993, requested that CDRH grant them a variance from the technique factor accuracy requirement, 21 CFR 1020.31(a)(4), the light illuminance and contrast ratio requirements, 21 CFR 1020.31(d)(2)(ii) and (iii), and the labeling and certification requirements, 21 CFR 1010.2, for the model 12 x-ray systems that they had in stock and in production at that time. Citing the financial burdens that would befall the company

² The performance standard for radiographic equipment is found in 21 CFR 1020.31. The visual definition standards that mobile and stationary general purpose x-ray systems must attain, including light illuminance and contrast ratio requirements, are found in 21 CFR 1020.31(d)(2)(ii) and (iii). These regulations both use the term "maximum SID" in defining the requirements.

Alan R. Smith contended that because his user manuals directed the user to place the x-ray system at a SID of 21 inches, 21 inches was the "maximum SID." Therefore, he argued, his x-ray units met the light illuminance and contrast ratio requirements because they complied with the performance standards at a SID of 21 inches. The design of defendants' mobile and wall-mounted podiatry x-ray systems and portable, general purpose x-ray systems, however, allows the systems to attain a maximum SID of 40 inches. WEAC tested a model 12 unit at a SID of 40 inches and found that it did not comply with the performance standards. CDRH notified the defendants that because the x-ray systems could be used at a maximum SID of 40 inches, the systems would have to comply at that distance. CDRH explained that it was not sufficient simply to instruct users to operate the equipment at 21 inches only.

if it had to cancel pre-existing orders or retrofit or discard the systems, and the fact that no significant risk of injury existed if the systems were used at a SID of 21 inches, defendants asked CDRH to allow them to distribute the remaining model 12 units that they had in stock.

3. The Second Warning Letter

CDRH sent defendants a second Warning Letter on January 6, 1994. The letter stated that the defendants' model 11 x-ray systems had the same light localizer and contrast ratio violations as the model 12. The letter demanded that defendants respond to CDRH within fifteen days to inform it whether the firm intended to refute the allegations, request an exemption from the standards, or provide purchaser notification and a corrective action plan.

4. CDRH's Response to Defendants' Request for a Variance

CDRH treated the defendants' November 4, 1993 request for a variance for the model 12 units as a request for a variance for the model 11 units as well. In a separate letter dated January 6, 1994, CDRH notified the defendants that their request for a variance was unacceptable for the portable, general purpose x-ray system.

By letter dated February 16, 1994, CDRH notified the defendants that their request for a variance and corrective action plan was approved for the mobile and wall-mounted podiatry x-ray systems. The variance and corrective action plan applied only to those systems that had been manufactured and imported by the defendants prior to August 9, 1993.³ The letter explained that the corrective action plan required the defendants to do the following: (1) affix a label to the collimator of all podiatry units introduced into commerce prior to August 9, 1993, which stated, "This collimator is certified under the provisions of variance number 99V dated February 16, 1994, for podiatry use only at a maximum source to image distance of 21 inches;" (2) confirm the calibration of the tube current accuracy when they attached the variance label to each unit; (3) notify the users of the mobile and wall-mounted podiatry x-ray systems about the recall; and (4) provide CDRH with a time frame for implementing the corrective action plan and details on how the corrective action plan would be accomplished.

5. Subsequent Correspondence Between CDRH and Defendants

CDRH sent letters to the defendants dated March 11, March 31, and May 3, 1994. These letters advised defendants that they had not yet (1) submitted a corrective action plan for the portable, general purpose x-ray systems; (2) applied the variance labels to the mobile and wall-mounted podiatry x-ray systems already in commerce; (3) provided any plan for accomplishing the approved corrective action plan for the mobile and wall-mounted podiatry x-

³ Defendants subsequently requested, by letter dated March 3, 1994, that x-ray units en route from Japan be included in the variance. CDRH denied this request by letter dated March 31, 1994. The letter explained that units that had not yet been introduced into United States commerce at the time the variance was granted, i.e., those that had not passed through United States Customs, were to meet full compliance without applying a variance.

ray systems; and (4) provided a user notification letter and a list of end-user addresses to FDA's District/Division/Program Office.

The defendants, in a letter to CDRH dated April 1, 1994, again questioned the definition of the term "maximum SID," contending that CDRH had incorrectly interpreted the language of the regulations. CDRH's May 3, 1994 letter to the defendants reiterated the definition of "maximum SID."⁴ The letter further advised the defendants that their testing and quality control program for the portable, general purpose x-ray systems had not been approved, and therefore, they could no longer sell or introduce their general purpose models into commerce until an acceptable replacement collimator had been located or designed.

