Chapter 6
JUDICIAL ACTIONS

This chapter contains the following sections:

NOTE: The District compliance officer (or, the Center CSO/Scientist, if the action was Center-initiated) assigned to the judicial action should diligently pursue and actively monitor the progress of the case through the Agency review process to its conclusion. The Office of Enforcement (Division of Compliance Management and Operations) can assist in situations where significant delays are experienced or assistance is needed to resolve technical, scientific, or policy issues. (Also, see section on Ad Hoc Committees in Chapter 10.)

6-1 SEIZURE

6-1-1 Purpose

This section provides procedures and instructions for the recommendation, accomplishment, adjudication, and reporting of seizure actions filed under 21 U.S.C. 334. Exhibits showing the format for processing documents are included on the ORA Internet website http://www.fda.gov/ora/compliance_ref/rpm_new2/ch6.html.

The United States of America, as plaintiff, proceeds under the Supplemental Rules for Certain Admiralty and Maritime Claims 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 institution of a seizure recommendation, the compliance officer and the district's management must consider several factors.

A. PRIOR WARNING

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

B. HOME DISTRICT CONCURRENCE

Home District

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

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

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

Seizing District

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

Supervising District

The district which exercises supervision over reconditioning lots in connection with seizure actions is the supervising district.

The home district's concurrence with a seizure recommendation must be obtained prior to submission of the recommendation. Background violations, prior warnings, current status of firm, and pending and adjudicated actions involving the same charges should be obtained from the home district.

C. VOLUNTARY HOLD OR EMBARGO

If there is concern that the product will be distributed before seizure can be effected, 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 the seizure will be approved by the agency or when direct reference criteria have been met.

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

For medical devices, there is a provision in the statute [21 U.S.C. 334(g)] providing for administrative detention of devices. This enforcement tool should be considered when there is likelihood that the device will be moved or distributed before seizure can be accomplished.

The RPM section "Administrative Detention", contains the specifics of the administrative detention procedure. Whenever possible, state embargoes should be used instead of administrative detention because the latter can be resource intensive.

D. SIZE OF LOT TO BE SEIZED

Where the invoice value of the lot in question is less than one thousand dollars ($1,000) 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.

Certain programs and policy guides such as Compliance Policy Guidance (CPG) manual, "Health Fraud," 7150.10 may also have governing limits or conditions for seizure action.

In some instances, lots larger than $1,000 may also be disposed of by state or local action and lots smaller than $1,000 may be seized, such as when there is a hazard to health or when the seizure is necessary to establish a legal precedent.

E. 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 minimize the chances that the seized goods will be marketed without being brought into compliance.

F. VIOLATIONS WHEN AGENCY HAS OTHER MEANS OF CONTROL

Seizure may not be the appropriate means of control when the agency has control over products through other means. An example would be unlicensed biologics when there is an ongoing attempt to obtain a license.

G. VOLUNTARY RECONDITIONING

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

H. CONTINUING VIOLATIONS

When considering a seizure recommendation for which there is evidence (or the likelihood) of repeated or continuing violations, the district should also consider whether the public could be

better protected by alternative or simultaneous injunctive action. Consideration may also be given to filing a seizure to quickly obtain control of the articles and, either adding injunctive relief to a consent decree or amending the seizure complaint to obtain injunctive relief.

I. 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 regulations at 21 CFR 2.10(c) provide 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.

J. 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.

K. VENUE, (PLACE OF TRIAL) IN ACTIONS ARISING UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

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

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

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

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

In all requests for change of venue, promptly advise the Office of Chief Counsel attorney assigned to the case.

6-1-3 Types Of Seizure Recommendations

When it is determined that seizure is the appropriate course of action, the district's compliance officer should determine, by use of the Compliance Policy Guides Manual (CPG) and Compliance Program Guidance Manual (CPGM), which of the following should be the recipient of the seizure recommendation:

A. CENTER
A recommendation to the appropriate center should be made when directed by the CPG or CPGM, or when no guideline exists and, in the judgment of the district, a seizure is the proper course of action.

B. OFFICE OF ENFORCEMENT (OE), DIVISION OF COMPLIANCE MANAGEMENT AND OPERATIONS (DCMO) - (DIRECT REFERENCE SEIZURES)
Recommendations should be referred directly to DCMO when the CPG (under specific commodities guidance) grants authority to bypass the center. Prior to forwarding the recommendation the district should determine that the article is available for seizure, and that all samples and charges meet the direct reference criteria.

On occasion, there are several lots or products at one location to be seized and some meet direct reference criteria, but others do not. In such a situation, discuss the matter with the center by phone to determine whether it is willing to waive its review of those articles not meeting direct reference criteria. If the center agrees, submit the entire case to DCMO with a note that the center has waived its review. If the center does not agree, submit the entire case to the center for its review.

C. THE UNITED STATES ATTORNEY
CPG 7106.05 (Section 527.100 Butter – Adulteration Involving Insufficient Fat Content), directs that seizure pleadings be forwarded directly to the U.S. Attorney. Provide a copy of the pleadings to OCC, CFSAN, and DCMO at the time they are forwarded. The district should ensure the availability of the article before the seizure is referred to the U.S. Attorney. The FDC file number should be obtained from DCMO and provided to the U.S. Attorney.

6-1-4 Methods Of Recommending Seizure

Seizure procedures will vary somewhat depending upon local court rules, U.S. Attorney preferences, and distance of the court from district offices. The physical methods of forwarding seizure recommendations will involve one or more of the following procedures:

A. Electronic Transmission (ET)
The use of ET is the recommended procedure for all activities involving seizure actions. ET is the means by which the district can communicate electronically within the agency. Currently this can be accomplished by everyone by sending attachments to e-mail messages. Transmission of documents by this method will provide the center and DCMO with a means for making corrections, additions, or deletions in documents, without complete retyping.

Other material that is needed for review, such as the collection report or work sheet, can be sent by facsimile or by scanning documents into .pdf files. However, if original labels or EIRs not previously sent are needed for review, other methods, such as express mail or courier services, would be preferred. Care must be taken to label successive versions of electronically transmitted documents held at two locations.

B. TELEPHONE SEIZURE RECOMMENDATIONS
When the nature of the article is such that it will be distributed extremely rapidly, or a health hazard presents a critical situation requiring immediate agency action, such as crab meat or

fresh fruits and vegetables adulterated with bacterial or pesticide substance, seizure may be recommended by telephone. It is anticipated that this method will be rarely used, especially given the availability of e-mail. Format of information necessary for telephone recommendations is shown in Exhibit 6-1.
In the case of devices, administrative detention authority should be considered when there is reason to believe that the device is adulterated or misbranded. See 21 U.S.C. 334(g) and the RPM section "General Guidelines for Seizures - Voluntary Hold or Embargo".

C. MAIL DELIVERY OF SEIZURE RECOMMENDATIONS
Use "overnight" courier service to ensure controlled, expedited delivery. Do not use internal agency mail system or U. S. Postal Service regular mail.

D. HAND DELIVERY RECOMMENDATIONS
This is the recommended method of delivery of recommendations to the U.S. Attorney. Hand delivery to the center or DCMO might also be used when fast action is indicated and other expedient methods are unavailable. This method also may be used when seizure documents are voluminous and necessary for center, DCMO or OCC review, particularly in mass seizure actions.

Mail delivery of recommendations to the U.S. Attorney is also an option to hand delivery.

E. SPECIAL COURIER DELIVERY
Air courier services will deliver packages to many points within 24 hours. You may wish to consider this method of delivery for bulky submissions.

6-1-5 Update Inspections

In situations in which there is a question about the continued existence of a violative condition at a firm or the availability of violative goods to be seized, the district office may be asked to conduct an update inspection (or a buy, sample collection, or similar activity) to confirm that the product or problem affecting products still exists. The assignment for an update inspection will issue from DCMO with a copy of the assignment being forwarded to the appropriate center. The request for reinspection should be made by OCC to DCMO after OCC agrees that the action can be brought if the evidence is updated.

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

The update (and any resulting report) will focus on documenting the continued existence of originally identified problems. The update findings and the district's recommendation based upon the current and previous evidence should be transmitted concurrently to DCMO and the center. The result of the center's review will be transmitted to DCMO; and DCMO will alert OCC for final action on the recommended seizure action.

6-1-6 Action On Seizure Recommendations

Seizure actions must be acted on promptly by the district, the center, DCMO, and OCC. In cases where rapid action is sought, an early alert of the contemplated action would be helpful to headquarter reviewers.

A. DISTRICT RESPONSIBILITIES

District Requirement 1
The district recommends a seizure by transmitting, at a minimum, a draft cover letter to U.S. Attorney, draft Complaint for Forfeiture, and a cover memo to the appropriate office, accompanied by the supporting evidence.

NOTE: The case process will be facilitated by presenting the case to headquarters in a well organized and clear fashion. See "ORGANIZATION OF SEIZURE PACKAGE" AND "CONTENT OF SEIZURE MEMORANDUM" for instructions on organizing the seizure package.

Jurisdictional Model
Before preparing the referral and pleadings for a seizure the district should download the jurisdictional model from DCMO's Intranet web site. If a current model can not be located on the web site, contact DCMO by telephone (301-827-0391) and determine if a current jurisdictional model is available.

Letter to U.S. Attorney
Follow as a model the last seizure action for your district signed by the Chief Counsel; for general guidance follow the models on DCMO's Intranet website.

Explain why seizure is being requested. The letter should identify the person having possession of the article and the nature of this person's association with the article. Any prior warnings given to the responsible person should be included, if applicable. The letter should also reference any similar actions filed in the same or other districts as well as previous similar actions relating to the same owner. Explain in detail what is wrong with the product, and, if appropriate, how continued use of the product may cause harm to the consumer.

Always include a statement concerning results of analysis (if any) or findings during field examination or label review. Be specific. Do not use language such as "the product is contaminated by rodents." Rather, use statements such as "8 of the 20 bales examined by the investigator were found to be rodent gnawed, with rodent pellets in the product in 3 of these bales, dried rodent urine in the product in 5 other bales, and rodent hair adhering to the cut area of all 8 gnawed bales."

Identify the applicable tolerance or action level, when appropriate. Include an explanation of prior efforts to obtain compliance, if applicable.

This document, although a draft, should also be prepared in final form, except that it should be double spaced, leaving a blank for insertion of the OCC Attorney's name and phone number.

Insert the name and phone number of the compliance officer to whom the case is assigned. Prepare, transmit, and file this document in the same manner as the complaint.

Complaint

Follow, as a model, the latest approved complaint or for general guidance, the models on DCMO's Intranet website. The complaint "....shall describe with reasonable particularity the property that is the subject of the action and state that it is within the district or will be during the pendency of the action." "...(T)he complaint shall state the place of seizure ... and shall contain such allegations as may be required by the statute pursuant to which the action is brought." Supplementary Rule C(2).

Although the complaint is considered a draft that may be modified at headquarters, it should be prepared as a final document. It should also be free of typographical errors and contain accurate facts and proper charges, as reflected in the recommendation. A recommendation to headquarters which is prepared carefully, accurately, and thoughtfully will expedite processing the action. Prepare the document in ET form so that it will not need to be retyped before transmission. After reviewing the final typed document, transmit to the appropriate reviewing office and retain the original in your file. Retain document on the disc for later use in the event only minor changes need to be made. However, if the Complaint is to be amended after filing with the Court, verify that the offices offering corrections are working only from the filed version.

Cover Memo

In each recommendation, there are certain items of information which a reviewing office needs to know, but which do not fit into either a complaint or letter to the U.S. Attorney. These items should be spelled out in a cover memo to the headquarters reviewing office. The memo should explain:

1. Why seizure is the action of choice. Districts should consider and effect the most efficient use of resources to remove or prevent violative products from reaching the market. ORA is overhauling its databases to capture extrajudicial activities of district offices which achieve compliance within the regulated industry. This would include destructions, reconditioning activities, and capital improvements in which violative product is removed from or prevented from reaching the marketplace. These "compliance achievements" can result from an Establishment Inspection, the issuance of an FDA 483, notification of analytical results, in response to a Warning Letter, or a meeting of the firm with District management.

2. If not given, why prior warning is not necessary. Cite appropriate exemption to prior warning policy. If prior warning was given, a statement to that effect will be included in the letter to the U.S. Attorney. See the RPM section on "Prior Notice." State what response was received to the prior warning.

3. Possible weaknesses or problems the case may present or defenses that may be raised Include such things as: interstate records are not available, the goods were partially reconditioned, check analysis varies 20% from original analysis, or the analysis presented special problems. Include all information the reviewer should be aware of in order to make a fully informed proper judgment. Be open and honest and never attempt to conceal

information. Prepare, transmit, and file this document in the same manner as shown above for complaint.

The above information should be provided in the format set forth below in "ORGANIZATION OF SEIZURE PACKAGE" and "CONTENT OF SEIZURE MEMORANDUM."

NOTE: On major seizure actions (such as mass seizures, seizures of major public interest, novel seizures) the cover memo must be endorsed by the DD and RFDD.

Other Documents

In most cases the headquarters reviewing office will need to see more than just the above three documents in order to make a decision on the case. Such things as photographs, work sheets, labeling, FDA 483, EIRs, interstate documentation, or affidavits may be submitted via facsimile, or other rapid means to the reviewing unit. Please bear in mind the following considerations:

1. Always submit, via facsimile or by other means, a copy of the collection report and continuation sheets. Sample Summaries are no longer prepared.

2. Always submit, via courier service, if possible, the original label in any misbranding seizure case. In all other cases, submit easily legible, complete copies of labels via facsimile or hard copy.

Field and Headquarters components responsible for preparing and reviewing seizure pleading documents must have available complete labeling. That is labeling for individual and intermediate containers, outer cases and accompanying literature, brochures and flyers in order to prepare a seizure caption that accurately reflects and identifies for the U.S. Marshal exactly what is to be seized.

Photographs are useful in obtaining label information for liquid oxygen tanks mounted on trucks. In such case, photographs should be taken of the front and rear of the truck, showing the license plate number and State of issuance. Indicate on the Collection Report if any packaging is unlabeled.

In the case of a Documentary Sample, sufficiently describe the product to which the collected records relate.

District Requirement 2

The recommending district is responsible for ensuring that the home district concurs with the recommendation, and that the seizure recommendation follows current guidelines, including that of prior warning when necessary.

District Requirement 3

If a seizure involves more than one Center, send identical recommendations concurrently to each Center and so indicate on the forwarding memos. The district will continue to have the responsibility of identifying the lead center. The designated lead Center will continue to have the role of coordinating the review process by the Centers to assure that processing of the case is carried out in a timely manner.

District Requirement 4
The seizing district is responsible for ensuring appropriate follow-up on seizure actions until the action is adjudicated, and for promptly notifying the home district, appropriate center, DCMO (HFC-210), and OCC of the up-to-date status of the case.

District Requirement 5
A district recommending seizure of goods in another FDA district is responsible for contacting that district to obtain the proper format for the complaint and related papers for the jurisdiction and for obtaining the name of the compliance officer to whom the case will be assigned.

District Requirement 6
Whenever a district encounters changes in the U.S. Attorney letter, format for complaints, ancillary pleadings, or other requirements for filing a seizure action in the judicial district, DCMO must be notified as soon as possible. Models of forms that have been significantly revised should be forwarded to DCMO.

District Requirement 7
Upon receipt of approval for seizure from OCC, the seizing district must determine whether the lot is available for seizure. Do not forward the recommendation to the U.S. Attorney unless the lot is available. Prepare the appropriate number of copies of the complaint and the letter to the U.S. Attorney on OCC letterhead. The documents will be signed by means of a facsimile signature stamp. The documents will then be hand delivered, if practical, to the U.S. Attorney. Resident investigators may be used for delivery of the approved recommendation. Copies should also be forwarded to the home district. The district should also make distribution of the documents to the home district (if different than the seizing district) and local distribution.

District Requirement 8
In any seizure recommendation, consideration should always be given to seizing at the manufacturer's facility or principal distribution center to maximize the effect of the seizure. When seizure is not recommended at the manufacturer or chief distributor, an explanation should be provided.

District Requirement 9
The recommending district is responsible for drafting the appropriate pleadings for seizure recommendations that are converted by the Center into an injunction action. The draft pleadings may be submitted to the Center for review after the Center recommendation has been sent to OCC.

B. CENTER RESPONSIBILITIES

(See "ORGANIZATION OF SEIZURE PACKAGE" and "CONTENT OF SEIZURE MEMORANDUM" below for instructions on organizing the seizure package).

