Chapter 5
ADMINISTRATIVE ACTIONS

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NOTE: The District compliance officer (or, the Center CSO/Scientist, if the action was Center-initiated) assigned to the administrative 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.)

5-1 CITATIONS

5-1-1 Purpose

This section describes the Food and Drug Administration's (FDA) procedures for issuing Section 305 Notices (Citations).

5-1-2 Legal Authority

FDA issues Citations under Section 305 of the Federal Food, Drug, and Cosmetic Act (the Act), which states:

"Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding."

21 CFR 7.84 provides requirements about the issuance of such notice and opportunity.

NOTE: Citation is to be used only when a prosecution recommendation is contemplated. Do not use a Citation for warning purposes.

5-1-3 Citation Under Multiple Laws

On occasion, the same or related conduct that violates the Act may also constitute a violation

of one or more other federal laws, such as the licensing provisions for biologics under the Public Health Service Act (42 U.S.C. Section 262), 18 U.S.C. Section 1001 (Fraud and False Statements), and 18 U.S.C. Section 371 (Conspiracy to commit offense or to defraud United States).

In such a case, identify the section of each law under which action is contemplated, and the specific actions considered to violate that law.

5-1-4 Criteria For Citation

The basic criteria for consideration of citation are as follows:

1. A violation of the law has been established and the agency has evidence in its possession to support the case in court.
2. The violation is significant in terms of consumer protection.

Except in cases involving a health hazard, fraud, or extremely gross violations, prior warning must have been given to the firm and each individual involved. This prior warning may be in the form of conferences, previous meetings, letters or discussions of FDA 483s at the conclusion of inspections or previous court actions. See Chapter 10 for a discussion of Prior Notice. In instances where the prior warning was in the form of letters or a Section 305 Notice involving past violations, copies must have been directed to each individual to be cited. NOTE: Additional, more specific criteria in many areas may be found in Compliance Policy Guides (CPG) and the Compliance Program Guidance Manual (CPGM).

5-1-5 Determining The Need For Citation

The District Compliance Branch is responsible for deciding whether citation is warranted. The compliance officer assigned to the case should assure that all samples and other evidence have been considered. The search for other samples and evidence may include:

1. searching the Field Accomplishments and Compliance Tracking System (FACTS) for further information on the firm;
2. checking with the laboratory to find out if there are other samples that are in-process and need to be analyzed;
3. checking the collection report (C/R) on the initial sample to assure that all related samples are attached; and,
4. checking outstanding sample assignments in FACTS.

If there are other samples to be analyzed or the establishment inspection report has not been completed, and seizure has not yet been considered, you may wish to defer action until the entire case can be considered at one time. In such instances, discuss the matter with investigations branch and/or the laboratory to expedite processing of the report or the samples.

Conduct a thorough review of the evidence. For example, review the firm's regulatory history to determine who was responsible for the violations and whether prior warning has been given. Review inspection reports to assure that any inspectional observations that are inconsistent with analytical results are addressed. Assure that reserve samples are available, where required. In labeling violations, search the file to determine whether the firm has revised the

labeling since the shipment of the samples in question.

A citation may be based solely on establishment inspection evidence. A minimum of two documentary samples covering violative products is desirable.

NOTE: Under normal circumstances, notice and an opportunity to present information and views will always be given before violations are reported for criminal prosecution. However, there are certain circumstances under which notice and opportunity need not be provided. Notice and opportunity need not be given when there is reason to believe that alerting the prospective defendants by a Section 305 Notice may result in the destruction of evidence, or cause the proposed defendants to flee to avoid prosecution. (21 CFR 7.84(a)(2)). In addition, notice and opportunity need not be given when further investigation by the Department of Justice is contemplated. (21 CFR 7.84(a)(3)).

Such situations are infrequent and should be approved on a case-by-case basis. Submit the facts to the center and request concurrence from the center, OE, and OCC when you do not believe providing notice and an opportunity for presentation of views is appropriate.

5-1-6 Time Frames

The following time frames apply to citations:

Field: 15 working days after analysis of most recent sample involved in case.

Center: 15 working days after receipt of the recommendation.