6. Correspondence Between the Defendants and the----- Division/Program

On June 27, 1994, the defendants provided the District /Division/Program with draft versions of letters to be sent out to notify dealers who had purchased noncompliant x-ray systems from defendants. FDA's District /Division/Program Director wrote the defendants on July 5, 1994, suggesting some changes in the wording of these letters. The District /Division/Program Director's letter also notified defendants that they still had not met the conditions of the variance and they had not submitted any monthly recall status reports to the District/Division/Program.

In a letter dated July 15, 1994, the defendants disputed that their recall was ineffective or failed to meet the conditions of the variance. The defendants stated that the letters notifying users that the systems did not comply with the standards could not be finalized yet. They estimated that they would notify the model 11 x-ray system users, by letter, during the first week of August 1994. The defendants explained that they could not establish a time frame yet for notifying the model 12 x-ray system users. The defendants also promised to submit monthly reports to FDA's District /Division/Program.

By letter dated September 12, 1994, FDA's District /Division/Program addressed some of the issues raised by the defendants' July 15, 1994 letter. The District /Division/Program informed defendants that: (1) they already should have sent out letters notifying users of the violative nature of the x-ray systems; and (2) they should have completed their corrective action plan for the mobile and wall-mounted podiatry x-ray systems. The defendants were further reminded that they had delayed initiating the corrective action plan for more than a year, and they were warned that further delays would not be tolerated.

⁴ On October 5, 1994, the defendants sent another letter to CDRH requesting clarification of the term "maximum SID" in the performance standard. CDRH responded by letter dated December 6, 1994, reiterating the definition of the term previously stated in the letter to defendants dated May 3, 1994. CDRH's letter also delineated all of the violations associated with the defendants' podiatry and general purpose systems. The letter advised defendants that they were required to report to the _____ Division/Program and that they were to submit information to CDRH regarding the corrective action plan for the general purpose systems.

7. The First Inspection

An inspection conducted on June 20, 1994 revealed that the defendants knowingly continued to distribute x-ray systems that did not comply with the applicable performance standards, even after receiving Warning Letters explaining that the machines violated the performance standards. Specifically, after February 16, 1994, the date on which the variance was approved for the podiatry x-ray systems that were in defendants' inventory as of August 9, 1993, defendants sold one model 13 unit that had been imported prior to August 9, 1993 and was already in stock. The inspection further revealed that a shipment of ten model 11 units was received from Japan on October 10, 1993, and of that shipment, five were configured and sold as model 13 systems and one as a model 15 system. Therefore, the units received on October 10, 1993 should have been excluded from the variance and corrected under the approved corrective action plan prior to distribution.

8. The Second Inspection

A reinspection of ABC held on July 18, 1995, revealed that since the previous inspection, the defendants had refurbished and resold eight podiatry x-ray units, two of which were sold without variance labels attached. The inspection also revealed that of twenty-four model 11 units imported and received on November 4, 1994, the defendants sold one model 13 unit. The invoice noted that this unit, which was shipped to Macomb, Michigan, was to be installed in Canada. The inspection further revealed that defendants had not yet submitted a corrective action plan for the portable, general purpose x-ray systems.

Both inspections conducted at ABC identified a total of 270 violative model 11 and 12 x-ray systems that defendants had sold between January 21, 1988 and August 8, 1995. Defendants sold 121 of the 270 violative units between January 21, 1988 and January 18, 1991. Between January 18, 1991 and August 8, 1995, defendants sold a total of 149 violative systems, including 22 systems that were sold after September 24, 1993, the date on which defendants were notified that the x-ray systems failed to meet the performance standards.

9. Defendants' Failure to Comply with the Act

Each defendant has committed 441 violations of the Act. Defendants placed into commerce 149 x-ray units that did not comply with the light illuminance, contrast ratio, and labeling and certification requirements, 21 CFR 1020.31(d)(2)(ii) and (iii) and 21 CFR 1010.2, in violation of 21 U.S.C. 360oo(a)(1). Defendants certified that 22 of these units met the applicable performance standards, despite their knowledge that the units did not comply with the standards, in violation of 21 U.S.C. 360oo(a)(5)(B). Finally, defendants failed to notify the users of the 270 noncompliant systems already in commerce, and they failed to bring the 270 units into compliance, or replace the 270 units, or refund the cost of the 270 units, all in violation of 21 U.S.C. 360oo(a)(2).

To date, the defendants have failed to implement their corrective action plan for the mobile and wall-mounted podiatry x-ray systems, and they have failed to submit and implement a

corrective action plan for the portable, general purpose x-ray systems. Furthermore, they have not provided notice to purchasers or provided any status reports of their activities to the District /Division/Program.