Center Requirement 1
Centers should routinely acknowledge receipt of seizure packages from the field via e-mail. If available, the name of the center compliance officer should also be provided. In addition, the Centers should identify a contact person with particular expertise for each type of seizure who will be available to answer preliminary questions regarding that type of seizure, in order to

facilitate the movement of seizure recommendations into, within, and among Centers. The center compliance officer and contact person may be the same or different persons.

Center Requirement 2
Center management should assure that procedures are in place and resources are available to complete concurrent reviews of seizures which (1) contain multiple charges, (2) require review by different components within a Center, or (3) require review by more than one Center. Such seizures are often reviewed sequentially which results in unnecessary delays. When multi-Center review is required, the Centers should promptly agree on the charges and products each is responsible for, and notify all involved components by e-mail. Concurrent review will result in forwarding seizures more rapidly.

Center Requirement 3
Appropriate centers are responsible for the technical, regulatory policy requirements, scientific review, and approval of seizure recommendations. Centers are also responsible for ensuring that copies of the recommendation are forwarded to Central Records (HFA-224). Changes in the proposed recommendation should be made only after consultation with the district's compliance staff.

Approved referrals to DCMO should include the recommendation as submitted by the district as well as the center's proposed corrections, additions, or deletions. The center will also provide the recommending, seizing, and home district DD's a copy of the center's approval or disapproval memo. Disapprovals must contain complete information explaining the reasons for disapproval and center guidance (when appropriate) on follow up to be taken by the district.

NOTE: When more than one center is involved in a recommendation, one of the centers will take the lead in processing the recommendation. The lead center will be responsible for coordinating with any other center involved and for obtaining concurrence of that center for the seizure. Any disagreements will be resolved by the lead center. The lead center will also be responsible for furnishing copies of any necessary documents to the other center for review.

Center Requirement 4
For each approved case, the lead center is responsible for preparing an approval memo that provides the name of a center contact and fully discloses all discrepancies or potential problems in the case, which could have any bearing on DCMO and OCC review and approval.

If there are special circumstances that have allowed the center to approve the seizure, in spite of problems, these should be fully discussed. Information concerning scientific expert support must be forwarded to DCMO, either in the approval memo or in a separate memo.

Center Requirement 5
While reviewing each recommendation 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. The center's approval memo for seizures in cases involving widespread problems, single device seizures, or multiple seizure campaigns, should explain how the seizure fits into the overall enforcement strategy to correct the problem. When appropriate, the memo may simply refer to an existing strategy document.

Center Requirement 6 - Processing

a. Recommendations Received by Electronic Transmission
The center will either forward the disk or transmit the information contained on the disk via ET or hard copy, directly to DCMO, with the pertinent seizure documents.

If corrections, additions, or deletions are necessary in the documents, they should be made using the disk as well as directly on the hard copy of the documents sent to DCMO ("pencil changes" may be made directly on a photocopy of the district's drafts).

b. Recommendations Received by Telephone
The center will prepare a memo to DCMO if the seizure is approved, providing all information necessary for preparation of the complaint and letter to the U.S. Attorney. A copy of the approval should be sent to HFA-224.

c. Recommendations Received by Mail or Hand Delivered
If the recommendation is approved, the center will forward all pertinent seizure documents and the approval memo. A copy of the recommendation and approval should be sent to HFA-224. If the recommendation is disapproved, immediately notify the district in writing.

d. Forwarding Case Files
Centers should forward case files intact organized as submitted from the Field. Also, the original documents submitted by the Field should remain in the official case files forwarded to OE and OCC. If Center Compliance Officers would like portions of the case files, they can make a copy of the original case files for their use.

C. RESPONSIBILITIES OF DCMO

See "ORGANIZATION OF SEIZURE PACKAGE" below for instructions on organizing the seizure package.

OE, Division of Compliance Management and Operations will be responsible for:

1. Reviewing recommendations to ensure compliance with policy.

2. Final agency review of the appropriateness of the action and adequacy of the pleadings and transmittal letter; preparing other documents, as required, in final form; and determining which cases require an availability check, update inspection (in conjunction with center), or input from the OCC attorney assigned to the case prior to forwarding to the Chief Counsel for final sign-off. DCMO should use the ET submitted by the center if any changes are needed in the documents. Any medical-technical changes in the recommendation made by DCMO or OCC must have Center concurrence. DCMO will insert the OCC Attorney's name and phone number, and the FDC number in the letter to the U.S. Attorney, and make any other necessary changes in the documents.

3. Transmitting the approved documents by ET to the district where seizure will be made.

4. Making headquarters distribution of the approved seizure, including copies to the appropriate center and DOJ.

D. RESPONSIBILITIES OF THE OFFICE OF CHIEF COUNSEL

The Office of the Chief Counsel will provide final legal review and approval of seizure recommendations and will provide the legal assistance necessary for presentation of the action, including direct assistance to the U.S. Attorney and the district compliance staff.

Upon approval, OCC should send copies of the approved documents (complaint and letter and ancillary documents) to HFA-224 for the file. The original signed document will be filed.

E. NOTIFICATION

OCC should immediately notify by e-mail the designated contact persons in each forwarding component that it has received the case and should identify who the attorneys are on the particular case. This enhanced communication will enable the forwarding components to track the progress of the case and who to contact in the event that relevant new information is received.

F. RESPONSIBILITIES OF DISTRICT AND HEADQUARTERS UNITS

To facilitate review and ensure completeness of recommendations, all seizure packages will have a standardized content and organization, as described below:

G. ORGANIZATION OF SEIZURE PACKAGE

The following instructions are designed to facilitate the review and ensure the completeness of seizure packages.

1. All seizure recommendations should be bound in folders with metal prongs. All documents included in the recommendation should be secured with the prongs (no loose papers).

2. Each folder should have tabs and the information should be organized within the tabs, as described below. Include the tab in the folder even when there is no information relevant to that tab. Simply state in the tab section "no information."

   TAB A Documents prepared by DCMO in the following order:
   1. DCMO Memorandum setting forth any unusual factual, legal, or policy issues for OCC consideration;
   2. Letter to United States Attorney;
   3. Complaint (with verification, if applicable);
   4. Ancillary pleadings (if applicable)

   NOTE: DCMO's working drafts should not be included.

   TAB B The Center's Seizure Approved Memorandum (including all review memoranda). See below, "CONTENT," Tab C, items 1-7, for content of this document.

   TAB C The District's Seizure Recommendation Memorandum (and any responses to previous Disapproval memoranda) (if multiple memoranda, most recent on top). See below, "CONTENT," Tab C, items 1-6, for content of this document.

   TAB D All relevant correspondence and memoranda of meetings and telephone calls with regulated entity and its counsel (most recent first). Also, include with Tab D a copy of any district evaluation of a firm's response to the FDA 483.

NOTE: If the Center identifies such documents in its files that have not been included by the District, the Center should: (1) place such documents in this section, (2) prominently identify it as "new information provided by Center," and (3) send a legible copy of the information to the District.

TAB E All relevant FDA 483's (most recent on top). If there are no FDA 483's, do not place any documents in this section.

TAB F Clear, legible, and complete copies of all relevant EIRs with the most recent on top. If non-relevant EIR documents or exhibits are removed and not forwarded with the comments, place a separate cover memorandum on the top of the EIR that identifies the documents that have been omitted. Significant information that supports or undercuts the proposed charges should be highlighted with a light colored magic marker that does not hinder copying.

TAB G Clear, legible and complete copies of Collection Reports including (in the following order) all relevant labels, labeling, promotional material, sample analyses, and interstate documentation, such as affidavits, invoices, shipping documents, organized by product. Put the most current on top. The documents for each product should be segregated and separated by a colored sheet of paper clearly marked with the product name. If one document contains claims for more than one product (with the relevant product information highlighted with a light colored magic marker that will not hinder copying), or place the document in the first relevant section and refer to its location in each subsequent relevant product section.

TAB H Documents not described above that relate to the history of the regulated entity or product. These include import alerts, CPGs, federal register notices, inspections and correspondence from other regulatory agencies.

TAB I Miscellaneous information. Place in this section any information that you believe is relevant and that is not described above.

H. CONTENT OF SEIZURE MEMORANDUM

TAB B The Center's Seizure Approved Memorandum should contain the following information in the following order:

1. Under the caption, "Center Contacts," the date on which the District's recommendation was received by the Center and the name and telephone number of the persons who will be responsible for the seizure within the Center who should be contacted in the event new information is received by the District.

2. Under the caption "Summary of Decision," a short narrative statement describing the decision with respect to each product and each proposed charge, such as, "seizure is approved for all products and all charges as proposed by the District"; "seizure is approved for all products and all charges as proposed by the District, except the 342(a)(4) charge for the products A, B,

and C"; or "only the seizure or products A and B for the 351(a)(2)(b) charge is approved."

3. Under the caption "Reason for Seizure," state any special factors that strengthen the seizure that were not highlighted by the District, such as the nature of the health hazard; the products are part of a recent agency initiative or current publicity; additional warnings. If the Center supports all of the reasons set forth by the District, it is acceptable to refer to the District's Seizure Recommendation Memorandum.

4. Under the caption "Seizure Approved," separately list and clearly identify each product with sufficient particularity so that there can be no confusion. For example, list the products by product type, brand name, size, strength, or lot number and list each charge that is approved for the product. The precise statutory charges and relevant regulations should be indexed and indented under the relevant product caption; list the most significant charge first. If new charges are added by the Center, they should be listed under the relevant product caption and flagged with a parenthetical note to indicate that the Center has added the charge. Products that share identical charges may be grouped as a single caption. However, products that share only some of the charges should be listed separately. For example,

Products A, B, and C

351(a)(2)(B)
21 CFR 211.113(b) (no procedures to assure sterility of product)
21 CFR 211.100(b) (written procedures not followed)
352(f)(1) (back door new drug)

Product D

352(f)(1) (back door new drug)

5. Under the caption "Seizure or Charges Disapproved," separately identify each product and each charge that is not approved and state the reasons for the disapproval. If further data are needed to support the seizure, identify the data. If the seizure is approved as submitted, state "Not applicable."

6. Under the caption "Expert Witnesses," identify the name, address, and telephone number of each agency or independent witness who has committed to support the case and state exactly what charges and what product the witness will support. If the Center believes that no independent expert support will be necessary, state clearly why this is the case. If any expert has expressed reservations about any charge, summarize the expert's concerns.

7. Under the caption "Issues and Concerns," clearly explain in separate paragraphs each issue, concern, or potential weakness in the case that would

be considered by DCMO, OCC, and other intra-Center reviewers. When appropriate, discuss the medical necessity and availability of alternative products.

TAB C The District's Seizure Recommendation Memorandum should contain the following information, in the following order:

1. Under the caption "Contacts," the name and telephone number of the persons who will be responsible for the seizure within the District and who should receive all subsequent memoranda from the Center, DCMO, and OCC regarding the recommendation. Use of alternate contacts should be considered.

2. Under the caption "Summary of Recommendation," a short narrative statement describing the type and amount of products to be seized, the factual basis for the seizure, and the proposed charges. For example, "The Orlando District recommends seizure of ten lots of shrimp that contain salmonella (342(a)(1)) and five lots of crab meat that were packed under insanitary conditions (342(a)(4))".

3. Under the caption "Reason for Seizure," the District should explain in detail why the seizure is necessary to protect the consumer. Include the nature of the public health risk and the extent of economic fraud. Include the impact of the seizure, the retail dollar value of the lots to be seized, how many units of the product are distributed per month or year. And include related regulatory considerations, for example, the history of the manufacturer, prior warnings, if any, and involvement of other regulatory agencies; why voluntary compliance is not practicable or desirable; and if applicable, why the seizure at another locations such as at the manufacturer or a major distributor, is not practicable or more effective.

4. Under the caption "Articles to be Seized; Charges," separately list and clearly identify each product with sufficient particularity so that there can be no confusion as to the target product. List product type, brand name, container size, strength, or lot number and each charge that is recommended for each product. The precise statutory provisions and relevant regulations should be indexed and indented under the relevant product caption; list the most significant charges first. Products that share identical charges may be grouped under a single caption. However, products that share only some of the charges should be listed separately. See the section on Center "Seizure Approved Memorandum" for a format.

   Under each proposed charge for each product describe in detail and under a separate heading the evidence that supports each element of the charge and state precisely where in the file each particular piece of evidence may be found. Where the evidence for a different product is identical (that is there are no more and no fewer charges) it is acceptable to refer to the appropriate other product. For example,

Products A, B, and C

21 U.S.C. 351(a)(2)(B)

a. Products are drugs: see labels, Tab G for products.
b. GMP violations:
   1. 21 CFR 211.100(b) (failure to follow written procedures) – FDA 483 (Oct. 15, 1994), items 3, 5 and 13, Tab E; EIR (October 15, 1994), pp 13, 18, 44; Tab F; December 12, 1994 response to FDA 483, pp. 2, 3, Tab D.
   2. 21 CFR 211.113(b) -- (no procedures to assure sterility) – FDA 483...; EIR...; December 12, 1994 response to FDA 483, ...
c. Held for sale -- Johnson Affidavit, pp. 2, 3, and 4, Tab I.

Product D

a. Product is a drug: see label, Tab G.
b. GMP Violations
   1. 21 CFR 211.100(b) -- See products A, B, and C, item 1.
   2. 21 CFR 211.182 (failure to maintain equipment cleaning logs). (Citation format as above).

5. Under the caption "Expert Support," state whether the District believes independent expert support should be obtained and, if so, for which issues. If the District has suggestions as to which persons might serve as experts, the candidates should be identified in this section (name, address, telephone number, summary of qualifications or c.v.).

6. Under the caption "Issues and Concerns," clearly explain in separate paragraphs each issue, concern, or potential weakness or flaw in the case that should be considered by the Center, DCMO, and OCC. In addition, indicate whether seizure of a particular product will or will not impact on the supply of a necessary product.

I. OUTSIDE EXPERTS

Center, with District input as appropriate, should take responsibility for ascertaining whether outside experts are necessary to support a case and, if so, promptly take steps to secure such support. Outside expert support is usually not necessary for decomposition, insanitary conditions, and adulteration with listeria, salmonella, or *E. coli*. Outside expert support more likely will be necessary in situations in which FDA is seeking to expand its jurisdiction into a new product area; most GMP cases (except the most egregious); cases that involve ambiguous, implied labeling claims; many health fraud cases; and other cases in which litigation appears probable.

See Chapter 10, section 10-70 “Expert Support for Cases” for further information, including information on paying for expert support.

J. INDEPENDENT JUDGMENT

All reviewing officials (whether in the District, the Center, or DCMO) are expected to exercise independent judgment as to whether an action or a specific charge should be approved or not approved. It is not acceptable to "pass a case" to downstream components because of

pressure from another component; each component should approve or disapprove and state the reasons for the decision.

K. TIME MANAGEMENT

Centers and Districts should apply the following time management procedures to those seizures which require additional information from the Districts:

1-DAY HOLD

If, after contacting the District, a Center determines that the required information is readily available and can be provided that day or the next business day, the review clock keeps running. The Center will inform the District that the information must be received by close of business the next business day or the case will be placed in temporary abeyance.

TEMPORARY ABEYANCE (T/A)

If, after contacting the District, a Center determines that the required information can be provided within 5 business days, the review clock stops and the case will be placed in T/A. The Center will e-mail the District if the Center does not receive the information within 5 business days. The Center will prepare a memo of this communication to record the date of the decision.

RETURN TO DISTRICT

If, after contacting the District, a Center determines that the required information cannot be provided within 5 business days, the Center will return the case to the District. The Center will prepare a memo to the District describing the information needed to complete the review of the case.

L. FORWARDING CASES

When case files are forwarded to the next reviewing office, send the files by the most expeditious and practical method, either hand-delivered, or overnight carrier. Include electronic media such as floppy disk or CD of the referral and pleadings.

M. NEW INFORMATION

Centers and Districts should immediately notify -- by e-mail, facsimile, or telephone -- the designated contact persons in the components that have and are currently processing any seizure recommendation of all new information that could affect the evaluation of the approvability of the seizure action. Examples of new information 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. When a reply is warranted, the District and the Center (and, if legal issues are raised, OCC) should agree on which component will be responsible for drafting the response, any procedures for coordinated clearance of a response, a target date for issuing the response, and a process to ensure that the response is received by the appropriate components. A legible copy of the new information (clearly marked "new information" and date of forwarding) should also be immediately forwarded to the component that is currently reviewing the seizure.

N. CAPTIONS

The District, Centers, the Office of Enforcement and the Chief Counsel should include sufficient labeling information in the captions to assure that the U.S. Attorney's office and the

U.S. Marshal can identify the products to be seized. It is not necessary to expand the caption with other extraneous information.