There may be good reasons for exceeding these timeframes in a particular case. For example, analytical procedures may be lengthy, or there may be a need to obtain assistance from other districts to establish responsibility. Document the reasons for delays in the case file.

5-1-7 Field Office Citation Procedures

PRIOR CONSULTATION WITH OCI

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, and citations.

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 that decision to the district.

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

AUTHORIZATION TO CITE

Citation may issue either on a direct basis or after the submission of a recommendation to the appropriate center and receipt of concurrence to issue the Section 305 Notice.

It is incumbent upon the office issuing the Section 305 Notice to assure that the firm and each individual to be cited have received prior warning, unless such warning is not required.

Direct Citation
CPGs give field offices authority to issue Section 305 Notices in cases where specific criteria are met. Most of these guidelines involve filth violations or noncompliance with standards. Check the manual each time the district office believes citation is the action of choice to preclude submitting unnecessary recommendations to a center.

Citation Recommendation
Where the district office does not have direct citation authority, they should submit a citation recommendation to the appropriate center for approval.

The recommendation should include the full background of the case, the history of notification, and the facts supporting the violation(s) for which prosecution is being considered. Include the names and responsibilities of each individual to be cited, the proposed charges, and the supporting samples. Submit any labels, worksheets, and pertinent inspection reports. Identify and discuss any issues, concerns, discrepancies, or other problems with the case. The recommendation package should be well-organized, tabbed, and indexed. The recommendation should identify the location of supporting information it discusses. Interstate (IS) documentation remains the responsibility of the districts and need not be submitted. However, the center may request IS documentation if there's a special need to review it.

Citation Recommendation After or Concurrently with Seizure
When the district follows a seizure action with a citation recommendation based on the same underlying violations, it is acceptable to submit a memorandum that references information in the seizure recommendation, provided that the center has all of the labeling and other documents necessary to consider the citation.

When the district office is recommending citation at the same time it is recommending seizure, flag the recommendation memorandum as "Seizure and Citation Recommendation."

5-1-8 Determination Of Citees

Corporations, Partnerships, and Associations
Corporations, partnerships, and associations are "persons" under the Act, and may be prosecuted as separate legal entities. They should always be included in the citation.

Individuals

In every case, carefully consider citing individuals. Prior warning is a prerequisite except where the violation involves a danger to health, fraud, or where the violation is extremely gross.

It is FDA policy to cite officers of corporations and members of partnerships and associations, when the available evidence establishes that the individual stood in a "responsible relationship" to the violation. As the U.S. Supreme Court stated in U.S. v. Park: "The Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur."

Persons who have the power and authority, and therefore the responsibility, to carry out these duties and fail to do so, are logical candidates for citation. Obtain the type of information needed to demonstrate responsibility from observations reported by the investigators, through correspondence and/or memoranda of conferences with the individuals, or through other means. In addition, if there is a need, obtain information from officers and individuals located at a parent plant, as well as persons at the inspected plant.

5-1-9 Setting Date For Meeting

If the firm and individuals to be cited are located within a reasonable proximity of the office, in which the meeting is to be held, schedule the meeting for approximately 10 days after issuing the Section 305 Notice. If the citees must travel extensive distances or wish to have a corporate attorney in attendance, or the violations involved are complex, schedule the meeting approximately 20 days after issuing the Section 305 Notice.

When there are multiple citees, schedule a separate meeting for any citee who requests one in writing. The meeting may be held at a separate time on the same date or on a separate date. The citee must submit the request to the office that issued the Section 305 Notice, and the request must be received at least three working days before the date set in the notice.

5-1-10 Preparation Of Citation Documents

Section 305 Notice (Exhibit 5-1)
Insert the district address under the printed heading "Food and Drug Administration." Under the caption at the right, "In reply refer to," insert the key or file reference sample number for the action, and "et. al." if there are several samples involved. If there is only one product or class of products, such as "drugs," bakery products," etc., identify the product directly below the reference sample number. The complete list of samples will appear on the Charge Sheet along with the respective products. See Exhibits 5-2 and 5-3 for examples of charge sheets.

Enter the date that Notice issues directly above the rectangle on "Section 305 Notice" or centered under the city and state of the district's address.