E. RESPONSIBILITY OF INDIVIDUAL DEFENDANT FOR THE ALLEGED VIOLATIONS

Mr. Smith, as president of ABC, has ultimate responsibility for all facets of the firm's operations. The Warning Letters and other pertinent correspondence from FDA, as well as the investigators' verbal discussions concerning the violations found, were all directed specifically to Mr. Smith. Mr. Smith personally responded to FDA's letters, has personally met with CDRH to discuss the problems, and has had both the knowledge and authority to initiate the necessary corrections.

As the most responsible company official, Mr. Smith is legally liable in his individual capacity for civil penalties under the Act. 21 U.S.C. 360pp(b)(1); United States v. Park, 421 U.S. 658 (1975); United States v. Dotterweich, 320 U.S. 277 (1934); United States v. Hodges X-Ray, Inc., 759 F.2d 557 (6th Cir. 1985).

F. ISSUES RAISED BY THE REFERRAL

By this referral, we are seeking an injunction and civil penalties rather than a seizure of products. The seizure remedy is inadequate in this case because the stock of units on hand is small and the units cannot be identified as violative until configuration, consignment, and sale of the final components and accessories.⁵ Furthermore, an injunction would allow us to require the defendants to: (1) implement the approved corrective action plan for the mobile and wall-mounted podiatry x-ray systems; (2) submit and implement a corrective action plan for the portable, general purpose x-ray systems; and (3) notify the Secretary and affected users of the violations.

Also, please note that WEAC only tested the portable, general purpose model 12. We know, however, that the portable, general purpose model 11, and the mobile and wall-mounted models 11 and 12 podiatry x-ray systems, all violate the same performance standards as the portable, general purpose model 12. The certifiable parts of all of these systems are exactly the same. The defendants were notified that none of these units complied with the performance standards in their meeting with CDRH on September 24, 1993, and they received a written Warning Letter to that effect on January 6, 1994.

Several other issues are raised by this referral. First we recommend two charges against defendants for their reintroduction of refurbished, used units into commerce. Mr. Smith claimed to have sold eight reconditioned units under the variance provisions, stating that the firm placed the proper variance label on the units. FDA inspectors checked six of the eight units

⁵ A model 11 or model 12 unit in the stationary podiatry configuration meets all of the required performance standards, whereas the same unit in a mobile or wall-mounted podiatry configuration would violate the performance standards.

and found that two of them did not contain variance labels. Accordingly, we have recommended charging defendants only with placing two of these reconditioned units into commerce with false certification. Second, although the defendants may claim that they have notified some dealer distributors to obtain end-user locations, defendants have not followed-up or attempted to notify end-users and correct the units at the user level, as CDRH instructed them to do as part of the variance granted by letter dated February 16, 1994. Finally, it is possible that ABC and Alan R. Smith will claim that they will be driven into bankruptcy if forced to pay \$300,000 each in civil penalties. The financial solvency of the firm or the individual is irrelevant to the imposition of liability, although it is an equitable factor that the district court may take into consideration when determining the proper amount of penalties. Hodges X-Ray, 759 F.2d at 564.

G. CASE PROCESSING

We are enclosing a copy of our recommended Complaint for Injunction and Civil Penalties. The principal witnesses in the case will be the person who performed the test on the x-ray systems at WEAC, the FDA representatives who conducted the inspections and obtained pertinent records and affidavits, and experts from CDRH.

Please inform us promptly of the name of the attorney in your office to whom you assign this referral. [insert name and telephone number] is the assigned attorney in our office. We expect that she will participate fully in all phases of the case. All questions regarding this referral should be directed to her. If your office decides to forward this matter to the U.S. Attorney's office, please notify us promptly of the date you do so and, if known, the name of the Assistant U.S. Attorney assigned to the case.

Very truly yours,

Chief Counsel
Food and Drug Administration

Enclosures

Exhibit 6-30**EXAMPLE OF COMPLAINT FOR INJUNCTION AND CIVIL PENALTY**

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,)	
Plaintiff,)	Civil Action
v.)	No.
ABC COMPANY, INC., a corporation,)	Judge
And)	
ALAN R. SMITH, an individual,)	
Defendants)	

COMPLAINT FOR PERMANENT INJUNCTION AND FOR CIVIL PENALTIES

The United States of America, plaintiff, by its undersigned attorneys, respectfully represents to this Honorable Court as follows:

INTRODUCTION

1. This action is brought pursuant to the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 360pp to:
 - a. enjoin and restrain the defendants from violating 21 U.S.C. 360oo(a)(1), (a)(2), and (a)(5)(B), and
 - b. enforce the Act's radiological health civil penalty provisions, 21 U.S.C. 360pp(b)(1), in accordance with 28 U.S.C. 1355.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. 360pp(a) and 28 U.S.C. 1331, 1337, 1345, and 1355.
3. Venue in this district is proper pursuant to 21 U.S.C. 360pp(c), 28 U.S.C. 1391(b), and 28 U.S.C. 1395(a).