6-1-7 Mass Seizure

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

Therefore, as a general rule, the evidence of violative conditions supporting mass seizure (usually the last day of the 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. If timeliness is critical, the district should hand carry the recommendation package to headquarters. In that event, the following steps should be taken:

A. Because of the effect that a mass seizure can have on a company, extra care should be taken to assure that the evidence warrants the proposed action against all articles to be seized. In addition, the complaint should be more specific than in other types of seizures. Also, as noted, mass seizures must be approved by the DD and RFDD.
B. Notify the center and make arrangements for it to have someone available to review the case.
C. Prepare a model decree, which should usually include provisions for injunctive relief for quick settlement. Review carefully the specific provisions in the proposed decree.
D. The compliance officer bringing the case in should be thoroughly familiar with the facts, and should bring to headquarters all exhibits, photographs, the EIR (at least in draft), FDA 483, and all other pertinent documents.

6-1-8 Direct Reference Mass Seizure Authority

The agency is continuing a pilot program that permits districts to obtain concurrent center (CVM and CFSAN) review and DCMO review of mass seizure recommendations for food storage warehouses having live rodent activity or live bird or live insects. This direct reference authority reflects the agency's experience and success with food sanitation violations and the fact that the issues presented in these recommendations have been considered many times by center and DCMO reviewers. DCMO will accept the center's phone concurrence.

After the pilot program, CFSAN and CVM will review their experience and the agency will decide whether to implement the authority to permanently by-pass the centers and go directly to DCMO.

Criteria for referral to DCMO, CVM, and CFSAN regarding evidence needed in 342(a)(4) mass seizure is as follows. There must be compelling evidence of significant current live rodent,

insect or bird 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. The evidence should demonstrate that the infestation has resulted in widespread 342(a)(4) adulteration or that the live infestation is sufficiently dense and will probably spread to the food to be mass seized. Examples of mass seizure cases involving 342(a)(4) conditions are available from DCMO.

6-1-9 Seizure Accomplishment And Close-Out Documentation

After seizure has been approved, it is the seizing district's responsibility to encourage expeditious handling of the seizure, to track the action to its conclusion, and to report current status to the home district, OCC, the U.S. Attorney, the center, and DCMO.

A. CONTACTS WITH THE U.S. ATTORNEY

Seizure actions involving health hazards require prompt action. The U.S. Attorney's Manual states:

"Forfeiture actions should be commenced as soon as possible, particularly where continued distribution of the article may threaten the health of the public."

In discussions with the U.S. Attorney, the compliance officer should encourage prompt filing of the complaint and the forwarding of a copy of the complaint as filed, with the civil number and the date of filing, to OCC and to the district office. The district should ensure that a copy of the complaint is obtained promptly upon filing and a copy of the filed complaint should be forwarded to DCMO.

B. CONTACTS WITH THE U.S. MARSHAL

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

1. When a questions of the proper identity of the lot exist (e.g., commingled lots or complicated labeling).

2. When a mass seizure is involved.

3. 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.

C. SEIZURE ACTION REPORT

As soon as the articles have been seized, the seizing district will promptly notify the OCC trial attorney, the home district, the center, and DCMO via ET, the amount and value of each lot seized, and of the Marshal's return date.

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.

6-1-10 Disposition Of Seized Articles

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

1. Claimant may do nothing, in which case the article will be disposed of by default;

2. Claimant may 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;

3. Claimant may 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 district in whose territory the article was seized 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.

A. 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 usually prepared by the district with OCC concurrence in routine cases. 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:

1. Constructive Destruction - The article is destroyed by using it for a constructive purpose, such as donating misbranded but wholesome food to charity.

2. 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.

3. Conversion - Human food may often be converted to animal food, rather than destroyed. If conversion is the method of destruction chosen by the Marshal, 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.

4. 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 the NEPA. When questions arise concerning environmental impact, contact the ORA Safety Management Officer (HFC-21) for assessment of the proposed method of destruction.

B. CONSENT DECREE OF CONDEMNATION

1. 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). Notify the OCC attorney immediately when it is learned that a claim has been filed, and send a copy of the claim by facsimile as soon as it is obtained.

2. Consent Decree - Should a claimant appear, it may agree to the entry of a Consent Decree providing for attempted reconditioning of the article under seizure (see RPM "Compliance Officer and OCC Attorney Responsibilities in Default and Consent Decrees"). In the event that this method of response is chosen, there are several steps which the claimant must follow. These are discussed below:

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

   a. Condemnation of the article as being in violation of the law.
   b. A penal bond approximately twice the retail value of the article under seizure.
   c. Provisions for payment of costs for storage and handling by the U.S. Marshal and for supervision by FDA before release of the product.

d. A provision that claimant will attempt to bring the article into compliance under the supervision of, and to the satisfaction of, FDA. See the RPM section "Compliance Officer and OCC Attorney Responsibilities in Default and Consent Decrees."

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

C. 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.

D. BOND FORFEITURE PROCEDURES

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

E. CONTEST OF SEIZURE

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

1. File a proper, verified claim to the article, and,

2. 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.

F. RECONDITIONING OPERATIONS

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

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

1. Reprocessing by Reworking or Cleaning. - Unless the district has a recent precedent case of a similar nature, proposals for reprocessing must be referred to the appropriate center for guidance.

2. Relabeling - All proposals for relabeling of drugs, devices, cosmetics, special dietary foods, and fortified or infant foods, must be sent to the appropriate center for prior comment unless guidelines exist. Other foods may be relabeled when the district has a clear precedent for the use of the proposed labeling, but doubts should be resolved by referral to the center.

3. Denaturing - If there are outstanding instructions for the denaturing of the product involved, these should generally be followed. If no instructions exist, or if in the district's judgment the guidelines should not be followed, the proposal should be referred to the appropriate center for consideration.

   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 (IOM 720), the investigator supervising the operation is required to submit a detailed report.

   When the court's decree permits the seized articles to be moved to another district for reconditioning operations, the district in which the operation is to be performed will supervise the reconditioning operation. In such cases, the seizing district should determine that the bond has been posted and the articles released by the U.S. Marshal before permitting the goods to be shipped. The seizing district will forward to the supervising district a copy of the decree and other pertinent data, before the seized article begins its physical move.

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

G. POST SEIZURE SAMPLES

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

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

H. NOTICE TO CLAIMANT AND NOTICE TO U.S. ATTORNEY

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

I. COMPLIANCE OFFICER AND OCC ATTORNEY RESPONSIBILITIES IN DEFAULT AND CONSENT DECREES

The following general rules (which are subject to exceptions in unusual cases) are intended to reflect two principles.

1. Every person in the agency, including the compliance officer in the district, the Center case 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.

2. The maintenance of good working relationships with U.S. Attorneys' offices is a matter of concern to both the field and OCC. U.S. Attorneys' offices should be made aware that they can call upon the assistance of officers in the field and OCC attorneys at headquarters; both the field and OCC must affirmatively include the other in dealings with U.S. Attorneys' offices.

Requirement 1

All default decrees and consent decrees submitted to a U.S. Attorney's office for filing in court and decrees drafted by a U.S. Attorney's office and submitted to FDA for comment shall be cleared through the assigned OCC attorney and the Center case officer, after full consultation with the district compliance officer.

1. In the case of a default decree, the consultation and clearance shall at least consist of a telephone conversation between the attorney, Center case officer, and the compliance officer. They shall determine what additional consultation, if any, is needed.

2. In the case of a consent decree, a copy of the decree shall be sent to the OCC attorney and Center case officer.

Requirement 2

Where OCC is asked by the district office or by the U.S. Attorney's office to prepare a decree, the OCC attorney shall consult fully with the compliance officer and with the center, concerning the decree and, after reaching agreement with the parties involved, shall transmit the prepared decree directly to the U.S. Attorney's office, with a copy to the compliance officer and center.

Requirement 3

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.

Compliance officers shall not negotiate disposition of a filed case without prior approval of an attorney in OCC. Any such negotiation shall include an attorney from OCC, or be conducted with the advance knowledge of, and pursuant to guidance provided by, such attorney.

Requirement 4

As soon as it appears to the district compliance officer that special local customs or procedures may affect any case (for example, giving seized articles to charity), the compliance officer shall advise the OCC attorney of the local peculiarity. In participating in the disposition of cases involving a default or consent decree, OCC attorneys shall be sensitive to relevant

local customs, and shall respect such customs except when they are contrary to law or agency policy.

When an attorney believes that a local custom is contrary to law or agency policy, the attorney shall bring the matter to the attention of responsible officials in the manner that will interfere as little as possible with effective working relationships between OCC, the district office, and the U.S. Attorney's office.

6-1-11 Costs Of Supervision

The following rates shall be used in billing a claimant for supervisory services in connection with reconditioning, relabeling, or conversion 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

6-1-12 Monitoring Of Seizure Actions

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

6-1-13 Seizures Involving Other Agencies

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

A. 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 7l55a.02 and 7155j.01.

B. U.S. DEPARTMENT OF AGRICULTURE

After clearance as under NMFS, include a similar statement in the seizure recommendation. See Memorandum of Understanding 7l55a.03 and 7155a.04.

C. FEDERAL TRADE COMMISSION

See Memorandum of Understanding 7l55m.0l.

D. ENVIRONMENTAL PROTECTION AGENCY

See Memorandum of Understanding 7l55b.03.

E. DEPARTMENT OF LABOR

See Memorandum of Understanding 7l55i.01.

6-1-14 Exhibits

The district compliance officer may request DCMO to provide (normally by Fax or e-mail, if available) a copy of the latest referral for seizure (letter and Complaint) which is similar to the case being considered by the district (if not available on the on DCMO's Intranet website).

6-1 Telephone Seizure Recommendation
6-2 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

6-2 INJUNCTIONS

6-2-1 Purpose

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

6-2-2 General Guidelines

An injunction is a civil 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.

It is not mandatory to demonstrate that the law has been violated to seek an injunction, only that there is likelihood that it may be violated if an injunction is not entered.
When initiating requests for injunction with a Temporary Restraining Order (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. Injunctions with TROs have the highest priority ranking of all legal actions.

For an injunction action to be credible in the eyes of the Department of Justice (DOJ), the U.S. Attorney, and the court, the evidence must be current.

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 an injunction is filed by DOJ or a U.S. Attorney, a hearing may be placed on the court calendar at any time with extremely short notice. It is imperative that the district compliance officer maintain close contact with the Office of Chief Counsel (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.”

When seeking only a permanent injunction, FDA prepares, for filing, the following documents:

1. Complaint for Injunction (drafted by district)

2. Injunction Recommendation (prepared by district)

3. Consent Decree of Permanent Injunction (prepared by OCC based on "Conduct to be Enjoined" section in Injunction Recommendation)

When seeking a preliminary injunction (but no TRO), the following additional documents should be prepared:

1. District Director Declaration in support of Motion for Injunction (prepared by district)

2. Declaration of Experts (prepared by center)

3. Motion for Preliminary Injunction (prepared by district)

4. Notice of Motion for Preliminary Injunction (prepared by district)

5. Proposed Order of Preliminary Injunction (prepared by district)

6. Letter to DOJ/OCL (prepared by OCC)

In cases where a TRO is to be sought, the following additional documents should be prepared:

1. Temporary Restraining Order (prepared by district)

2. Motion for TRO (prepared by district)

3. Notice of Motion for TRO (prepared by district)

4. District Director Declaration in support of Motion for TRO (prepared by district)

6-2-3 Definitions

A. TEMPORARY RESTRAINING ORDER

Temporary restraining orders are court enforced cease and desist orders that are brought 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, but usually the court hears the matter ex parte by reviewing the documents and questioning government counsel, the FDA investigator, the district compliance officer, or other FDA personnel.

B. 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. A preliminary injunction may be dismissed, or a trial for permanent injunction may be set by the court, at the request of either party, at any time.

C. 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

Injunction should 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, multiple 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 an order of injunction. Injunction will be the action of choice when:

1. There is a current and definite health hazard or a gross consumer deception requiring immediate action to stop the violative practice; or

2. There are significant amounts of violative products owned by the same person in many locations, voluntary recall by the firm was refused or is significantly inadequate to protect the public, and multiple seizures are impractical or uneconomical. Products deemed violative, but which have not moved in interstate commerce, can be controlled through injunction if the likelihood that the product will move in interstate commerce is demonstrated; or

3. There are long-standing (chronic) violative practices that have not produced a health hazard or gross consumer fraud, but which have not been corrected through use of voluntary or other regulatory approaches.

With respect to 1 and 2 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 the facts warrant, but especially in those cases where an imminent danger to health can not be alleged.

When similar violative practices are found at more than one facility under the same corporate management, the home district where the corporate office is located should evaluate the compliance histories of other corporate facilities to determine whether there are patterns of violations or trends that indicate the presence of systemic problems that should be addressed on a corporate-wide level. The Office of Enforcement (Division of Compliance Management and Operations) can assist in developing a regulatory approach in these situations. (Also, see section on Ad Hoc Committees in Chapter 10.)

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.

Although there is no legal requirement to name individuals in complaints for injunction, the agency believes that by doing so, individuals will be more inclined to take immediate and active interest in seeing that the violation ceases. 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. 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.

A. METHODS OF GIVING NOTICE

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

NOTE: Rarely in injunction cases will issuance of the FDA 483 constitute adequate notice, in the absence of further notice from agency compliance officials or senior managers.

The factors listed below will apply in determining the adequacy of notice:

Agency records should show that sometime during case development:

1. The individuals with authority to prevent or correct violations have been given appropriate notice of the general conditions that are violative.

2. There is sufficient information to conclude that proper action to correct the violations has not been taken or will not be taken promptly.

3. 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: Normally, there should not be exceptions to meeting the requirements of 1-3 above concerning documentation of prior notice. However, recognizing the uniqueness of each situation, there may be cases where exceptions to the rule are justified. Justification for such exceptions must accompany the case submission.

6-2-6 Refreshing Evidence - Update Inspections

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 projected time of filing.

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

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

6-2-7 Prerequisites For A TRO Or Preliminary Injunction

1. Timeliness

2. Adequate Notice

3. Seriousness of the Violation

To avoid the need for updating the evidence in requests for TRO or preliminary injunction, 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.

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

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

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 recommendations which contain TRO provisions. These persons should also be available from each reviewing unit to hand-carry the case to each succeeding level, for review.

6-2-8 Procedures And Timeframes For Review And Referral Of Injunction

The principal features of timely injunction actions include carefully prepared recommendations that are fully supported by facts, the early alert of headquarters to probable injunction situations, and concurrent review of injunction recommendations by the Center and OCC.

1. When the district is considering injunction as the probable action of choice, the compliance officer or CSO must orally alert and consult with their supervisor, the appropriate center compliance unit, and, if legal or strategic issues are apparent, OCC (Deputy Chief Counsel for Litigation) and DCMO at the earliest possible date. A conference call among these offices should be considered as the means of that early alert. The district should make every effort to make this, and any other consultation with the center and OCC and DCMO, informative enough to preclude later "surprises." The district representatives will promptly prepare a memorandum of any decisions or assignments coming out of such contact and promptly send a copy to those participating in the discussion. The district will keep the center, and OCC and DCMO contacts apprised of significant developments prior to and after the recommendation is made.

   Once the initial decision to seek injunction has been made, the district should ensure that high priority is given to preparing the EIR, completing relevant sample analyses, and preparing the necessary documents.

   The center will assign a compliance officer and, as necessary, technical staff to assist the district in processing the injunction recommendation, if injunction seems appropriate based on the early contacts. The center will promptly notify the assigned district compliance officer or director of the compliance branch of the names and telephone numbers of the center contact persons.

OCC will, as necessary, assign an attorney to advise the district in the inspection/evidence gathering stage or in preparation of the injunction recommendation.

The centers and OCC will assign persons who will be available to work on the injunction with no current conflicts in schedule through adjudication.

NOTE: If it becomes necessary during the case development/review process to resolve agency policy or reach an agency decision on a controversial issue (including the action of choice), the district, center, or OCC should contact the Director of OE (HFC-200) who will promptly convene an ad hoc committee for timely resolution (in person or by conference call).

The district will forward copies of the FDA 483 from the most recent inspection and other significant supporting documentation of apparent violations to the assigned center contact at the earliest possible time, as it becomes available, by expeditious means (such as by FAX, over-night delivery). If a TRO is being sought, such copies should also be sent concurrently to OCC (to the assigned attorney or, if no attorney has been assigned, to the Deputy Chief Counsel for Litigation) and DCMO. The district will promptly call the center contact (and OCC and DCMO, if applicable) to advise that the documents were sent and to ensure their receipt. Except in TROs and unusual circumstances, when a preliminary or permanent injunction is sought, the district should send only the FDA 483 and the injunction recommendations to OCC. OCC will review the entire injunction upon referral from the center.