In the space for addressee, insert the name and address of the firm or sole owner cited (primary citee). When the citation also names responsible individuals, address it in the following manner:

Standard Pharmaceutical Co.
and Mr. Henry Jones

and Mr. John Doe
125 Main Street
Canton, Ohio 28531

(Do not show titles of individuals listed as citees.)

In the body of the Notice, following the phrase "with respect to the following," enter clear, concise statements identifying the specific interstate shipment and product for each sample on which citation is issuing. In each statement include the name of the product, sufficient quotation from the label to identify the brand, size, etc., the date of shipment, where the shipment originated, and where and to whom it was consigned. When there is more than one sample, show sample numbers in parenthesis following the description of each shipment. If there is insufficient space on the form to enter the samples and shipments involved, enter the notation "See Page 2" conspicuously in the body of the Notice and continue the additional information regarding the samples on a separate page captioned as follows: "Page 2 - Section 305 Notice".

NOTE: When charging violations involving items other than shipments, include a concise factual statement of the violations (see Exhibits).

Following the words, "A meeting has been scheduled for," insert the day, date, specific time and location of the meeting. Add any other information that may facilitate the citee's appearance in parentheses following this statement (e.g., availability of parking near the building).

Type the name of the Compliance Officer who will conduct the meeting at the bottom of the form, and have that individual sign the copies mailed to the firm and each individual cited.

If individuals have been cited along with the firm, show distribution on all copies of the Notice under the parenthetical statement: "(IMPORTANT: NOTE ALL ENCLOSURES CAREFULLY)" such as: 1 cc to Mr. John Doe and to Mr. Robert Roe each with Charge Sheet and Information Sheet.

Charge Sheet (Form FDA 1854) (Exhibit 5-2)
Use Form FDA 1854. Under the title, list each sample and product in ascending numerical order. If the list of samples is long, arrange it in two columns.

Under the heading "PROHIBITED ACT" state the section(s) of the law(s) violated and the statutory description from the law. In charges involving Title 18 or Title 42, cite those laws.

At the left of the sheet, following the above paragraph type the word "CHARGES". If only one sample and charge are involved, enter the statement "The article is violative in that" followed by the non-legal description of the violation. In the case of multiple charges, enter the statement: "The article is violative in the following respects:" and list each charge separately, numbered as "1," "2," "3," etc.

When a number of samples and charges are involved, use the statement "The articles are violative in the following respects:" and list the charges as described above. Show the sample numbers involved at the left of each charge.

State the charges in “lay language.” There is no need to reference specific sections of the Act (other than the "Prohibited Act") or the regulations. Exhibit 5-3 contains examples of charges.

Legal Status Sheet (Form FDA 454) (Exhibit 5-4)
Enter the sample numbers involved in the citation in the upper right hand side of the form following the caption "Sample No."; and the date(s) of the alleged violations over the "(Date)" caption following line "A." If more than two dates are involved, show the earliest and latest dates only; for example "3/3/94 thru 4/12/94." The district office makes no other entries.

Information Sheet (Form FDA 466a) (Exhibit 5-5)
This form describes the purpose and nature of the meeting. It is not necessary to type any information on the form; however, it is mandatory that a form accompany the Section 305 Notice sent to each individual cited.

5-1-11 Distribution Of Citation Documents

Distribute the Section 305 Notice, Charge Sheet, Legal Status Sheet, and Information Sheet as follows:

Send a signed, original copy of the Section 305 Notice, a Charge Sheet, an Information Sheet, and a Legal Status Sheet to the primary citee (generally the firm).
Send a signed copy of the Section 305 Notice, a copy of the Charge Sheet, and an Information Sheet, to each of the other citees, if it is a joint citation.
Forward one copy of the Section 305 Notice, together with one copy of the Charge Sheet to HFA-224, to the factory file, the reading file, and, if applicable, to the District Resident Post.
Retain three copies of the Section 305 Notice and the Charge Sheet in the District Sample File for use when making a recommendation for disposition of the charges.

MAILING INSTRUCTIONS
Mail the Section 305 Notice in a regular, letter size envelope with the typed name and address of the citee. Do not use window envelopes. When individuals are cited along with a firm, circle or underline their names on their respective copies and mail each citee's copy in a separate envelope. Where the interests of the individual citees may be at odds, you may send the individual notices to the home addresses of the citees.