COUNT ONE**(Presenting a Cause of Action to Restrain Violations of 21 U.S.C. 360oo)**

4. Defendant ABC Company, Inc. (ABC), is a corporation organized and existing under the laws of the State of Illinois and at all times relevant to the allegations in this Complaint, trading and doing business

at 38 Main Street, Peoria, Illinois, within the jurisdiction of this Court. The firm became incorporated on March 23, 1967.

5. Defendant, Alan R. Smith, an individual, is and has been since 1989, the President and

Chief Executive Officer of ABC. Prior to that time, Mr. Smith was the firm's Vice President. He also currently holds the position of Corporate Treasurer. At all times relevant to this action, Mr. Smith performed his duties at 38 Main Street, Peoria, Illinois, within the jurisdiction of this Court. Mr. Smith has ultimate responsibility for all facets of the firm's operations.

6. Defendants are, and at all times relevant to this action have been, engaged in the business of importing and manufacturing diagnostic x-ray systems which are "electronic products" within the meaning of 21 U.S.C. 360hh(2). Accordingly, each defendant was and is a "manufacturer" of electronic products within the meaning of 21 U.S.C. 360hh(3).

Failure to Cease Introduction of Violative Products Into Commerce

7. Pursuant to 21 U.S.C. 360ii(a), the Commissioner of Food and Drugs under authority delegated to him by the Secretary of Health and Human Services ("Secretary") under 21 CFR 5.10(a)(3), promulgated regulations prescribing performance standards for diagnostic x-ray systems and their major components. These regulations are codified, in pertinent part, at 21 CFR 1020.30-33.

8. On August 9, 1993, the United States Food and Drug Administration ("FDA") notified defendants that their model 12 x-ray systems failed to meet, inter alia, the light localizer illuminance requirements, the contrast ratio requirements, and the labeling and certification requirements, 21 CFR 1020.31(d)(2)(ii) and (iii) and 1010.2, respectively.

9. X-ray systems use a light localizer to define the light field so the operator of the equipment can adjust the x-ray field to the proper image receptor site. The contrast ratio requirement exists to permit the operator to align the film with the edges of the x-ray field. Failure of a system to meet these two requirements could cause the operator to visualize inaccurately the x-ray field, and could result in an x-ray field that is larger than necessary for the examination. An x-ray field that is too large or misaligned could overexpose the patient to radiation, and could unnecessarily expose sensitive body organs to radiation. If critical organs are exposed to radiation, there is an increased risk to the patient of cell damage and cancer.

10. Defendants met with FDA's CDRH on September 24, 1993. At that time, CDRH notified defendants that their mobile and wall-mounted podiatry x-ray systems, models 13, 14, 15, and 16, and their portable, general purpose x-ray systems, models 17 and 18, all failed to meet the requirements cited in the Warning Letter of August 9, 1993. By follow-up letter dated October 5, 1993, and by second Warning Letter dated January 6, 1994, CDRH reiterated to defendants that all of the above-mentioned units were noncompliant. On February 16, 1994, CDRH approved a corrective action plan for the podiatry units defendants placed into commerce prior to August 9, 1993. CDRH notified defendants that they were to submit a corrective action plan for the general purpose x-ray systems.

From August 9, 1993 through March 30, 1995, the defendants exchanged numerous correspondences with CDRH and FDA's Chicago District regarding the noncompliance of the x-ray units.

11. Nevertheless, after September 24, 1993, the date on which FDA notified defendants that their mobile and wall-mounted podiatry x-ray systems and their portable, general purpose x-ray systems did not comply with the applicable performance standards, the defendants sold the following 22 units in violation of applicable performance standards, including 16 model 13 units, 1 model 15 unit, 1 model 17 unit, and 4 model 18 units:

Model 13 Units (16 total)

<u>SHIPPING DATE</u>	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
03/16/94	20603	16226	Podiatry Supply Co. (Heights, OH)
05/05/94	21004	16218	"
12/01/94	22625	16996	"
		16997	"
05/25/94	21175	16645	"
		16646	"
		16649	"
06/06/94	21235	16235	"
		16648	"
		16651	"
03/28/94	20668	16232	Healthcare (Brooklyn, NY)
10/04/94	22221	15549	Podiatry (Stony Brook, NY)
11/11/93	19660	13682	Supply Service (Gettysburg, PA)
04/20/94	20885	16231	"
12/13/94	22708	16223	"
02/07/95	23194	17002	"