2. Within 10 working days after completion of the inspection, the compliance branch director will sign off on the district's injunction recommendation. The district will hand-carry the recommendation to the center contacts, or send it by other expeditious means; and send a copy of the recommendation (memorandum and draft legal documents only) to DCMO (HFC-210). The recommendation should state clearly the injunctive relief sought and should be accompanied by a draft complaint, the appropriate ancillary pleadings, and all supporting evidence. The recommendation, and not the complaint, should contain the district's proposed detailed prayer for relief. See the RPM section "Injunction Recommendation". To facilitate headquarters' review, the district recommendation, District Director Declaration, and draft complaint must cross-reference evidence discussed to the FDA 483, EIR, analytical worksheet, items of correspondence, etc.

   Districts are encouraged to recommend potential expert witnesses, either FDA or external, when forwarding the recommendation.

3. The assigned Center CSO is responsible for:
   a. reviewing the findings reported by the district, the district’s draft documents, and the defendants’ response, if any, for technical/scientific supportability, and regulatory policy and requirements, including the adequacy of prior notice;
   b. approving the district’s proposed conduct to be enjoined, ensuring that the requirements are adequate and reasonable;
   c. identifying scientific, technical and/or policy expert witnesses who will support the action, and prepare the first draft of their declarations, if needed.

NOTE: All changes to the draft documents should be made as tracked changes on an electronic file copy, or shown on a paper copy submitted with the package. The center's concurrence memo to OCC should reference where changes have been made in the draft documents.

The center will forward its concurrence memo and the case documents to OCC as soon as possible; and send a copy of the concurrence memo with its attachments to the district, DCMO (HFC-210), and HFA-224. The concurrence memo should identify the strengths and any weaknesses in the case and the status of expert witness testimony, including the name, title, address, and telephone number of experts who have agreed to review the case or support the case. Referral of the case will not be held up 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.

If it does not concur with the recommendation, the center should promptly and orally notify the district, DCMO, and Office of Chief Counsel (Deputy Chief Counsel for Litigation). The center should also promptly prepare and send a non-concurrence memo to the district, any OCC contact persons, and DCMO/OE (HFC-210). The memo should include a detailed explanation for the non-concurrence. The district may ask OE to convene an ad hoc committee if there is a credible basis to dispute the disapproval and discussion with the center has failed to resolve the difference of opinion.

4. OCC will conduct a legal review, prepare the referral letter, revise the complaint as necessary, prepare the consent decree, and forward the final referral for injunction to DOJ within 10 working days. OCC will have final responsibility for ensuring that pleadings documents conform to the style and other requirements of the appropriate district court.

6-2-9 Documentation

The following sections give instruction and guidance for preparing the documents. Examples are given at the end of this chapter. As each case is unique, the examples should be used only as general guides. The structure of the documents must conform to the case at hand.

6-2-10 Injunction Recommendation

The memorandum prepared by the district should be entitled "Permanent Injunction Recommendation" or "Preliminary Injunction Recommendation," or "Injunction with Temporary Restraining Order," as appropriate. Include a statement that a TRO has been considered and the reasons for or against recommending a TRO in the action. The recommendation should contain sections as outlined below:

A. BUSINESS AND INDIVIDUALS TO BE ENJOINED

Report the full name and address of the business and each individual to be enjoined. Where action is to be brought against an individual, either separately or with a business, the place where the individual resides should be stated. Service of process, unless made personally upon an individual (usually at the place of business), must be made at his/her residence.

Where an action is to be brought against a business, state the name and address, as well as the job title (if known) of the officer or agent upon whom service of process may be made, as injunctions are usually filed in the judicial district where the subject plant is located.

B. LEGAL STATUS

Give the exact corporate name (as it appears on the records of incorporation collected by the district), the state in which incorporated, and the name, address, and job title of each officer and employee named in the complaint. If a corporation is operating as a foreign corporation within the state where injunction is sought, determine who is registered as the agent for the corporation in that state.

In the case of a partnership or sole ownership, give the full names and addresses of the individual partners or owners. In the case of individuals, give their relationship to the business or conduct to be enjoined.

C. PRODUCTS INVOLVED

Identify the specific products or class of products involved in the injunction action.

D. ALLEGED VIOLATION

List the sections of the prohibited acts violated, and, where applicable, sections of the Acts, as codified in the U.S. Code, which form the substantive basis of the complaint (for example 21 U.S.C. 352(a), 351(a)(2)(B)). Give a brief statement of how each section of the Act has been (or will be) violated. Provide a summary of the specific practices sought to be enjoined. Because the proposed Complaint for Injunction and affidavits will contain specific details, these details should not be repeated in the summary. However, be specific enough so that the headquarters reviewing units will understand clearly the practices you are seeking to enjoin. Do not report that the firm has "gross deviations from GMP." Rather, report specifics, such as, "the firm does not assay finished products," or "the firm has had six recalls of subpotent drugs because of inadequate process controls."

E. SUMMARY OF EVIDENCE

Refer to the appropriate paragraphs in the complaint and district director declaration for the evidence which supports the requested relief. Do not repeat the detailed information on inspectional findings which will be contained in the affidavits and complaint. Do report results of analysis on pertinent samples. In separate paragraphs, point out strengths and any weaknesses in the case and provide the district's rationale for why injunction (or TRO) remains appropriate.

F. CONDUCT TO BE ENJOINED

State clearly, completely, and precisely the relief to be sought. Do not use the short form presented in the draft complaint.

6-2-11 Cover Letter To DoJ

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

the facts (see Exhibits 6-11 & 6-12), and should not repeat, in detail, the information contained in the complaint (or accompanying affidavits) except as is necessary to summarize the findings and explain their significance.

The cover letter should contain a summarized background section which includes a statement of the proposed defendants' business, the kinds of products the proposed defendants make or distribute, the importance to the public of the products and their intended uses, problems generally recognized in the production or distribution of these products, and the risks or consequences that may result from a failure to comply with the laws involved. One issue that generally requires explanation is recordkeeping, its purpose and the possible consequences of incomplete and inadequate records.

Because the Department of Justice (DOJ) and Assistant U.S. Attorneys (AUSAs) are often reluctant to file injunction cases unless they believe that the administrative process has been exhausted, the cover letter should contain a section justifying the need for injunctive relief that refers to the prior notice and warnings and history of the defendants described in the affidavit of the District Director.

To forestall a potential negative impression about the case by AUSAs who are often unaware of the very strong case law in support of injunctions under the Act, the cover letter will also contain standard legal paragraphs. One paragraph will explain, with case citations, the special rules that apply to statutory injunctions under the Act; for example, the fact the irreparable harm need not be shown (see Exhibit 6-13). The other standard paragraph, where appropriate, will contain a brief legal discussion of the law with respect to the violation at issue (see Exhibits 6-14, 6-15, and 6-16).

6-2-12 Complaint For Injunction

The district will draft a proposed Complaint for Injunction which will be reviewed by the center and OCC.

The complaint consists of 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.
NOTE: Complaints for Injunction should not contain lengthy descriptions or prayers. They will be primarily summaries. Detailed information will be provided in the other documents submitted to the court.

The **HEADING** of the complaint should follow the local court format. All court requirements as to the form of the complaint must be followed.

Next there should be an **INTRODUCTORY** paragraph establishing that the complaint is being filed under the Act, 21 U.S.C. 332(a), and referring generally to the activities the government is seeking to enjoin. Citations to additional statutes establishing jurisdiction and venue should be added to this introductory paragraph or included in a separate paragraph. See Exhibit 6-17, model ¶ 1.

Following this is a paragraph identifying the **CORPORATE DEFENDANT** by name, where it is incorporated, and all addresses where business is done within the court's jurisdiction. The district should confirm current corporate status with the Secretary of State. See Exhibit 6-17, model ¶ 2.

In situations where the local plant problems stem from action (or inaction) of a corporate headquarters located in another judicial district, the injunction should be drafted in a manner and filed in a venue that will address and correct the basic cause of the problem. For example, there may be one or more other plants operating under the same policy of corporate neglect. In such a case, limiting the action to the problem in the one plant, or bringing the case against local management of the one plant may not result in correction of the basic problem. Rather, in such a case, the action should be brought against the corporate headquarters and be drawn so as to apply to all corporate facilities.

Next, separate paragraphs should identify **EACH INDIVIDUAL DEFENDANT** by name, title, address where he/she does business within the court's jurisdiction, and include a summary of his/her positions and responsibility. See Exhibit 6-17, model ¶ 3.

It is not sufficient to name an individual simply because he/she has a title that suggests responsibility. FDA is interested in those individuals who have the actual authority to correct the conditions and prevent their recurrence. In most situations, this will usually include, at a minimum, the president of the firm and the person in charge of the plant. While it is not necessary to have had personal contact with the president, the evidence should indicate that the defendant is the active chief executive, and not just the holder of an honorary title.

In charging an individual who is not physically located within the jurisdiction where the case is brought, include wording such as: "The defendant, John C. Doe, an individual, is the Area Director of Operations of said corporation and as such is responsible for the manner in which the corporation's plant is operated within the jurisdiction of this Court."

The next paragraph identifies the **NATURE OF THE BUSINESS**, with specific mention of the PRODUCTS sought TO BE ENJOINED by name and its (their) intended use, if applicable. Reference to the INTERSTATE NEXUS should also be made in this paragraph.

The length of this statement will depend on the complexity of the case and on the tactical benefit of having a statement early in the complaint. See Exhibit 6-17, model ¶ 4.
The next paragraph establishes that the products fall within the **APPLICABLE DEFINITIONS** covered by the Act (that is it is a drug, device, or food), and that describes the adulteration, misbranding, or other charges. This paragraph can be combined with Paragraph 5. See Exhibit 6-17, model ¶ 5.

Next are paragraphs summarizing the defendants' **MOST RECENT VIOLATIVE INSPECTION** or **ACTIVITY**. If applicable, mention should also be made in the paragraphs immediately following, to prior enforcement actions including, seizures, regulatory correspondence warning of similar conduct, and state inspections. However, detailed descriptions of prior illegal conduct, such as details of previous inspections and regulatory history, should not be given. See Exhibit 6-17, model ¶ 6. The summarizing statement will include, in most cases, a list of specific or significant inspectional observations from only the most recent inspection. These

inspectional observations should be arranged so that the most significant observations are listed first.

If there is more than one "recent inspection," list the significant observations made during each inspection. A "recent inspection" is one that has been concluded within 60 calendar days of the district's Injunction Recommendation to headquarters.

Next are paragraphs identifying the **SPECIFIC PROHIBITED ACTs**, under 21 U.S.C. 331, which has been violated. See Exhibit 6-17, model ¶ 7.

Next is a paragraph establishing that the defendant has had **PRIOR NOTICE** of his/her illegal conduct, and alleging that this conduct has continued despite warnings. This paragraph should list the warnings, most recent first, and state the dates and manner of the warnings. See Exhibit 6-17, model ¶ 8.

Next is a paragraph alleging that the **VIOLATIONS MAY WELL CONTINUE UNLESS THE DEFENDANT IS ENJOINED**. See Exhibit 6-17, model ¶ 9.

Next is a **SUMMARY PRAYER FOR RELIEF** requesting that the defendants, and all those acting in concert with them, be enjoined from directly or indirectly engaging in certain specified illegal acts and be further restrained from engaging in illegal activity until certain conditions have been met. (A detailed prayer for relief, identical to that included in the proposed consent decree, should not be put in the complaint.) The prayer in the complaint will usually be one paragraph. See Exhibit 6-17, model ¶ 10.

NOTE: The proposed Consent Decree of Permanent Injunction will contain the complete relief sought by the government.

The prayer is completed with paragraphs requesting (1) a temporary restraining order, a preliminary injunction (if applicable), and permanent injunction; (2) a provision for costs; and (3) a request for such other relief as the court deems just and proper. See Exhibit 6-17, model ¶ 10.

The complaint ends with a **SIGNATURE PAGE**. See Exhibit 6-17, model 11.

6-2-13 Declarations

Most jurisdictions will accept declarations in support of a motion for preliminary relief or for a Temporary Restraining Order. If the court requires live testimony in support of a motion for TRO or preliminary injunction, the declaration may be converted to testimony.

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 6-18. The 28 U.S.C. 1746 declaration should state, "Pursuant to 28 U.S.C. 1746, I hereby declare under penalty of perjury that the foregoing statement is true and correct to the best of my information and belief."

If the court requires affidavits from investigators or analysts or others having firsthand knowledge of the facts, they should be furnished by the district along with the draft complaint. 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 declarations of (1) the district director or designee, (2) an investigator (where necessary to support information in the complaint not contained in the FDA 483 or to summarize the significance of the findings), (3) appropriate center official (to document such things as the lack of an NDA or the failure to register a product or facility), and (4) experts, are the only declarations that will routinely be used in support of injunctions.

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 lucid, succinct, and impressive support of the complaint.

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

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

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

The facts in the district director's declaration are derived from a review of documents contained in the district files and the declaration should so state. 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 set-up 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, and seizures and FDA attempts to obtain correction, broken promises or other evidence of bad faith, such as statements by defendants clearly showing an intent to continue the violations, in detail as pertains to each defendant; and
12. a statement that, despite the previous actions, the defendants are still engaged in violative conduct.

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

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

6-2-14 Consent Decree

OCC will prepare the consent decree, using the Conduct-to-be-Enjoined section of the district's Injunction Recommendation, as cleared by the center. See model provisions in Exhibit 6-19. Any substantive changes or additions made by OCC after the center's initial clearance must be cleared by the center and district.

In drafting a consent decree, OCC is expected to seek Center approval on matters germane to their original review, including reconditioning or reprocessing plans, CGMP requirements, commanded recalls, cessation of product manufacturing or distribution operations, and measures that could affect availability of medically necessary products. OCC is expected to seek the district’s approval on matters requiring district follow-up activities, such as reinspection frequency and rates, reviews of defendant’s corrective actions, 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 is acceptable to the agency (district, center, and OCC).

Local court rules or local U.S. Attorney's practices may require additional relief from the standard model. The relief should be clearly stated and each paragraph numbered. Elaborate outline format with numerous subparagraphs should be avoided. 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.

The following should be included in consent decrees:

1. An INTRODUCTORY UNNUMBERED PARAGRAPH establishing that a Complaint for Injunction was filed on a specific date and naming each corporate and individual defendant against whom the complaint was filed, and a statement that the defendants has consented to entry of the decree without contest (See Exhibit 6-19, model ¶ 1.);
2. A TRANSITIONAL DIRECTIVE that states, “IT IS HEREBY ORDERED, ADJUDGED, AND DECREED, that:…” (See Exhibit 6-19, model ¶ 2.);
3. A paragraph establishing the COURT'S JURISDICTION. Such as “This court has jurisdiction over the subject matter and all parties to this action.” (No specific jurisdictional cite is necessary.) (See Exhibit 6-19, model ¶ 3.);
4. A paragraph stating that the CLAIM FOR RELIEF is appropriate (No specific statutory cite is necessary.) (See Exhibit 6-19, model ¶ 4.);
5. A paragraph incorporating introductory language establishing that the DEFENDANT, and ALL THOSE in active concert with the defendant are PERMANENTLY ENJOINED from doing the acts enumerated in the Decree:
   a. The statutory cite for the definition of the article that is the subject of the injunction (See Exhibit 6-19, model ¶ 5.);
   b. A statement that defendants are permanently enjoined from committing any illegal act with respect to the article or the specifically named articles, the same articles designated by any other name, as well as any other products having or purporting to have a similar composition, appearance, name, or intended use_ (or similar appropriate language. (See Exhibit 6-19, model ¶ 5.); and
   c. When decrees allow for activity to resume after procedures have been implemented ensuring compliance with the terms of the decree, a further paragraph requiring that defendants remain in compliance with these procedures (See Exhibit 6-19, model ¶ 5.);
6. A paragraph providing for ADDITIONAL INSPECTION AUTHORITY (See Exhibit 6-19, model ¶ 6.);
7. REQUIREMENTS IMPOSED ON DEFENDANTS, should ADDITIONAL INSPECTIONS REVEAL VIOLATIVE CONDITIONS (See Exhibit 6-19, model ¶ 7.);
8. REIMBURSEMENT for additional inspection costs and contempt proceedings, IF THE DECREE IS VIOLATED (See Exhibit 6-7, model ¶ 8.);
9. NOTICE to THOSE ASSOCIATED WITH DEFENDANT; AFFIDAVIT of COMPLIANCE (See Exhibit 6-19, model ¶ 9.);
10. OPTIONAL NOTICE to CUSTOMERS; AFFIDAVIT of COMPLIANCE (See Exhibit 6-19, model ¶ 10.);
11. OPTIONAL NOTICE to EMPLOYEES; AFFIDAVIT of COMPLIANCE (See Exhibit 6-19, model ¶ 11.);
12. OPTIONAL RECALL/REFUND provision; AFFIDAVIT of COMPLIANCE (See Exhibit 6-19, model ¶ 12.);

13. OPTIONAL DESTRUCTION PROVISION (See Exhibit 6-19, model ¶ 13.);
14. NOTICE to FDA PRIOR to CHANGES in CORPORATE STRUCTURE/NOTICE to SUCCESSORS or ASSIGNS (See Exhibit 6-19, model ¶ 14.);
15. STANDARD of REVIEW PROVISION (See Exhibit 6-19, model ¶ 15.);
16. CONTINUING JURISDICTION (See Exhibit 6-19, model ¶ 16.);
17. PROVISION for COSTS (See Exhibit 6-19, model ¶ 17.); and
18. SIGNATURE PAGE (See Exhibit 6-19, model ¶ 18.).