Send the Section 305 Notice by certified mail with return receipt requested.

POSTPONEMENT OF MEETINGS
Districts may grant a reasonable postponement of a meeting upon written request by a citee or person representing a citee (see exception below). The length of the postponement will depend on particular circumstances, but should avoid excessive delay. Confirm the new date by a letter to the citee or representative who requested the postponement. Provide an information file copy to the center.

Exception: If an office in headquarters directed that the meeting be scheduled within a certain time frame, do not agree to postponements without first consulting with that office.

5-1-12 Transfer Of Meeting

Occasionally citees will request a transfer of the scheduled meeting to another city in the district area, to another district office, or to Washington headquarters. The citee also has the option of answering by other means when personal appearance at the district headquarters is impractical.

Transfer Within District Area
Do not grant requests for transfer of the meeting to another city in the district area. The cost to the public of holding the meeting in another city outweighs any benefit or convenience to the citee.

Transfer to Another District
A request to transfer a meeting to another district may be granted if reasonable grounds are presented, the request is addressed to the office that issued the Section 305 Notice, and the request is received in that office at least 3 working days prior to the date set in the notice. (See 21 CFR 7.84(e)). However, before granting the request to transfer the meeting, check with the District involved to make sure it can handle the meeting.

Once the request is granted, verify the transfer by letter to the citee, providing an information copy to HFA-224. Send two copies of the letter to the new district with attachments:

1. complete file on the samples involved
2. pertinent Establishment Inspection Reports (EIR's)
3. a FACTS printout of firm's record, if pertinent to the case

The home district should establish a temporary jacket as a record of the transfer.

The transferee district will reschedule the meeting promptly and advise accordingly. This may be done by letter with reference to the original Section 305 Notice and to the letter approving transfer from the original district. Forward copies to the home district and HFA-224.

After the meeting, send the Record and any exhibits to the home district along with the original files.

Prepare a skeleton sample jacket containing a copy of the Record, transcripts (if any), and copies of any collateral correspondence that may have issued on the case.

Transfer to Headquarters
Discourage requests by citees, before or during the meeting, to transfer the meeting to headquarters.

If, however, the citee insists that the meeting be held at headquarters, refer the request to the center involved. If granted, the center will inform the citee and home district of the new date set for the meeting. The district should then promptly forward the case file to the center for review and use during the meeting. The center will return the case file with the Record to the home district for disposition of the charges.

5-1-13 Correspondence With Attorneys

Attorneys representing clients who received a Section 305 Notice will often correspond with the district compliance officer regarding the Section 305 Notice. Because the issuance of a Section 305 Notice is confidential and generally not releasable to the public until all potential criminal matters are resolved, district compliance officers are responsible for assuring that representatives of the citee provide appropriate documentation regarding their authorization (see 21 CFR 7.84(g)).

It is not necessary to send citees copies of correspondence from their attorneys. However, when a citee is identified as having received a copy of their attorney's correspondence, and we have responded to that correspondence, you may wish to send the citee a copy of our response.

5-1-14 Drug Advertising Citations

Due to the specialized nature of medical advertising, the Division of Drug Marketing, Advertising and Communications (DDMAC), Center for Drug Evaluation and Research (CDER) is the primary reviewer of drug advertisements. With few exceptions, DDMAC will initiate citations based on violative drug advertisements.

After determining that an advertisement is violative and that citation is warranted, DDMAC may initiate a request for samples to support an action. Samples that are obtained are routed to the home district of the responsible firm.

DDMAC will prepare citation instructions for issuance by the appropriate district. The instructions will specify whether the meeting is to be held at the district office or at headquarters. In most cases, meetings are held at headquarters.

The district will issue the Section 305 Notice in the normal manner, with a copy to DDMAC.

Following the meeting, DDMAC will make a decision on the disposition of the charges and notify the district of that decision.

5-2 SECTION 305 MEETING

5-2-1 Purpose

This section summarizes the authority, policies, and procedures pertaining to the opportunity, under Section 305 of the Act, for a person to present their views before criminal prosecution is recommended to a United States Attorney.