Model 15 Unit (1 total)

<u>SHIPPING DATE</u>	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
03/23/94	20635	16650	Podiatry (Stony Brook, NY)

Model 17 Unit (1 total)

<u>SHIPPING DATE</u>	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
09/28/93	19359	16116	Supply Service (Gettysburg, PA)

Model 18 Units (4 total)

<u>SHIPPING DATE</u>	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
10/15/93	19486	16360	Tech, Inc. (Walnut, CA)
01/06/94	20033	16357	Ocean, Ltd. (San Jose, CA)
		16363	"
03/09/94	20495	16361	A.S. (Calcutta, India)

By introducing into commerce these 22 x-ray systems that did not comply with the applicable performance standards, defendants committed 22 violations of 21 U.S.C. 360oo(a)(1).

12. Between March 20, 1991 and September 24, 1993, the date on which defendants were notified that their mobile and wall-mounted podiatry x-ray systems and their portable general purpose x-ray systems violated the applicable performance standards, defendants introduced into commerce the

following 121 x-ray systems in violation of applicable performance standards, including 27 model 15 units, 1 model 16 unit, 49 model 13 units, 10 model 14 units, 15 model 17 units, and 19 model 18 units:

Model 15 Units (27 total)

<u>SHIPPING DATE</u>	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
08/01/91	13639	14418	Medical Equipment Co. (Chicago, IL)
06/09/93	18608	16119	X-Ray Supply Corp. (Miami, FL)
12/18/91	14629	14424	Podiatry Supply Co. (Heights, OH)
		14427	"
01/29/92	14906	14576	"
04/23/92	15588	15434	"
03/11/93	17949	16040	"
09/06/91	13904	14262	Healthcare (Brooklyn, NY)
10/02/91	14066	14423	"
12/05/91	14507	14432	"
01/24/92	14858	14582	"
04/23/92	15577	15446	"
05/22/92	15824	15439	"
06/12/92	15966	15444	"
	15967	15435	"
04/02/91	12728	14258	Equipment Distributors (Syossett, NY)
12/05/91	14465	14428	"
01/03/92	14691	14585	"
01/22/92	14827	14580	Podiatry, Inc. (Freeport, NY)
02/14/92	15029	14567	"
05/21/91	13100	14259	Supply Service (Tyler Hill, PA)
01/21/93	17558	16031	"
02/11/93	17753	16034	"
		16045	"
03/16/93	17993	16030	"
		16041	"
04/21/93	18296	16123	"

Model 16 Unit (1 total)

<u>SHIPPING DATE</u>	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
01/28/93	17633	15339	Podiatry, Inc. (Freeport, NY)

Model 13 Units (49 total)

	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
03/20/91	12628	14256	Flag X-Ray (Bay, NY)
08/20/92	16439	15542	Medical Equipment Co. (Chicago, IL)
09/15/92	16629	15544	"
11/11/92	17068	15975	"
02/12/93	17768	16042	"
02/23/93	17830	16049	"
03/22/93	18030	16033	"
08/04/93	18990	16121	"
03/20/91	12630	14260	Supply Co. (Akron, OH)
		14264	"
		14269	"
12/18/91	14629	14421	"
03/10/92	15245	13669	"

04/08/92	15490	14583	"
04/23/92	15588	15437	"
		15442	"
06/01/92	15893	15427	"
09/11/92	16610	15533	"
		15538	"
		15543	"
		15551	"
09/25/92	16721	15545	"
03/11/93	17949	15977	"
09/01/93	19202	16236	"
		16237	"
03/20/91	12631	14261	Podiatry Supply (Islip, NY)
	12632	14266	"
04/23/91	12893	14255	"
12/19/91	14620	14417	"
		14577	"
02/26/92	15144	14584	Healthcare Distributors, Inc. (Palo Alto, CA)
03/10/92	15235	14425	"
05/27/92	15843	15436	"
06/30/92	16111	15430	"
09/15/92	16609	15540	"
11/11/92	17070	15973	"
		15980	"
11/11/92	17073	15978	Medical Supply (Reno, NV)
04/12/91	12829	14253	Medical Healthcare (Montauk, NY)
07/30/92	16326	15537	Stone & Palo, Inc. (Plainview, NY)
08/27/93	19180	16222	"
06/20/91	13341	14263	Best Service (Philadelphia, PA)
12/12/91	14600	14419	"
12/23/91	14653	14570	"
09/14/92	16605	15547	"
09/15/92	16630	15539	"
02/11/93	17753	16037	"
03/16/93	17993	16036	"
12/10/92	17288	15979	Eastern Supply, Inc. (Boston, MA)