6-2-15 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 Office of Chief Counsel before notifying the firm by letter that they may resume operation (see Exhibit 6-10) and before sending an initial bill setting forth the charges for all work performed to get the firm in compliance (see Exhibit 6-20). Distribute as shown in the model. 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.

6-2-16 Compliance Follow-Up

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

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

1. Consult with Office of Chief Counsel (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.

Find out whether the firm has hired a qualified expert, and determine his/her qualifications. FDA does not 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 211.22).

4. 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 to managerial personnel and document that you have done so. This will facilitate any contempt action that may be necessary.

Following determination by the district that the defendants appear to be in compliance with the requirements of the "unless and until" provisions of the decree, the defendants should be so notified in writing and advised that such determination does not, however, relieve them of their responsibility for compliance with the Act or other provisions of the decree that continue in effect (see Exhibit 6-10).

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

If the district's follow-up discloses that the firm has met the provisions of the decree and notice has issued, the district will schedule a follow-up inspection to be performed in 3 to 4 months and quarterly thereafter until the firm maintains a 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 reinstate the "unless and until" provisions of the existing 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 an 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)

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, DCMO, and OCC.

Recommendations for any action taken as the result of a violation of a decree shall be processed in the same manner and with the same urgency as the original injunction. The district compliance office will prepare a recommendation. For criminal contempt, see the RPM section "Contempt of Court; Violation of Probation". For prosecution see the RPM section, "Criminal Prosecution After 305 Notice". Should contempt be the action of choice, the district will also prepare a Petition for Order to Show Cause why the defendants should not be held in contempt. . (See Exhibits 6-21 and 6-22)

Change in ownership or identity of defendant firm should be noted. In the case of a change in ownership or corporate identity of the firm, report detailed facts on the changes to the center and the OCC for a determination whether the new ownership or corporate entity are covered by the injunction. Rule 65(e), Federal Rules of Civil Procedure, discusses persons covered by injunctions.

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

1. Maintain the file as an open injunction for one year.

2. Check the status of the firm at the end of six months and one year after being reported out of business.

3. Make an effort to determine whether the firm has moved to another location and another district should be notified of the status of the firm. Notify any such district about the injunction.

4. If the injunction is against an individual as well as a firm, determine the individual's present occupation, and whether or not it is similar to the type of business for which he/she was enjoined. If so, notify the center and OCC.

5. If the firm remains out of business after one year, notify OCC and the appropriate center of your intention to close the file in 60 days unless either component has further information which requires consideration.

6. After the 60 day waiting period, if no further information is received, and the injunction was a preliminary one, notify the U.S. Attorney in writing that the firm has ceased operations and the government recommends closing the injunction file.

FDA does not usually initiate dismissal of an injunction. If the defendants have requested dismissal, the district should prepare a recommendation for action on the dismissal. FDA has a general rule that it will not consider dismissal until the firm has operated in compliance continuously for at least three years. A long violative history or lack of cooperation by the defendant will justify a further extension of the decree. The recommendation and all current information on the injunction should be forwarded to the responsible center compliance office. The center will consult with OCC and will inform the district of the headquarters' position. The district and OCC will then inform the U.S. Attorney of FDA's position and offer assistance, as necessary.

6-2-17 Distribution

A. Approved Cases

The center should send their approval memo and the case documents to OCC by the quickest means available; and send a copy of their approval memo and its attachments to the district, DCMO (HFC-210), and HFA-224.

When the transmittal letter to DOJ is signed by OCC, it will send that letter, and the case documents to OCL/DOJ; and send a copy of the transmittal letter and its attachments to the district, the center, HFA-224, and DCMO (HFC-210).

B. Disapproved Cases

The center should send their disapproval memo to the district, any OCC contact persons, and DCMO (HFC-210).

Once the center approves (or disapproves) the case, all units creating correspondence on the case will ensure that copies are transmitted to HFA-224 through the center, with a copy for Office of Chief Counsel, so that the Administrative File is complete. Ultimately, the center will furnish a complete set of the district's submitted documents to HFA-224 along with a copy of the center's memo.

6-2-18 Exhibits

Attached for your guidance are model letters, paragraphs, affidavits, and complaints that have been approved in the recent past. Bear in mind that they are to be used only as guides and,

with the possible exceptions of legal citations, should not automatically be used verbatim in any case (see Exhibits 6-10 through 6-22).

Models are included as Exhibits as follows (attached documents and ancillary pleadings are not included):

6-10 Model Letter Acknowledging Compliance
6-11 Introductory Language Model - Drug GMP/Adulteration/Misbranding Case
6-12 Model Introductory Language - Food Adulteration Case
6-13 Standard Paragraph Regarding The Law Of Injunctive Relief In Cases Arising Under The Federal Food, Drug, And Cosmetic Act
6-14 Standard Drug GMP Paragraph
6-15 Standard Dirty Warehouse Paragraph
6-16 Standard Misbranding (343(A) And 352(A)) Paragraph
6-17 Examples Of Complaint Provisions
6-18 Affidavit/Declaration
6-19 Examples Of Consent Decree Provisions
6-20 Model Letter Billing Charges
6-21 Petition for Order to Show Cause
6-22 Order to Show Cause

6-3 INSPECTION WARRANTS

6-3-1 Purpose

To provide procedures for obtaining inspection warrants. Procedures for Search Warrants are discussed in a separate section.

6-3-2 Inspection Warrants

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

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

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

Before seeking an inspection warrant, the agency needs to assure 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. That 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, the Office of the Chief Counsel (OCC) is not involved with the procedures to determine the need for an inspection warrant until the centers and the Division of Compliance Management and Operations (DCMO) determine that the application should proceed.

A. DISTRICT

Preliminary Steps
When the criteria for requesting an inspection warrant are not clear, the district should consult with DCMO, prior to submitting a request for an inspection warrant. DCMO (HFC-210) is located at 1350 Piccard Drive, Fourth Floor, Rockville, MD 20850. Telephone (301) 827-0391; FAX (301) 827-0342.

When the district makes a decision to recommend an inspection warrant, the district should contact DCMO by telephone to provide advance notice, ascertain the DCMO contact person, obtain any additional guidance, and forward the following documents to DCMO by FAX, electronic transmission, or overnight delivery:

What to Include
1. Cover Memorandum. The cover memorandum should summarize the events that led to the determination that a warrant should be requested. The memo must cover the following elements:
   a. the statutory or regulatory authority to conduct the inspection or to obtain the information.
   b. why there is a compelling need to conduct the inspection or obtain the information.
   c. 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.
   d. each type of information sought and refused, and an explanation why the information can not be obtained through other means.
   e. the status of the inspection (ongoing, terminated, or anticipated).
   f. the reason for the inspection; prior warrants obtained; and, if applicable, violations observed.
   g. any other pertinent information, for example, the location is a personal residence; or the district anticipates resistance during execution of the inspection warrant, in which case a strategy for dealing with the anticipated resistance should be outlined.

h. include factors that are known to involve danger to the public, the inspecting persons, or others, (for example, weapons, guard dogs, or hazardous chemicals).

2. 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:
   a. 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.
   b. The statutory authority to inspect the establishment and the items sought.
   c. Any violations observed during the course of the current investigation or the most recent inspection, specifically citing the language and section of the Act being violated. Although it is not required that a violation has occurred in order to obtain approval of an inspection warrant, the Department of Justice (DOJ) has asked that such information be included in the Application, when available.
   d. 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.
   e. 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.
   f. A description of the items that will be sought during the execution of the warrant.
   g. 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.

3. A Draft Warrant. Include a draft copy of the inspection warrant.

4. 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/DCMO, telephone (301) 827-0391.

Processing

The cover memo, draft application, and warrant should be sent to DCMO electronically. Three sets of the supporting or background documents should be transmitted to DCMO by overnight delivery in order to expedite processing.

The district will promptly forward copies of approved, filed warrants to DCMO and keep DCMO informed of the progress of the inspection under the warrant.

DOJ prefers, and FDA encourages that U.S. Marshals accompany FDA investigators when warrants are executed. If this presents a problem for the district, DCMO should be notified immediately.

The recommending district should anticipate and set forth in the cover memorandum any situation that may result in a refusal or delay of an inspection conducted under a warrant. Whenever possible, an agency decision and implementation strategy regarding anticipated resistance, possible arrests, or use of force during execution of the inspection warrant should be considered and made prior to execution of the warrant.

If problems are encountered during the application for or execution of the warrant, DCMO should be contacted immediately. If there is a legal issue, contact Office of Chief Counsel and DCMO 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 forwarded to DCMO for distribution to the centers and Office of Chief Counsel.

B. DIVISION OF COMPLIANCE MANAGEMENT AND OPERATIONS

When DCMO receives a recommendation for an inspection warrant, DCMO will forward a copy to the responsible centers electronically or by courier for concurrent review. The centers and DCMO 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. DCMO will monitor and coordinate the concurrent review and processing of the inspection warrant with the recommending district, center, and subsequently with Office of Chief Counsel, and DOJ. If a warrant application is not approved, a written explanation of the decision will be sent to the district by DCMO.

If a warrant application package is approved, DCMO will revise the documents as needed and will forward the revised documents electronically or by courier to the Deputy Chief Counsel for Litigation, Office of Chief Counsel (OCC). After review and approval of the warrant application package by OCC, DCMO will prepare a transmittal memorandum addressed to DOJ from the Director, Office of Enforcement (OE).

DCMO transmits the warrant package approved by the Director, OE 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, DCMO transmits the DOJ approved (or denied) warrant application package to the district, including any necessary guidance or instructions for the application and execution of the warrant.

The assigned DCMO warrant coordinator notifies the Associate Commissioner for Regulatory Affairs (ACRA) and designated contacts in the Office of External Affairs of the strategy ,and impending action immediately prior to forwarding a warrant application package to the Department of Justice. DCMO maintains the files of all warrant recommendations and tracks their disposition.

C. CENTER

The responsible centers promptly reviews all warrant application documents forwarded to them by DCMO, assuring 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 transmitted electronically to DCMO. Disapprovals are documented in writing and transmitted over the signature of the Director, Office of Compliance, or his/her designee, to the district and DCMO.

D. OFFICE OF CHIEF COUNSEL

Office of Chief Counsel promptly reviews the warrant and application package for legal sufficiency. Revisions are forwarded to DCMO for typing and transmittal to DOJ. Any disapprovals should be documented in writing and transmitted to the district, center, and DCMO.

6-3-4 Exhibits And Models

Exhibits/Models are available through DCMO, telephone (301) 827-0391.

6-4 SEARCH WARRANTS

6-4-1 Purpose

To provide procedures for obtaining search warrants. Inspection warrants are discussed in section 6-3.

6-4-2 Search Warrants

Search warrants are effective tools for obtaining evidence of criminal conduct, 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 (www.house.gov/judiciary/Crim2002.pdf). Also, see U.S. Attorneys' Manual (www.usdoj.gov/usao/eousa/foia_reading_room/usam/index.html). Criminal search warrants are particularly useful when there is reason to believe that relevant evidence may be hidden or destroyed.

A search warrant need not be limited to the inspection authority provided in Section 704 of the Federal Food, Drug, and Cosmetic Act. For example, records that constitute evidence that a crime has been committed may be obtained under a search warrant, even though such evidence (such as manufacturing records for a food) would not be available under an administrative inspection warrant.

To obtain a search warrant, probable cause to believe that evidence, instrumentalities, or fruits of a crime will be found, must be clearly shown in the affidavit for the warrant. The allegation that the property sought is at the location to be searched must be based upon recently gathered evidence that would lead a judge or magistrate judge to conclude that the items

sought are still at the location to be searched. Accordingly, the request for a search warrant must be submitted promptly to ensure that the probable cause information has not become stale.

FDA personnel should not seek a search warrant or officially endorse searches requested by other agencies, including the Department of Justice (DOJ), unless they have documented assurance that the necessary FDA approval has been obtained.

A center may initiate a request for a search warrant, but must coordinate with the appropriate District Director/Regional Director prior to submitting the warrant request.

The following procedures do not apply to the ORA/Office of Criminal Investigation (OCI). OCI has its own clearance procedures for search warrants.

6-4-3 Procedures

The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters. District management must communicate with its local OCI office, as instructed in “Office of Criminal Investigations” below, before pursuing a criminal search warrant.

6-5 PROSECUTION

6-5-1 Purpose

This section establishes guidelines for the uniform submission and review of prosecution recommendations, including referrals for criminal investigation. Five different procedures, depending upon the distinguishing case features, are included in order to eliminate unnecessary review and to expedite the case review process.
NOTE: With the exception of prosecution recommendations involving gross, flagrant, or intentional violations, fraud, or danger to health, each recommendation should ordinarily contain proposed criminal charges that show a continuous or repeated course of violative conduct. This may consist of counts from two or more inspections, or counts from separate violative shipments at different points in time. This is because the agency ordinarily exercises its prosecutorial discretion to seek criminal sanctions against a person only when a prior warning or other type of notice can be shown. Establishing a background of warning or other type of notice will demonstrate to the U.S. Attorney, the judge, and the jury that there has been a continuous course of violative conduct and a failure to effect correction in the past.

In most cases, the person against whom criminal proceedings is being contemplated must be given the opportunity to present his views with regard to such criminal proceedings. This is usually done in the form of a Section 305 Citation. See RPM Chapter 5, Administrative Actions for instruction concerning Citations and conducting Section 305 Meetings.

6-5-2 Office Of Criminal Investigations

The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters.

FDA personnel must refer all criminal matters, regardless of their complexity or breadth, to OCI. This includes criminal search warrants, misdemeanor prosecutions, felony prosecutions, referrals for criminal investigation, and Section 305 meetings.

District management must communicate with its local OCI office before pursuing any criminal matter. This communication is absolutely essential to preclude potential interference with other on-going criminal investigations and to prevent confusion among the components of the Office of Chief Counsel and the Department of Justice that are responsible for handling FDA's criminal cases. During this communication, OCI is to be provided with all of the facts of the potential case and any additional information that is relevant to, or could impact, the case in any way. OCI will decide promptly whether or not it is interested in pursuing the case and will communicate its decision back to the District Office.

If OCI chooses not to pursue a criminal matter, the District Office is at liberty to proceed with the case in accordance with the procedures in this chapter.

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

6-5-3 Processing A Summary And Recommendation

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

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

Each recommendation must be accompanied by the written concurrence of the District Director (DD) and the Regional Food and Drug Director (RFDD). The DD's approval must state why

prosecution is the action of choice, and the RFDD must concur. This concurrence will appear on the last page of the S&R.

See section 6-5-12 for detailed guidance for preparing an S&R.

6-5-4 Criminal Prosecution After Section 305 Notice

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

1. When a district does not have direct reference authority to issue a Section 305 notice, the district will submit a Citation Recommendation to the appropriate center(s) for review, after contacting OCI (as described in “Office of Criminal Investigations” above. Generally, the citation recommendation includes: (a) the names and responsibilities of each individual and the charges to be presented in the notice; (b) the full background history of notification of the persons to receive a notice; and (c) facts supporting the proposed charges, including assurance of interstate documentation. All pertinent evidence, such as work sheets, labels, and inspection reports, should be submitted with the recommendation. The center may request the interstate documentation if a special need to review it exists.

2. If the district or the center identifies an issue requiring consultation with the Office of Enforcement (OE), OCI, Office of the Chief Counsel (OCC), or an ad hoc committee, the component identifying the issue will obtain prompt resolution as early in the review process as possible.