5-2-2 Authority

The Secretary of Health and Human Services delegates broad authority to the Commissioner of Food and Drugs under 21 CFR 5.10, and, unless specifically prohibited, gives the Commissioner the authority to redelegate this authority. District Directors, Regional Food and Drug Directors, and Directors and Deputy Directors of the Centers, are authorized under 21

CFR 5.28(a), to designate officials to hold hearings under section 305 of the Act. A Compliance Officer has authority to hold Section 305 meetings by such designation.

21 CFR 7.85 provides requirements about the conduct of such meetings.

5-2-3 Preparation

Except in unusual circumstances, the Compliance Officer who holds the meeting is the individual who issued the Section 305 Notice. As there is normally a time lapse between the issuance of the Section 305 Notice and the meeting date, the compliance officer should review the case immediately prior to the meeting. The Compliance Officer will need to be completely familiar with the charges, the law and regulations, and fully understand any analytical results and methodology that are part of the case (if necessary, through discussion with the analyst).

The Compliance Officer should assemble any necessary references, such as the Act, regulations, official compendia, etc. The compliance officer may also wish to mark or photocopy pertinent information in the files to avoid searches for data during the meeting. Such information may include records relating to samples, EIRs, and FDA 483s, and documents relating to prior warnings to the firm or individuals in the form of citations, seizures, prosecutions, office interviews, letters, etc. To avoid the need to reread all of the material, it is best to organize this information at the time of the initial review, when preparing the Section 305 Notice.

5-2-4 Respondents' Request For Special Information

Respondents, their attorneys, and others occasionally attempt to obtain detailed information concerning the government's case. Such requests constitute requests for information under the Freedom of Information Act (FOIA). Point out that under the FOIA, they must submit requests in writing to the Director of FDA's Division of FOI. Refer the requester to http://www.FDA.Gov/FOI/FOIA2.htm, and mention that the request must be processed according to law and FDA's procedures. For example, FDA's Associate Commissioner for Public Affairs might determine that some or all of the information about FDA's case may be withheld from disclosure under 21 C.F.R. 20.62 (pre-decisional information, attorney work product, etc.) and/or 21 C.F.R. 20.64 (open investigatory, personal privacy, confidential source, etc.).

NOTE: If a respondent requests a portion of a sample, follow the procedures set forth in 21 CFR 2.10(d) and 2.10(c).

5-2-5 Conducting The 305 Meeting

Respondents are occasionally quite upset due to the receipt of the Section 305 Notice and may tend to be discourteous or argumentative. The 305 meeting is not a debate and nothing can be gained by the Compliance Officer losing objectivity or by the respondent becoming abusive. The Compliance Officer should politely point out that the proceedings are not a trial but rather an opportunity for the respondents to give their side of the story and discuss any mitigating circumstances, corrective actions taken or planned, etc., and that FDA will consider

this information when deciding whether or not to forward the case to the Department of Justice for the institution of criminal proceedings.

The Compliance Officer should strive for continuity and relevancy. Some respondents may digress into time-consuming, irrelevant or repetitious discussion unless there is a diplomatic effort to focus upon relevant matters. Listed below is a suggested routine format for achieving orderly progress during the meeting:

IDENTIFICATION OF RESPONDENTS
After the respondents have been introduced and seated, make notes showing the name, address, position, and business connection of each respondent. The notes are for ready reference during the meeting and useful during the dictation of the Record.

FAILURE OF RESPONDENT TO APPEAR
Frequently, a cited individual does not attend the meeting. Determine if anyone present purports to represent such respondent and enter any responses into the record.

Designated representative(s) must have a signed written statement of authorization for each respondent for whom he/she has authority to act. If a representative appears without written authorization, the meeting may proceed with respect to any respondent for whom the representative appears, only if the Compliance Officer first verifies by telephone, or other appropriate means, the authenticity of the representative's authority (21 CFR 7.84(g)).

ATTENDANCE BY INDIVIDUALS NOT CITED
Occasionally, an individual who was not named in the Section 305 Notice will appear and, during the course of the meeting, it will become apparent that the person shares the responsibility for the violation. In such instances, request a short delay and have the legal clerk prepare a supplemental Section 305 Notice including the individual's name, present it to him, and proceed with the meeting.