Model 14 Units (10 total)

<u>SHIPPING DATE</u>	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
11/09/92	17043	15340	Equipment & Supply (Denver, CO)
02/12/93	17768	15471	"
08/04/92	16348	15475	B & S Supply Co. (Pittsburgh, PA)
05/26/93	18584	16271	"
01/21/93	17562	15219	Chris & Sons (Las Vegas, NV)

03/25/92	15347	15224	Pebbles & Sam Co. (Phoenix, AZ)
01/04/93	17435	15215	"
11/20/92	17127	15338	Foot Service Inc. (Maspeth, NY)
01/21/93	17558	15335	"
06/09/93	18619	16282	Southern Supply (San Jose, CA)

Model 17 Units (15 total)

<u>SHIPPING DATE</u>	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
01/07/92	14739	14430	BB X-Ray (Detroit, MI)
01/14/92	14781	14575	"
09/23/92	16689	15541	"
07/08/91	13452	14270	Advantage Podiatry (Atlanta, GA)
06/03/91	13203	14429	Veterinary Supply (Baldwin, NY)
05/05/92	15670	15432	Tech, Inc. (Walnut, CA)
03/22/93	18029	16044	Podiatry Supply Co. (Heights, OH)
04/09/93	18210	16118	"
05/17/93	18470	16047	"
12/16/92	17335	16035	Brokerage (Orlando, FL)
		16048	"
11/13/91	14354	14420	S & S X-Ray Service (Pittsburgh, PA)
06/25/93	18729	16032	"
10/04/91	14089	14251	X-Ray Supply (Provo, UT)
05/05/92	15682	15440	B.C.A. Inc. (San Francisco, CA)

Model 18 Units (19 total)

<u>SHIPPING DATE</u>	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
04/22/93	18309	16270	36 X-Ray (Greenwood Lake, NY)
05/05/92	15670	15222	Tech, Inc. (Walnut, CA)
05/14/93	18592	16364	Tech, Inc. (Walnut, CA)
		16365	"
08/23/93	19135	16359	"
05/11/93	18424	16273	Industries Inc. (Atlantic City, NJ)
04/07/93	18195	15216	X-Ray Service (Terra Haute, IN)
09/22/92	16680	15224	Available Supply (Boise, ID)
11/06/92	17034	15341	"
		15477	"
02/02/93	17662	14878	"
		15342	"
03/17/93	17999	15224	"
04/13/93	18234	16268	"
04/14/93	18238	16272	"
06/07/93	18605	16275	"
08/09/93	19019	16274	"
		16283	"
05/07/93	18400	16276	California Labs (Los Angeles, CA)

By introducing into commerce these 121 x-ray systems that did not comply with the applicable performance standards, defendants committed 121 violations of 21 U.S.C. 360oo(a)(1).

Failure to Meet Certification Requirements

13. Pursuant to 21 U.S.C. 360kk(h), every "manufacturer" of an electronic product to which a performance standard is applicable is required to certify that such product conforms to all applicable performance standards. Such certification shall be based upon a test, in accordance with the performance standards, of the individual article to which it is attached. The manufacturer must furnish that certification to the dealer or distributor, in the form of a label or tag permanently affixed to or inscribed on such product. 21 CFR 1010.2.

14. Defendants failed to comply with the certification requirements for electronic products when they certified that the 22 podiatry units described in paragraph 11 met all applicable performance standards. The defendants, in the exercise of due care, had reason to know that such certifications were false or misleading in a material respect, in that FDA had notified them that the units failed to meet the applicable performance standards. Therefore, by affixing materially false or misleading certifications to the 22 units described in paragraph 11, the defendants committed 22 violations of 21 U.S.C. 360oo(a)(5)(B).

Failure to Notify and Failure to Repair, Replace, or Refund

15. Pursuant to 21 U.S.C. 360ll, every manufacturer of electronic products who discovers that an electronic product produced, assembled, or imported by him does not comply with the performance standards, must immediately notify the Secretary and the dealers, distributors, and/or first purchasers of any electronic products that have a defect or that do not comply with any applicable performance standard, and must also: (1) without charge, bring such product into conformity with the applicable standard or remedy such defect; (2) replace each product with a like or equivalent product which complies with each applicable standard; or (3) refund the cost of such product. The Commissioner has promulgated regulations, 21 CFR 1002, 1003, and 1004, which prescribe how such notification and correction shall be accomplished.

16. FDA determined that the 143 units described in paragraphs 11 and 12 did not comply with the light localizer, contrast ratio, and labeling and certification requirements, 21 CFR 1020.31(d)(2)(ii) and (iii) and 1010.2, respectively.