3. If, following the meeting held in response to the Section 305 notice, there is no significant change in the facts, as set forth in the district's Citation Recommendation, the district will notify the center, which will promptly forward the district's Citation Recommendation package to the Division of Compliance Management and Operations (DCMO), (HFC-210), in OE. Concurrently, a final S&R will be sent by the district to DCMO with copies to the center, and to the Records Section (HFA-224).
   If there is a significant change in the facts or strength of the proposed case, the district will submit the prosecution recommendation package to the appropriate center solely to determine whether prosecution remains warranted in view of the new information. If prosecution is warranted, the center will promptly forward to DCMO the prosecution S&R and the center's approval memo presenting the basis for its decision in light of the new information.

   NOTE: When a district has evidence sufficient to meet the requirements for direct reference authority to issue a Section 305 notice ("direct reference cite authority"), the procedures in # 1 above do not apply. (Except that OCI must be contacted, as described in “Office of Criminal Investigations” above.) After the Section 305 process has been completed and, if no new information is presented that affects the basis for the direct reference authority, the district should promptly submit its prosecution S&R directly to DCMO for a limited review. The district should concurrently send a copy of the S&R to the center and HFA-224.

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

4. DCMO will perform a limited review to determine whether the proposed prosecution conforms to agency policy and enforcement strategies and objectives. If DCMO 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 DCMO 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.

6-5-5 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 305 notice usually provided when the agency is recommending further investigation.

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

1. The district is to consult with DCMO, 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 DCMO and OCC agree that no Section 305 notice should be issued, DCMO will so notify the district. The district will then prepare an S&R and obtain approval from the Region before submitting the S&R to DCMO, with concurrent copies to the center and OCC for review. A copy should also be submitted to HFA-224. The district will explain under the heading "No Section 305 Notice" why such notice is not required. (Should DCMO and OCC decide that a Section 305 notice should be issued, DCMO will so notify the district who will then follow the procedure under RPM, "Prosecution after 305 Notice".)

2. If the center and DCMO concur in the recommendation, each will prepare a memo reflecting its views on the relevant issues. The center will forward its memo to DCMO.

3. DCMO 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.

6-5-6 Contempt Of Court; Violation Of Probation

The district will prepare an S&R outlining the facts that establish the violative conduct and forward it, and a copy of the pertinent court order to DCMO, with concurrent copies to the center and the Records Section (HFA-224).

The center and DCMO will have 10 working days each to comment on the proposed action.

If no adverse comment is provided by either the center or DCMO, or if a response has been received but a consensus to proceed is reached, the district will forward its S&R and supporting evidence to DCMO for logging and prompt forwarding to OCC for review. If OCC agrees that the action is supportable, it will prepare a referral letter.

6-5-7 Development of Felony Violation

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

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

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

6-5-8 Referrals For Criminal Investigation

An agency referral to DOJ for further criminal investigation, including an investigative grand jury, should follow the process described below:

1. The initiating unit, district or center, will notify OCI in accordance with the RPM section "Office of Criminal Investigations". If OCI has no interest in the matter at that time, then the district or center may notify DCMO and request an ad hoc committee meeting, and provide an S&R of the existing evidence. Relevant, organized, and tabbed background material will be assembled by the initiating unit and submitted with the S&R sent to DCMO. Information should cross reference and cite specific pages of the background material.

2. Prior to scheduling the meeting, DCMO will review the background package and ensure that it is in a form that will facilitate review and identification of issues.

3. DCMO will promptly forward the background package to the committee members, accompanied by a memorandum setting a time and place for the meeting, and identifying 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.

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, DCMO will promptly prepare a memorandum of the decision and forward it to OCC as the agency's recommendation. OCC will revise the district's draft of the referral letter, as necessary.
   b. Should the committee believe that additional investigation is needed, the committee will issue the appropriate assignments, record them in a memo - distributed to committee members, 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. DCMO will monitor the status of the assignments and schedule the follow-up meeting. A minimum of 5 working days will be provided for members to review new information prior to the meeting. DCMO will prepare a memorandum of any subsequent meeting.

5. 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, DCMO will promptly forward to OCC any relevant materials that may not have previously been provided along with a written request that OCC refer the matter to DOJ.

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

   As soon as the district determines that it would like to prosecute Title 21 or Title 18 charges based upon violations involving FDA regulated articles, it will notify DCMO, for an FDC number, the centers, and OCC of its intent to do so and will promptly forward a recommendation to DCMO, 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.

6-5-9 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.

6-5-10 Grand Jury Investigations And Secrecy

Grand jury investigations are subject to Rule 6 of the Federal Rules of Criminal Procedure (see Exhibit 6-27). 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, 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.

6-5-11 Format For Summary & Recommendation

Refer to Exhibit 6-23 for model format.

6-5-12 Preparation Of Summary And Recommendation

See Exhibit 6-24 for example model in a food sanitation case.

The Sample Index is an outline of the support samples related to the prosecution.

A. SAMPLE NUMBER, PRODUCT, DATE SHIPPED

The order of the counts in an Information or Indictment is variable, but should be determined by the significant or seriousness of the violations, rather than the sequential order of the sample numbers or the date of sample collection. However, where all samples or schemes have the same degree of seriousness, list in descending chronological order (most recent offense in Count I, next most recent offense in Count II, and so forth.

The column headings may be changed to provide whatever information the district feels is significant. Beneath the sample number indicate the proposed count number. In cases where supporting samples are unnecessary, describe the scheme or violation and outline the elements of the offenses.

B. CITATION UNDER SECTION 305 OF THE FD&C ACT

List complete names and addresses of all persons issued Section 305 notices. Prepare brief, concise paragraphs explaining significant new evidence obtained since the Recommendation for Citation was submitted. Also include any changes in the status of responsible individuals or the firm that have occurred since the center approved the issuance of 305 notices or, in the case of direct reference cite authority, since the Section 305 notice issued. See the RPM section "Criminal Prosecution after Section 305 Notice".)

If this is a recommendation without a Section 305 notice, prepare a brief paragraph explaining the facts, including identifying the basis of concurrence with this approach, for example, "Ad Hoc meeting."

C. 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 6-25 or in person so that the records are received in a form suitable for introduction into evidence (see Exhibit 6-26).

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.

D. 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.

E. 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.

F. PRIOR NOTICE

As more fully explained in Chapter 10, it is FDA's policy to provide individuals and firms with prior warning prior to initiating enforcement action, unless the violation constitutes a danger to health, or represents intentional, gross, or flagrant violations of the law.

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 in this situation.

G. OTHER CORRESPONDENCE

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

H. 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 6-23.

I. 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.

J. 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 section on Prior Notice.

K. PERMANENT ABEYANCE OF SAMPLES OR INDIVIDUALS

If the district decides to place any of the samples listed in the Section 305 notice in permanent abeyance or to not include cited individuals as proposed defendants, the reasons for these decisions should be given in this section.

Excluded samples should not be destroyed until the termination of the action by plea or trial.

If all samples and individuals listed in the Section 305 notice are included in the prosecution recommendation, this section may be omitted.

L. 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 proferred for delivery. Occasionally, the receiving date in a 301(k) violation is not available. In such a case, the date of the offense is the day on which the investigator can testify that she or he saw the subject lot at the proposed defendant's premises.

Occasionally, a 305 notice will issue with the date of shipment being the date furnished in an affidavit signed by the dealer, but subsequent investigation uncovers records indicating

that the lot was actually shipped or delivered on another date. As long as the 305 notice stated "on or about" with respect to the date, this is acceptable.

The correct date will be listed in the Information or Indictment, even if it differs from that listed in the Section 305 notice. Complete information regarding the conflicting dates should be furnished under the caption "Documentation of Interstate Commerce."

b. DATE LOT SAMPLED/BY WHOM

If the sampling of the lot takes place over a period of several days, that should be stated here. In the case of a 301(k) violation, if the lot remains in the regular storage area for saleable goods, the Information or Indictment will indicate that it was held for sale between the date of receipt and the last day of the inspection. If the lot is moved to a quarantine area and it is clear that it is not to be sold, the day the product was moved (or destroyed, denatured, or embargoed) will be used in the Information or Indictment.

In addition to the name of the collecting investigator, indicate where he or she is located at the time of the writing of the recommendation. If the investigator has transferred to another district, resigned, or retired, he or she should be contacted when the Information or Indictment is submitted to DOJ, advised that prosecution is pending, and requested to keep the district informed of his or her location so that the investigator can be contacted if the case goes to trial.

c. DESCRIPTION OF LOT AND SAMPLE SIZE

The size of the lot should be listed and, in 301(k) sanitation cases, a brief description of the lot should be given. For example, the description should contain the statement that the investigator looked at (number of) bags, found urine on (number of) bags, (number of) bags were rodent gnawed, and should indicate whether filth was only on the exterior of the lot or on containers covered by other containers, whether or not the lot was received palletized, whether containers in the lot had been restacked by the firm, etc.

d. ANALYSTS

As with the collecting investigator, the current location of the analysts should be recorded and contact should be made with the analysts when the Information or Indictment is submitted to DOJ.

e. ANALYTICAL METHODS

The method of analysis should be given. If there was any deviation from an official method, complete information concerning the modification and reasons therefore should be given. (In the analysis of official preparations, the method in the compendium should be followed.)

f. NUMBER OF SUBS ANALYZED

If every sub has been analyzed, merely state "all." (It is incumbent upon the district's Compliance Branch to ensure that sufficient analytical work has been performed.)

g. ANALYTICAL FINDINGS

The results of each analysis of the product should be listed. If the problems which were encountered necessitated additional work, or deviation in or from an official method such as new methodology or analysis to resolve discrepancies in analytical results, such matters should be disclosed and discussed.

In cases involving filth in foods, the analytical findings should be broken into two groups; those demonstrating actual contamination in the product [402(a)(3)] and those demonstrating 402(a)(4) conditions. The results regarding the findings of actual product contamination should be summarized basically as follows:

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.

6-5-13 Distribution Of Summary And Recommendation Documents

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

1. A copy of all prosecution recommendations, regardless of whether they are submitted to the center, DCMO, or OCC, should be submitted to:
   Records Section (HFA-224)
   5600 Fishers Lane
   Rockville Maryland 20857

   The Records Section will log in the S&R so other units will know there is a regulatory action under review at the headquarters level.

2. Prosecutions Requiring Center Approval:
   Submit to the appropriate center, the original plus two copies of the S&R and one set of clearly legible copies of any supporting documents. The documents should be indexed with tabs and should include:
   a. Section 305 Notice and Charge Sheet
   b. Record of Section 305 meeting and any documents presented at the meeting
   c. Written answer to the Section 305 notice (if meeting was not held)
   d. Any correspondence or memoranda of telephone conversations with proposed defendants since the Citation Recommendation was submitted.
   e. Guaranty (if applicable)
   f. Articles of Incorporation **(DO NOT HOLE PUNCH)**

NOTE: If the recommendation meets the circumstances outlined in "Processing a S&R" and does not require further review by the center, submit the original plus one copy of the S&R and one set of legal copies as described under "Distribution of S&R" to DCMO. A copy of the S&R should be directed to the appropriate center for their information.

3. Direct Reference Prosecutions
   The S&R prepared as described should be addressed to the Division of Compliance Management and Operations, OE (HFC-210) and should contain the same information as described in "Distribution of S&R". An information copy of the S&R and all attachments should be submitted to the appropriate center.

6-5-14 Exhibits

The district compliance officer may request DCMO to provide (normally by FAX) a copy of the latest referral for prosecution that is similar to the recommendation being considered by the district. This will include the letter and any related Information or Indictment requesting DOJ to initiate legal proceedings.

6-23 Format for Prosecution Summary and Recommendation
6-24 Model Prosecution Summary and Recommendation Memorandum
6-25 Model Letter Request for Articles of Incorporation
6-26 Rule 44. Proof of Official Record
6-27 Rule 6. The Grand Jury

6-6 CIVIL PENALTIES – ELECTRONIC PRODUCT RADIATION CONTROL

6-6-1 Purpose

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

GENERAL STATEMENT

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

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

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

6-6-2 Scope

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

Injunction considerations are included because there is precedent where the recommended, approved, and executed action was a joint civil penalty and injunction action. (See Exhibit 6-29)

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.

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

A. This prohibited act only applies to a manufacturer, excluding diagnostic x-ray assemblers, of an electronic product.

B. A non-compliant product must have been delivered for introduction or introduced into interstate commerce.

C. 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.

D. 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.)

E. 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.

SECTION 538(a)(2) [21 U.S.C. 360oo(a)(2)] FAILURE TO GIVE NOTIFICATION OR TAKE CORRECTIVE ACTION

A. 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.

B. The Agency should be in a position to demonstrate that the manufacturer was aware of the noncompliant or defective product either through the Food and Drug Administration's (FDA's) notification or otherwise if that question is raised.

C. 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.

D. The Agency must be able to demonstrate that at least one of the following violations has been committed:

1. The manufacturer has not notified the Agency of a defect or noncompliance.
2. The manufacturer has not notified the known purchasers of the defect or noncompliance.
3. 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.
4. 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.
5. 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.

SECTION 538(a)(3) [21 U.S.C. 360oo(a)(3)] FAILURE TO MAINTAIN RECORDS OR PERMIT INSPECTION

A. 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.

B. The manufacturer is required to maintain records which demonstrate the adequacy of its manufacturing practices to assure the Agency that its safeguards against hazardous radiation are adequate and that its products comply with an applicable performance standard.

C. Dealers and distributors of electronic products subject to the distribution recordkeeping requirement as specified in Table 1 of 21 CFR 1002.1must 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.

D. 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.

E. 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: (a) introduction of noncompliant or defective electronic products into commerce by the manufacturer, (b) disapproval of the manufacturer's testing program of products for which there is an applicable standard, or (c) 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.

F. Dealers and distributors, other than those who are also considered to be manufacturers, are only required to permit inspection of records described in paragraph 3 above.

SECTION 538(a)(4) [21 U.S.C. 360oo(a)(4)] REPORTING

A. 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.

B. 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).

C. 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.

D. 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 D(I) above.

E. 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).

F. 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.

SECTION 538(a)(5) [21 U.S.C. 360oo(a)(5)] PRODUCT CERTIFICATION

A. It is a prohibited act under Section 538 (a)(5)(A) for a manufacturer to fail to certify that its product is in compliance with an applicable performance standard. The manufacturer must furnish the certification in the form of a label or tag, as prescribed by 21 CFR 1010.2.

B. 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 of the Regulatory Procedures Manual (RPM).

6-6-5 Penalties

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

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

EXAMPLE:

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

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

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

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

Total = 3 counts

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

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

6-6-6 District Responsibilities

1. The District is responsible for deciding if the circumstances warrant recommendation of a civil penalty. Every effort should be made to determine that all necessary documentation has been obtained, all related samples are included, and the supporting Establishment Inspection Reports (EIRs) are complete.

2. The District should document as fully as possible who was responsible for the violations.
3. The District is responsible for seeing that all violations are documented.

A. Documentation for each violative product should consist of the following:

1. Sample Collection Report

2. Complete interstate documentation where Section 538(a)(1) of the Act is charged.

3. Appropriate affidavits by dealers, purchasers, users, etc., where applicable
.
4. Copies of appropriate records of proof of sale or installation of equipment, where applicable.

5. Copies of appropriate labeling.

6. Clear and distinct photographs of labels, and the equipment, where applicable.

7. Copies of all documents that can be considered prior notice or warning.

B. The recommendation packet should consist of the following:

1. 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.

2. 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.

3. 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.

4. Copies of appropriate sample records.

5. Copies of EIRs reporting the violation.

6. If an injunction is being sought in the same complaint, an affidavit, as referenced in the RPM subchapter for Injunctions, should be prepared and submitted.

4. The District shall notify CDRH's Field Programs Branch (HFZ-306) that a recommendation is being submitted, and the recommendation shall be submitted by the most expeditious means. An electronic copy on a diskette should also be attached to the recommendation.

5. If the approved letter to the U.S. Attorney and the Complaint for Civil Penalty are returned to the District electronically for submission to the U.S. Attorney, it will be the responsibility of the District to see that they are delivered to the U.S. Attorney's office. (If the Complaint includes an injunction, the documents should be delivered to the U.S. Attorney's office by the most expeditious and practical means.)

6. The District shall be in direct contact with the U.S. Attorney's office with regard to timeliness

of filing of the complaint, and scheduling of any hearings, etc.

7. In the event of any hearings in the action, the District shall be responsible for arranging for the presence of any necessary witnesses, funding, and assuring that all necessary documents are available.