17. Moreover, defendants sold 127 units in violation of applicable performance standards from January 21, 1988 to February 19, 1991. The sales of the 127 units included 71 model 15 units, 50 model 13 units, and 6 model 17 units, and were as follows:

Model 15 Units (71 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
01/21/88	4217	11549	Medical Co. (Brook, MN)
05/09/88	5060	11944	"
06/15/88	5335	12007	"
		12008	"
11/07/88	6421	12428	"
01/13/89	6901	12314	"
07/17/89	8314	12903	"
05/02/90	10435	13670	"
01/21/88	4218	11551	Podiatry Supply Co. (Heights, OH)
01/28/88	4261	11550	"
		11559	"
		11566	"
05/04/88	5026	11953	"
		11955	"
		11964	"
01/13/89	6902	12425	"
		12426	"
02/01/89	7043	12320	"
08/22/89	8537	12910	"
09/11/89	8671	12902	"
10/18/89	8949	12891	"
	8950	12890	"
01/30/90	9727	13020	"
		13031	"
04/07/90	10264	13026	"
04/10/90	10271	13664	"
08/14/90	11180	13776	Flower Podiatry Supply (Morristown, NJ)
12/05/89	9295	13032	Dental/Medical and Co. (Blacksburg, VA)
		13038	"
01/29/89	7026	12423	Equipment Distributors (Monticello, NY)
02/24/89	7264	12420	"
		12430	"
03/14/89	7387	12325	"
05/09/89	7874	12664	"
		12670	"
06/21/89	8161	12892	"
06/21/89	8162	12900	"
07/25/89	8362	12893	"
08/30/89	8592	12887	"
10/16/89	8952	12895	"
02/05/90	9794	13021	"

04/03/90	10220	13674	New York Distributors (Albany, NY)
05/14/90	10532	13665	"
09/11/90	11377	14056	"
		14062	"
11/29/90	11878	14217	New York Medical Co. (Geneva, NY)
12/21/90	12035	14218	"
12/11/89	9337	13040	Green Surgical Supply (Dayton, OH)
02/22/89	7263	12315	Supply Service (Groton, CT)
		12317	"
		12318	"
		12326	"
		12328	"
08/23/89	8590	12897	"
09/13/89	8690	12915	"
		13041	"
		13049	"
10/10/89	8891	12888	"
		12908	"
		12916	"
11/29/90	11879	14223	"
		14224	"
01/20/91	12210	14230	"
12/08/89	9327	13024	C & R X-Ray (Birmingham, AL)
		13036	"
		13045	"
08/15/90	11195	13773	"
		13780	"
		13782	"
		13787	"
		13790	"

Model 13 Units (50 total)

<u>SHIPPING DATE</u>	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
01/27/88	4243	11571	Equipment Co. (Olney, MD)
	4244	11568	"
03/21/88	4687	11059	"
		11569	"
05/05/88	5039	11954	"
		11957	"
06/15/88	5334	12018	"
		12031	"
07/06/88	5490	11948	"
10/07/88	6178	12022	"
10/26/88	6317	12020	"
12/06/88	6631	12024	"
02/03/89	7054	12319	"
05/22/90	10587	13673	"
01/18/91	12198	14252	"
03/22/88	4735	11507	Podiatry Supply Co. (Heights, OH)
05/04/88	5027	11952	"
		11958	"
02/07/89	7068	12323	"
03/27/89	7537	12019	"
04/04/89	7603	12673	"
		12675	"
05/08/89	7860	12667	"
		12669	"
11/10/89	9133	13025	"
02/13/90	9884	13468	"
03/29/90	10182	13668	"
		13677	"
04/07/90	10264	13034	"
08/28/90	11277	14063	"
06/21/89	8175	12913	Podiatry Supply (Buffalo, NY)
07/17/89	8317	12896	"
08/14/89	8493	12889	"
01/26/90	9697	13465	"
03/01/90	9987	13464	"
03/29/90	10204	13679	"
07/19/90	10984	13774	"
01/29/89	7026	12421	Medical Equipment Inc. (New Orleans, LA)
08/30/89	8591	12914	"
01/28/90	9698	13023	"
05/14/90	10531	13672	New York Supply (Tarrytown, NY)
09/11/90	11377	14058	"
12/11/90	11962	14229	Medical Equipment Inc. (Erie, PA)
09/06/89	8632	13035	Surgical Supplies (Louisville, KY)
02/02/90	9783	13473	"

03/21/89	7491	12322	Service for Surgery (Dover, DE)
		12427	"
11/29/90	11880	14225	"
01/02/91	12106	14216	"
01/20/91	12210	14221	"