6-6-7 CDRH Responsibilities

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

CDRH will forward a copy of the District's original recommendation to the Office of Enforcement's Division of Compliance Management and Operations (DCMO), even though it may prepare an amended copy to include any deletions or additions of its own.

2. CDRH will prepare a memorandum to DCMO reflecting the issues considered by CDRH in reviewing the case and providing the scientific assurances which support the case. A copy of CDRH's concurrence memorandum should be sent to the recommending District, at the time that it is forwarded to DCMO. In case of disapproval, CDRH shall state clearly the reason for such disapproval and include any guidance necessary for the District to present an acceptable case. If follow-up for additional information is indicated, CDRH shall be specific as to what is needed, and so advise the District. If a case is disapproved, a copy of the disapproval memorandum shall be sent to DCMO.

3. It will also be CDRH's responsibility to see that a copy of its approval or disapproval memorandum, as well as the recommendation, is submitted to the Records Section (HFA-224).

4. CDRH will identify a qualified expert(s) for any court cases.

5.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 DCMO Responsibilities

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

DCMO will be responsible for determining that the necessary distribution is made of the final documents, as approved by OCC to the appropriate offices including HFA-224. Approved actions for submission to the U. S. Attorney shall be forwarded to the District by electronic transmission.

6-6-9 OCC Responsibilities

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

6-6-10 Appeals

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

6-6-11 Consent Decree Of Civil Penalty

The defendant may seek to negotiate a penalty below the maximum for each count. Such negotiated settlement should be in the form of a Consent Decree of Civil Penalty. All proposed settlements will be presented to OCC. All negotiations with the defendant's lawyers will be conducted by the lawyer representing the Agency, in consultation with DCMO, the District, and CDRH.

6-6-12 Case Termination

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

6-6-13 Injunction and Civil Penalties

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

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

1. The manufacturer has repeatedly committed the same violation, or same type of violation.

2. The violative product could cause significant risk of injury to any person.

3. The manufacturer is continuing to commit the same violations (e.g., introduction of noncompliant products into commerce) after being advised of the Agency's finding and request to cease and desist.

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

inspection, certification of products, etc.).

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

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

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

6-6-14 Exhibits

Exhibit 6-28 - Example of Letter to the Department of Justice, Re: Injunction and Civil Penalty

Exhibit 6-29 - Example of Complaint for Injunction and Civil Penalty

6-7 EXHIBITS

6-1 TELEPHONE SEIZURE RECOMMENDATION
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 MODEL LETTER ACKNOWLEDGING COMPLIANCE
6-11 INTRODUCTORY LANGUAGE MODEL - DRUG GMP/ADULTERATION/MISBRANDING CASE
6-12 MODEL INTRODUCTORY LANGUAGE - FOOD ADULTERATION CASE
6-13 STANDARD PARAGRAPH REGARDING THE LAW OF INJUNCTIVE RELIEF IN CASES ARISING UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT
6-14 STANDARD DRUG GMP PARAGRAPH
6-15 STANDARD DIRTY WAREHOUSE PARAGRAPH
6-16 STANDARD MISBRANDING (343(A) AND 352(A)) PARAGRAPH
6-17 EXAMPLES OF COMPLAINT PROVISIONS
6-18 AFFIDAVIT/DECLARATION
6-19 EXAMPLES OF CONSENT DECREE PROVISIONS
6-20 MODEL LETTER BILLING CHARGES
6-21 PETITION FOR ORDER TO SHOW CAUSE

Exhibit 6-1
TELEPHONE SEIZURE RECOMMENDATION

SAMPLE NO.

LOCATION AND IN POSSESSION OF:

AMOUNT AVAILABLE FOR SEIZURE:

NAME OF PRODUCT:

LABEL: Ctn:

DATE OF SHIPMENT:

SHIPPER AND SHIPPING POINT:

CAR NUMBER:

CARRIER:

CONSISTING OF:

ANALYSIS:

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, libelant;

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 Unites 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 _____District, 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.) June 17, 20__
FDC _____, Civil #_____ U.S. vs. 12 cases ***** and
Shelled Walnuts 9 cases ***** Walnuts

Firm Name
Street Address
City, State, Zip

Gentlemen:

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	$XXX.XX
	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
_____ District 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
_____ District Office

Enc: cc this ltr.
cc: Fiscal Branch

Exhibit 6-8
SECOND NOTICE

(Sample No.) July 17, 20__
FDC _____, Civil #_____ U.S. vs. 12 cases ***** and
Shelled Walnuts 9 cases ***** Walnuts

CERTIFIED MAIL - RETURN RECEIPT

Firm Name
Street Address
City, State, Zip

Gentlemen:

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
_____ District 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.) July 25, 20__
FDC _____, Civil #_____ U.S. vs. 12 cases ***** and
Shelled Walnuts 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
_____ District Office

Exhibit 6-10
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,

District Director

Exhibit 6-11
INTRODUCTORY LANGUAGE MODEL - DRUG GMP/ADULTERATION/MISBRANDING CASE

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 drugs in interstate commerce in violation of 21 U.S.C. 331(a) (adulterating 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 6-12
MODEL INTRODUCTORY LANGUAGE - FOOD ADULTERATION CASE

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 6-13
STANDARD PARAGRAPH REGARDING THE LAW OF INJUNCTIVE RELIEF IN CASES ARISING UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Since we seek a statutory injunction, the rules of private litigation are not binding. United States v. Diapulse Corporation of America, 457 F.2d 25, 27 (2nd Cir. 1972). Where the public interest is involved, the powers of an equity court are broader and more flexible than in a suit at law. Hecht Co. v. Bowles, 321 U.S. 321 (1944). In considering the propriety of an injunction which restrains violations of a law of the United States, such as the Federal Food, Drug, and Cosmetic Act, the rule is that where an injunction is authorized by statute it is enough if the statutory conditions are satisfied. Where the Government seeks by statutory injunction to protect the public health, it need not meet the usual equity requirements of showing irreparable harm. United States v. City and County of San Francisco, 310 U.S. 16 (1940). The statute itself represents a legislative conclusion that violation would cause irreparable injury. United States v. Diapulse Corporation of America, supra, at 28. The Government's burden has been met when it shows that the statute applies to the defendants and there exists some recognizable danger of recurrent violations. United States v. W.T. Grant Co., 345 U.S. 629 (1953). Under the Federal Food, Drug, and Cosmetic Act, neither intent nor awareness of wrongdoing on the part of the defendants need be shown in civil or in criminal actions. United States v. Park, 421 U.S. 658 (1975); United States v. Wiesenfeld Warehouse Co., 376 U.S. 86 (1964); United States v. Dotterweich, 320 U.S. 277 (1943). Of course, since the purpose of the Act is to protect the public health, it is to be and consistently has been given a liberal interpretation by the Courts. See, for example, United States v. An Article of Drug ... Bacto-Unidisk, 394 U.S. 789 (1969).

Exhibit 6-14
STANDARD DRUG GMP PARAGRAPH

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 incipiency, 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 6-15
STANDARD DIRTY WAREHOUSE PARAGRAPH

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 6-16
STANDARD MISBRANDING (343(A) AND 352(A)) PARAGRAPH

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-Dynameter, 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 6-17
EXAMPLES OF COMPLAINT PROVISIONS

(Jurisdiction Model)

1. 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)

2. 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)

3. 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)

4. 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 Liquamycin, 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))

5. 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)

6. 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.

7. 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 6-18
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,	)	STATEMENT OF
NAME IN CAPS, and	)	NAME IN CAPS
NAME IN CAPS, individuals	)	
	)	
	)	
Defendants.	)	
State of _____	)	
County of _____	)	

1. I am District Director, _____ District, _____ Region , 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, _____ Region, _____District, which includes the States of _____, _____, _____ and _____.

3. I am familiar with the investigation of Firm, Inc. performed by the _____ District, and the laboratory at the _____ District Office, Food and Drug Administration. The official records of the Food and Drug Administration, contained in the files located in the _____District, 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 _____ District 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 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 Director

Subscribed and sworn to before me in the City and District aforesaid this_____day_____20__.

_____
Notary Public

Exhibit 6-19
EXAMPLES OF CONSENT DECREE PROVISIONS

1. Plaintiff, United States of America, having filed its Complaint for Injunction on the _____ day of _____, 20__, and defendants _____, Inc., a corporation, and _____, an individual, having appeared and having consented to the entry of this decree without contest and before any testimony has been taken, and the United States of America having consented to this decree, and having moved this Court for this injunction,

2. IT IS HEREBY ORDERED, ADJUDGED, AND DECREED, that:

3. This Court has jurisdiction over the subject matter and all parties to this action.

4. The Complaint for Injunction states a claim for relief against the defendants under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. 301 et seq.

Principal Injunctive Relief

5. That the defendants, _____, Inc., and _____, and each and all of their officers, directors, agents, distributors, representatives, employees, attorneys, successors, and assigns, and those persons in active concert or participation with them or any of them who have received actual notice of this consent decree by personal service or otherwise, are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. 332(a), from directly or indirectly doing or causing to be done any of the following acts:

... from directly or indirectly doing or causing to be done any of the following acts with respect to any device, as defined in 21 U.S.C. 321(h) ...

(Another Model; Medical Device)

Defendant, _____, an individual, and his agents, employees, attorneys, and any and all persons in active concert or participation with him are perpetually restrained and enjoined under the provisions of 21 U.S.C. 332(a) from directly or indirectly doing or causing to be done any of the following acts with respect to injectable silicone (polydimethylsiloxane), an article of device within the meaning of 21 U.S.C. 321(h) or any substance purporting to be such device or that is substantially equivalent to injectable silicone, unless and until there is in effect with respect to such device an approved application for premarket approval under 21 U.S.C. 360e:

(a) introducing it or delivering it for introduction in interstate commerce;

(b) receiving it in interstate commerce and then delivering it to any other person;

(c) holding it for sale or use in medical, surgical, or any other procedure, after shipment in interstate commerce;

(d) promoting, counseling, or demonstrating to any person its use in medical, surgical, or any other procedure; and

(e) using it in medical, surgical, or any other procedure.

The provisions of the foregoing sentence apply regardless of whether the proscribed activity is undertaken in connection with the practice of medicine.

Hiring of Consultants (Optional)

The defendant(s) select a qualified person to make such inspections of the facility to determine whether the methods, facilities, and controls established by the firm are operated and administered in conformity with current good manufacturing practice (as particularized in regulations codified at 21 CFR 210.3 and 211.1 through 211.108). On the basis of such inspection(s) said person shall, if warranted, certify in writing to the Food and Drug Administration (FDA) that the requirements set forth in _____ have been met. When the defendant(s) independently conclude that the facility is in compliance with current good manufacturing practice, they shall personally so certify to FDA.

(Another Variation of This Option)

The defendant(s) retain a qualified person who shall conduct audit inspections, no less than four times a year for a period of two years, to assure that the facility remains in compliance with the requirements set forth in _____. Said person shall prepare a written report on the facility and its operation. Said report shall be available, upon request, to any FDA investigator during the course of an FDA inspection conducted under this decree or under authority of 21 U.S.C. 374.

Authority to Inspect

6. Duly authorized representatives of the FDA are authorized, as they deem necessary, to inspect defendant's facilities, and all equipment, finished and unfinished materials and product, containers, labeling, and other promotional material therein, to take photographs, and to examine and copy all records relating to the receipt, processing, packing, labeling, promotion,

holding, and distribution of any of defendant's products to assure continuing compliance with the terms of this decree. Such inspections shall be authorized upon presentation of a copy of this decree and appropriate credentials. Such inspection authority granted by this decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. 374.

Post Compliance Shutdown

7. Defendants shall immediately cease and discontinue manufacturing, packing, labeling, distributing, and dispensing any article of device if, based on the results of an inspection and/or any analysis of samples, FDA notifies defendants in writing that defendants' methods, facilities, and controls for manufacturing, packing, and storing articles of device are not established, operated, or administered in substantial compliance with good manufacturing practice regulations for devices, 21 CFR Part 820. (Note: A copy of cited regulations should be attached as an appendix only if the local rules/practice so dictate.)

Any cessation of operations as described above shall continue until receipt by defendants of written notification by FDA that defendants appear to be in compliance with GMP regulations and/or that their final product appears to meet the standards defined above. Upon defendants' written request, the FDA shall, within a reasonable time, endeavor to determine whether defendants appear to be in compliance and, if so, issue its written notification permitting resumption of operations.

Reimbursement

8. The defendant shall reimburse FDA for the costs of all FDA inspections, supervision, analyses, and examinations that FDA deems are necessary to evaluate the defendant's compliance with this decree, as follows: at the rate of $____ per hour or fraction thereof per representative for inspectional work; $____ per hour or fraction thereof per representative for analytical work; ____ cents per mile for travel expenses; and $____ per day for subsistence expenses. If the defendant violates this decree and is found in civil or criminal contempt thereof, the defendant shall, in addition to other remedies, reimburse the plaintiff for its attorney fees, investigational expenses, and court costs relating to such contempt proceedings.

Notification Provision - General

9. Within ten (10) days of the date of entry of this decree, the defendant shall serve a copy thereof, by personal service or registered mail return receipt requested, upon each of his agents, representatives, distributors, employees, attorneys, successors, and assigns, and upon all persons in active concert or participation with him.

Within twenty (20) days of the date of entry of this decree, defendant shall provide to the FDA District Director, _____ District Office, Street address, City, State Zip, and to plaintiff's attorneys, an affidavit stating the fact and manner of his compliance with paragraph _____, and identifying the names and positions of all persons upon whom this decree has been served.

Notification Provision - Consumers

10. The defendant shall notify, by letter, his customers and all other persons involved in the sale or purchase of such products referred to in paragraph _____ that pursuant to an order of this court the products may no longer be marketed because they are misbranded drugs and medical devices (product 1, product2, and product 3) and unapproved new drugs (product 1), and that any continued marketing of the products is a violation of the Act, 21 U.S.C. 301 et seq. This letter must be submitted to and approved in writing by the FDA District Director, City, State, prior to its distribution.

Within thirty (30) days of the date of entry of this decree, defendant shall provide to the FDA District Director, _____ District Office, Street address, City, State Zip, and to plaintiff's attorneys, an affidavit stating the fact and manner of his compliance with paragraph _____, and identifying the names, addresses, and positions of all persons notified pursuant to paragraph _____. This affidavit shall include a copy of the letter(s) sent evidencing defendant's compliance with paragraph _____.

Notification - Employees

11. Defendants shall post a copy of this decree in plain view on a bulletin board or other conspicuous location in the employee common area at _____, within ten days of the entry of this decree, and shall ensure that the decree remains posted at that location for a period of _____ months. At the expiration of this time period, the defendants shall provide to the District Director, _____ District Office, FDA, an affidavit of compliance stating the fact and manner of compliance with this paragraph.

Recall Provision

12. Defendants shall, as FDA deems necessary, recall devices manufactured by defendants, which in FDA's judgment are adulterated or misbranded as determined by inspection or analysis. Such recall(s) shall be conducted in cooperation with FDA. All costs of the recall(s) shall be borne by the defendants. The costs of FDA's involvement in the recall(s) shall be borne by the defendants at the rates specified in paragraph _____. This remedy shall be separate and apart from, and in addition to, all other remedies available to the United States.

Recall with Customer Refund

The defendant shall, in writing, direct all of his agents, distributors, customers, and all other persons who, between February 2000 and the date of this decree, were involved in the sale or purchase of a) product 1, b) product 2, c) product 3, or d) any other drugs or medical devices that have been promoted by defendant for use in the diagnosis, cure, mitigation, treatment or prevention of any human disease, to return to the defendant, for full refund, all such products (whether unused or partially used), labeling, or promotional literature or tapes for such products.

Within thirty (30) days of the date of entry of this decree, defendant shall provide to the FDA District Director, _____ District Office, Street address, City, State Zip, and to plaintiff's attorneys, an affidavit stating the fact and manner of his compliance with paragraph _____, and identifying the names, addresses, and positions of all persons notified pursuant to paragraph _____. This affidavit shall include a copy of the letter(s) sent evidencing defendant's compliance with paragraph _____.

Destruction of Violative Articles

13. Within 45 days from the date of entry of this decree, the defendants shall destroy, under FDA supervision, all products, including those identified in paragraph _____ above, in their possession, custody, or under their control, unless (a) said products have been brought into compliance with the Act in the manner described in paragraph _____, and (b) the defendants have received a notice in writing from FDA that the products appear to be in compliance with the Act. All costs of the destruction shall be borne by the defendants. The costs of FDA's supervision of the destruction shall be borne by the defendants at the rates specified in

paragraph _____. Defendants shall be responsible for ensuring that the destruction is carried out in compliance with all Federal and local laws.

Notification - Change of Ownership/Sale of Assets

14. The defendant shall, in writing, notify the FDA District Director, _____ District Office, at least thirty (30) days before any change in ownership, character, or name of his business, including reorganization, assignment, or sale resulting in the emergence of successor entity or corporation, the creation or dissolution of subsidiaries or any other change in the corporate structure or identity of _____, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this decree. The defendant shall serve a copy of this decree on any prospective successor or assign no later than thirty (30) days prior to such sale or change in business, and shall furnish plaintiff with an affidavit of compliance with this paragraph no later than fifteen (15) days prior to such sale or change in business. As noted in paragraph _____, this decree shall apply to all of the defendant's successors and assigns.

15. All decisions in this decree are vested in the discretion of FDA which decisions, if necessary, shall be reviewed by the court under the arbitrary and capricious standard set forth in 5 U.S.C. 706(2)(A).

16. This court retains jurisdiction over this action and the parties hereto for the purpose of enforcing and modifying this decree and for the purpose of granting such additional relief as may be hereafter necessary or appropriate.

17. Except as provided above, the parties shall bear their own costs and attorneys' fees in this action.

18. Dated this _____ day of _____ 20 .

_____
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the form and contents of the foregoing consent decree of permanent injunction and to its entry.

_____
_____, individually
and as President of _____, INC.

_____
Attorney for Defendants
McQUAIDE, BLASKO, SCHWARTZ,
FLEMING & FAULKNER, INC.
Street
City, State Zip
Phone

_____
Assistant Attorney General
Civil Division

_____
United States Attorney

_____
Assistant U.S. Attorney
Street
City, State Zip

_____
Attorney
Office of Consumer Litigation
Civil Division
U.S. Department of Justice
Mail Address
Washington, D.C. 20044
Phone Number
Attorneys for Plaintiff

OF COUNSEL:

NAME
Chief Counsel
Food and Drug Administration

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

Exhibit 6-20
MODEL LETTER BILLING CHARGES

Sample Number Date
INJ ___, FDC _____

Firm
Street Address
City, State Zip

Gentlemen:

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	$XXX.XX
	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

Enc: cc this letter

Exhibit 6-21
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: _____

Respectfully submitted:

NAME IN CAPS
Assistant Attorney General

NAME IN CAPS
Chief Counsel

NAME IN CAPS
United States Attorney

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

_____

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 6-22
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 6-23
FORMAT FOR PROSECUTION SUMMARY AND RECOMMENDATION

Memorandum

FROM:_____ District (HFR-____)

SUBJECT: PROSECUTION

Lead Sample Number, et al.

TO: Office of Enforcement, Division of Compliance Management and Operations (HFC-210) 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.

CITATION

LEGAL STATUS

ALLEGED VIOLATION

HISTORY

PRIOR NOTICE

OTHER CORRESPONDENCE

WITNESSES FOR INSPECTIONAL AND ANALYTICAL FINDINGS

OTHER WITNESSES

RECOMMENDATION

PERMANENT ABEYANCE OF SAMPLES AND/OR INDIVIDUALS

SAMPLE 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 Director

Concurrence by: Regional Director

Enclosures:
Case files

Exhibit 6-24
MODEL PROSECUTION SUMMARY AND RECOMMENDATION MEMORANDUM

DATE:

FROM: _____ District (HFR-)

SUBJECT: PROSECUTION
Lead Sample Number, et al.

TO: Office of Enforcement, Division of Compliance Management and Operations (HFC-210)

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 March 20, 2003. Therefore, the case was sent directly to DCMO (HFC-210).

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.

OTHER CORRESPONDENCE

Attached are copies of correspondence between the state and the corporation covering the

period from 1995 to the present time.

WITNESSES FOR INSPECTIONAL AND ANALYTICAL FINDINGS

SAMPLE NO.	COLLECTING INVESTIGATOR	ANALYST
_____(COUNT I)	(Name)	(Name)
_____(COUNT II)	(Name)	(Name)
_____(COUNT III)	(Name)	(Name)
_____(COUNT IV)	(Name)	(Name)

All investigators and analysts are presently located at the Dallas District office.

OTHER WITNESSES

Name, address, phone number, title - An expert on rodent and insect contamination of storage products.

RECOMMENDATION

Prosecution of: Firm, Inc. (All Sample Nos.)
and
Individual A, and
Individual B
(all defendants on each sample)

The proposed defendants have received prior warning during inspections, FDA 483s, Warning Letter, and accomplished seizures.

PERMANENT ABEYANCE OF SAMPLES AND/OR INDIVIDUALS

Above named corporation (Sample No.) and individuals (Sample No.). We have recommended permanent abeyance of these two numbers only to restrict the proposed information to four counts per wishes of the local District Court.

SAMPLE DATA

COUNT I

(Sample No. - Lima Beans)

Date Lot Received: 1-27-2002

Date Lot Sampled/By: 5-9-2002 by (Name) (_____-DO)

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 (_____-DO)

Analytical Methods: Macroscopic, Microscopic, and Xanthydrol

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 Director

Concurrence by: Regional Director

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 6-25
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 6-26
RULE 44 - PROOF OF OFFICIAL RECORD

(**a) Authentication**.

(1) Domestic.

An official record kept within the United States, or any state, district, or commonwealth, or within a territory subject to the administrative or judicial jurisdiction of the United States, or an entry therein, when admissible for any purpose, may be evidenced by an official publication thereof or by a copy attested by the officer having the legal custody of the record, or by the officer's deputy, and accompanied by a certificate that such officer has the custody. The certificate may be made by a judge of a court of record of the district or political subdivision in which the record is kept, authenticated by the seal of the court, or may be made by any public officer having a seal of office and having official duties in the district or political subdivision in which the record is kept, authenticated by the seal of the officer's office.

(2) Foreign.

A foreign official record, or an entry therein, when admissible for any purpose, may be evidenced by an official publication thereof; or a copy thereof, attested by a person authorized to make the attestation, and accompanied by a final certification as to the genuineness of the signature and official position (i) of the attesting person, or (ii) of any foreign official whose certificate of genuineness of signature and official position relates to the attestation or is in a chain of certificates of genuineness of signature and official position relating to the attestation. A final certification may be made by a secretary of embassy or legation, consul general, vice consul, or consular agent of the United States, or a diplomatic or consular official of the foreign country assigned or accredited to the United States. If reasonable opportunity has been given to all parties to investigate the authenticity and accuracy of the documents, the court may, for good cause shown, (i) admit an attested copy without final certification or (ii) permit the foreign official record to be evidenced by an attested summary with or without a final certification. The final certification is unnecessary if the record and the attestation are certified as provided in a treaty or convention to which the United States and the foreign country in which the official record is located are parties.

(b) Lack of Record.

A written statement that after diligent search no record or entry of a specified tenor is found to exist in the records of his office, designated by the statement, authenticated as provided in subdivision (a)(1) of this rule in the case of a domestic record, or complying with the requirements of subdivision (a)(2) of this rule for a summary in the case of a foreign record, is admissible as evidence that the records contain no such record or entry.

(c) Other Proof.

This rule does not prevent the proof of official records or of entry or lack of entry therein by any other method authorized by law.

Exhibit 6-27
RULE 6. THE GRAND JURY

(a) Summoning a Grand Jury.

(1) *In General.*

When the public interest so requires, the court must order that one or more grand juries be summoned. A grand jury must have 16 to 23 members, and the court must order that enough legally qualified persons be summoned to meet this requirement.

(2) *Alternate Jurors.*

When a grand jury is selected, the court may also select alternate jurors. Alternate jurors must have the same qualifications and be selected in the same manner as any other juror. Alternate jurors replace jurors in the same sequence in which the alternates were selected. An alternate juror who replaces a juror is subject to the same challenges, takes the same oath, and has the same authority as the other jurors.

(b) Objection to the Grand Jury or to a Grand Juror.

(1) *Challenges.*

Either the government or a defendant may challenge the grand jury on the ground that it was not lawfully drawn, summoned, or selected, and may challenge an individual juror on the ground that the juror is not legally qualified.

(2) *Motion to Dismiss an Indictment.*

A party may move to dismiss the indictment based on an objection to the grand jury or on an individual juror's lack of legal qualification, unless the court has previously ruled on the same objection under Rule 6(b)(1). The motion to dismiss is governed by 28 U.S.C. § 1867(e). The court must not dismiss the indictment on the ground that a grand juror was not legally qualified if the record shows that at least 12 qualified jurors concurred in the indictment.

(c) Foreperson and Deputy Foreperson.

The court will appoint one juror as the foreperson and another as the deputy foreperson. In the foreperson's absence, the deputy foreperson will act as the foreperson. The foreperson may administer oaths and affirmations and will sign all indictments. The foreperson—or another juror designated by the foreperson—will record the number of jurors concurring in every indictment and will file the record with the clerk, but the record may not be made public unless the court so orders.

(d) Who May Be Present.

(1) *While the Grand Jury Is in Session.*

The following persons may be present while the grand jury is in session: attorneys for the government, the witness being questioned, interpreters when needed, and a court reporter or an operator of a recording device.

(2) *During Deliberations and Voting.*

No person other than the jurors, and any interpreter needed to assist a hearing-impaired or speech-impaired juror, may be present while the grand jury is deliberating or voting.

(e) Recording and Disclosing the Proceedings.

(1) *Recording the Proceedings.*

Except while the grand jury is deliberating or voting, all proceedings must be recorded by a court reporter or by a suitable recording device. But the validity of a prosecution is not affected by the unintentional failure to make a recording. Unless the court orders otherwise, an attorney for the government will retain control of the recording, the reporter's notes, and any transcript prepared from those notes.

(2) *Secrecy.*

(A) No obligation of secrecy may be imposed on any person except in accordance with Rule 6(e)(2)(B).

(B) Unless these rules provide otherwise, the following persons must not disclose a matter occurring before the grand jury:

(i) a grand juror;

(ii) an interpreter;

(iii) a court reporter;

(iv) an operator of a recording device;

(v) a person who transcribes recorded testimony;

(vi) an attorney for the government; or

(vii) a person to whom disclosure is made under Rule 6(e)(3)(A)(ii) or (iii).

(3) *Exceptions.*

(A) Disclosure of a grand-jury matter—other than the grand jury's deliberations or any grand juror's vote—may be made to:

(i) an attorney for the government for use in performing that attorney's duty;

(ii) any government personnel—including those of a state or state subdivision or of an Indian tribe—that an attorney for the government considers necessary to assist in performing that attorney's duty to enforce federal criminal law; or

(iii) a person authorized by 18 U.S.C. § 3322.

(B) A person to whom information is disclosed under Rule 6(e)(3)(A)(ii) may use that information only to assist an attorney for the government in performing that attorney's duty to enforce federal criminal law. An attorney for the government must promptly provide the court that impaneled the grand jury with the names of all persons to whom a disclosure has been made, and must certify that the attorney has advised those persons of their obligation of secrecy under this rule.

(C) An attorney for the government may disclose any grand-jury matter to another federal grand jury.

(D) An attorney for the government may disclose any grand-jury matter involving foreign intelligence, counterintelligence (as defined in 50 U.S.C. § 401a), or foreign intelligence information (as defined in Rule 6(e)(3)(D)(iii)) to any federal law enforcement, intelligence, protective, immigration, national defense, or national security official to assist the official receiving the information in the performance of that official's duties.

(i) Any federal official who receives information under Rule 6(e)(3)(D) may use the information only as necessary in the conduct of that person's official duties subject to any limitations on the unauthorized disclosure of such information.

(ii) Within a reasonable time after disclosure is made under Rule 6(e)(3)(D), an attorney for the government must file, under seal, a notice with the court in the district where the grand jury convened stating that such information was disclosed and the departments, agencies, or entities to which the disclosure was made.

(iii) As used in Rule 6(e)(3)(D), the term ''foreign intelligence information'' means:

(a) information, whether or not it concerns a United States person, that relates to the ability of the United States to protect against—

• actual or potential attack or other grave hostile acts of a foreign power or its agent;

• sabotage or international terrorism by a foreign power or its agent; or

• clandestine intelligence activities by an intelligence service or network of a foreign power or by its agent; or

(b) information, whether or not it concerns a United States person, with respect to a foreign power or foreign territory that relates to—

• the national defense or the security of the United States; or

• the conduct of the foreign affairs of the United States.

(E) The court may authorize disclosure—at a time, in a manner, and subject to any other conditions that it directs—of a grand-jury matter:

(i) preliminarily to or in connection with a judicial proceeding;

(ii) at the request of a defendant who shows that a ground may exist to dismiss the indictment because of a matter that occurred before the grand jury;

(iii) at the request of the government if it shows that the matter may disclose a violation of state or Indian tribal criminal law, as long as the disclosure is to an appropriate state, state-subdivision, or Indian tribal official for the purpose of enforcing that law; or

(iv) at the request of the government if it shows that the matter may disclose a violation of military criminal law under the Uniform Code of Military Justice, as long as the disclosure is to an appropriate military official for the purpose of enforcing that law.

(F) A petition to disclose a grand-jury matter under Rule 6(e)(3)(E)(i) must be filed in the district where the grand jury convened. Unless the hearing is ex parte—as it may be when the government is the petitioner—the petitioner must serve the petition on, and the court must afford a reasonable opportunity to appear and be heard to:

(i) an attorney for the government;

(ii) the parties to the judicial proceeding; and

(iii) any other person whom the court may designate.

(G) If the petition to disclose arises out of a judicial proceeding in another district, the petitioned court must transfer the petition to the other court unless the petitioned court can reasonably determine whether disclosure is proper. If the petitioned court decides to transfer, it must send to the transferee court the material sought to be disclosed, if feasible, and a written evaluation of the need for continued grand-jury secrecy. The transferee court must afford those persons identified in Rule 6(e)(3)(F) a reasonable opportunity to appear and be heard.

(4) ***Sealed Indictment.***

The magistrate judge to whom an indictment is returned may direct that the indictment be kept secret until the defendant is in custody or has been released pending trial. The clerk must then seal the indictment, and no person may disclose the indictment's existence except as necessary to issue or execute a warrant or summons.

(5) ***Closed Hearing.***

Subject to any right to an open hearing in a contempt proceeding, the court must close any hearing to the extent necessary to prevent disclosure of a matter occurring before a grand jury.

(6) *Sealed Records.*

Records, orders, and subpoenas relating to grand-jury proceedings must be kept under seal to the extent and as long as necessary to prevent the unauthorized disclosure of a matter occurring before a grand jury.

(7) *Contempt.*

A knowing violation of Rule 6 may be punished as a contempt of court.

(f) Indictment and Return.

A grand jury may indict only if at least 12 jurors concur. The grand jury—or its foreperson or deputy foreperson—must return the indictment to a magistrate judge in open court. If a complaint or information is pending against the defendant and 12 jurors do not concur in the indictment, the foreperson must promptly and in writing report the lack of concurrence to the magistrate judge.

(g) Discharging the Grand Jury.

A grand jury must serve until the court discharges it, but it may serve more than 18 months only if the court, having determined that an extension is in the public interest, extends the grand jury's service. An extension may be granted for no more than 6 months, except as otherwise provided by statute.

(h) Excusing a Juror.

At any time, for good cause, the court may excuse a juror either temporarily or permanently, and if permanently, the court may impanel an alternate juror in place of the excused juror.

(i) "Indian Tribe" Defined.

''Indian tribe'' means an Indian tribe recognized by the Secretary of the Interior on a list published in the Federal Register under 25 U.S.C. § 479a–1.

Exhibit 6-28

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).

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 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-ray systems; and (4) provided a user notification letter and a list of end-user addresses to

FDA's Chicago District 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 Chicago District
On June 27, 1994, the defendants provided the Chicago District with draft versions of letters to be sent out to notify dealers who had purchased noncompliant x-ray systems from defendants. FDA's Chicago District Director wrote the defendants on July 5, 1994, suggesting some changes in the wording of these letters. The District 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 Chicago District.

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 Chicago District.

By letter dated September 12, 1994, FDA's Chicago District addressed some of the issues raised by the defendants' July 15, 1994 letter. The District 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.

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 had 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 Chicago District.

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 (l934); 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 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

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.

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.

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.

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 Chicago District and that they were to submit information to CDRH regarding the corrective action plan for the general purpose systems.
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.

Exhibit 6-29
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)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
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)

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

Model 17 Unit (1 total)

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

Model 18 Units (4 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
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)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
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)

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

Model 13 Units (49 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
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)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
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)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
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)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
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: (l) 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 l9, 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)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
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)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
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
[insert address]
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