Model 17 Units (6 total)

<u>SHIPPING DATE</u>	<u>INVOICE#</u>	<u>SERIAL#</u>	<u>SOLD TO</u>
02/08/91	12356	14226	S-5 X-Ray (St. Louis, MO)
02/19/91	12433	14228	Associate Radiology (Seattle, WA)
01/01/91	12157	13997	A & A X- Ray (Scranton, PA)
01/23/91	12213	14055	"
11/02/90	11741	13997	X-Ray Supply (Dallas, TX)
11/29/90	11881	14226	SMA Surgical Supply (Houston, TX)

18. On February 16, 1994, FDA notified defendants that for all of the 270 violative units that were already in commerce, they were required to notify the first purchasers, dealers, or distributors of the x-ray units, and the end-users of such products, as required by 21 U.S.C. 360ll(e), and they were further required to: (1) without charge, bring such products into conformance with the standard; (2) replace the products with like or equivalent products; or (3) make a refund of the cost of the products, as required by 21 U.S.C. 360ll(f).

19. Nevertheless, defendants failed to notify the first purchasers, dealers, or distributors and end-users of the 270 x-ray units described in paragraphs 11, 12, and 17, and they failed to (1) without charge, bring such products into conformance with the standard, (2) replace the products with like or equivalent products, or (3) refund the cost of the products, thereby committing 270 violations of 21 U.S.C. 360oo(a)(2).

COUNT TWO

(Presenting a Cause of Action to Enforce the Civil Penalties Provisions of 21 U.S.C. 360pp(b)(1))

20. This Count realleges and incorporates by reference paragraphs 1 through 19 of this Complaint as if fully set forth herein.

21. Pursuant to 21 U.S.C. 360pp(b)(1), any person who violates 21 U.S.C. 360oo shall be subject to a civil penalty of not more than \$1,000. Any violation with respect to any act or omission made unlawful by 21 U.S.C. 360oo constitutes a separate violation for purposes of 21 U.S.C. 360pp(b)(1), and the

maximum civil penalty imposed on any person for any related series of violations is not to exceed \$300,000.

22. Each defendant committed a total of 435 violations of 21 U.S.C. 360oo, including: (1) 143 violations of 21 U.S.C. 360oo(a)(1); (2) 22 violations of 21 U.S.C. 360oo(a)(5)(B); and (3) 270 violations of 21 U.S.C. 360oo(a)(2). For each violation, a civil penalty of \$1,000 may be imposed. Therefore, under 21 U.S.C. 360pp, a civil penalty of \$300,000 per defendant may be imposed.

WHEREFORE PLAINTIFF PRAYS:

I. That defendants, ABC and Alan R. Smith, and all of their officers, agents, representatives, employees, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with them, or any of them, be permanently restrained and enjoined under the provisions of 21 U.S.C. 360pp(a) from directly or indirectly doing or causing to be done any of the following acts:

- a. Introducing, or delivering for introduction into commerce as defined in 21 U.S.C. 360hh(4), any diagnostic x-ray system subject to, but not in compliance with, applicable performance standards in 21 CFR 1010 and 1020;
- b. Issuing certification that x-ray equipment meets the applicable standards when they, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect;
- c. Failing to comply with 21 U.S.C. 360oo(a)(2), which specifically requires manufacturers to (1) notify the purchasers of x-ray equipment that it does not comply with the performance standards; and (2) without charge, bring their manufactured diagnostic x-ray systems into conformity with the applicable standards prescribed in 21 CFR 1010 and 1020, or replace such products with a like or equivalent product that complies with the applicable standards, or refund the cost of the violative products;
- d. Failing to implement the FDA-approved corrective action plan for ABC's mobile and wall-mounted podiatry x-ray systems, models 13, 14, 15, and 16; and
- e. Failing to submit and implement a corrective action plan for ABC's portable, general purpose x-ray systems, models 17 and 18.

II. That the defendants, ABC and Alan R. Smith, each be required to pay to the plaintiff a civil penalty, pursuant to 21 U.S.C. 360pp(b)(1), in the amount of \$300,000, for the violations herein above alleged in paragraphs 7 through 19. This amount represents a penalty to each defendant of \$1,000 per violation of 21 U.S.C. 360oo, up to the maximum penalty of \$300,000 per defendant allowed pursuant to 21 U.S.C. 360pp(b)(1).

III. That the plaintiff be granted judgment for its costs herein, and that this court grant such other and further as it deems just and proper.

Dated this [insert date] day of [insert month and year].

Respectfully submitted,

[insert name]
Assistant Attorney General

[insert name]
United States Attorney

[insert name]
Assistant U.S. Attorney
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