Respondents may arrive at a meeting accompanied by many adherents. When this situation occurs, the Compliance Officer should have each person identify themselves by name, state their relationship to the respondent, and, for the record, state that they are attending on behalf of the respondent. The Compliance Officer should then announce to the group that the meeting is not open to the public, that it concerns only the respondent, and that the only legitimate business other persons have in being there is that they are there at the request of, and on behalf of, the respondent; otherwise, they may not be present. Afterwards, the Compliance Officer will hear comments from all persons remaining present. If these actions are not taken, the respondent may claim that FDA deprived him/her of his/her rights to fully respond and explain.

MORE THAN ONE RESPONDENT
Requests for separate meetings should be in writing and should be received at least three working days before the date set in the notice (21 CFR 7.84(e)). However, if there is more than one respondent, advise the respondents in advance that they are entitled to separate meetings if they so wish.

LEGAL STATUS SHEET, FORM FDA 454
Ask for the Legal Status Sheet. The respondent may complete the sheet before or at the

meeting. However, you may not demand completion or submittal of the sheet since there is no legal requirement that respondents furnish the sheet.

EXPLAIN THE PURPOSE OF THE MEETING AND THE CHARGES
Although the Information Sheet (Form FDA 466a), which accompanies the Section 305 Notice and Charge Sheet, contains information concerning the reason for the notice, the Compliance Officer should reiterate the purpose of the notice prior to the discussion of the charges and advise the respondents that:

The meeting is being held in accordance with Section 305 of the Act to give them an opportunity to present any facts they believe are relevant prior to the FDA making its decision whether to recommend prosecution to the Department of Justice.
The purpose of the meeting is not to resolve conclusively whether violations occurred, and therefore FDA will not present either witnesses or evidence at the meeting.

The Compliance Officer should briefly state the information in the FDA's possession, which indicates that violations of the Act (and other laws, if pertinent) occurred and that the individuals listed in the Section 305 Notice were responsible, either through their actions or their failure to take action. This may be by reference to the pertinent inspections, FDA 483s, warning letters etc., to provide a brief summary of the relevant time and acts. Request that the respondents follow their copies of the Section 305 Notice and Charge Sheet as the Compliance Officer either reads verbatim or summarizes the pertinent information concerning the shipment or receipt of each product and the charges pertaining to it, or the acts that constitute violations.

The Compliance Officer should ask the respondents whether they understand the charges. If the response is negative, answer any questions to assure that the respondent understands the basis of the allegations. If the respondent indicates that the shipping or receiving dates are incorrect, clarify the discrepancies. If they indicate that they will make no admissions with regard to the shipment or receipt of the products, do not pursue the matter.

MIRANDA WARNING
In the past, there were questions regarding whether the Compliance Officer needs to give the "Miranda Warnings" prior to conducting a Section 305 meeting. They are not to be given.

In Miranda v. Arizona, the court ruled that when an individual is taken into custody or otherwise deprived of his freedom and subjected to questioning, the person must be notified of his right to remain silent, that anything he says may be used against him, and that he has the right to an attorney. This warning does not apply to Section 305 meetings because a respondent to a Section 305 Notice is not "taken into custody or otherwise deprived of his freedom." In addition, even though not required, FDA notifies the respondents (Form FDA 466a) that they are not compelled to answer and that an attorney may represent them. In 1976, in Beckwith v. United States, the Supreme Court held that even when the investigation has "focused" on an individual, he is not entitled to Miranda warnings unless he is in custody. In Oregon v. Mathiason, decided in January 1977, the Supreme Court held that a meeting at which the individual was free to leave did not require Miranda warnings.

RESPONDENTS' STATEMENT
After discussing the purpose for the meeting and the charges, the Compliance Officer should

invite the respondents to state their views with respect to the alleged violations. Take notes regarding the various points covered by the respondents to assure that pertinent comments are not inadvertently omitted when the summary is dictated.

Occasionally respondents appearing at a meeting present a prepared written response. In such instances the Compliance Officer should, if practical, read the written response aloud while the respondents follow their copies. The Compliance Officer should ask questions regarding any points that need clarification. In the dictation of the meeting summary, refer to the written response, which will be attached to the record as an exhibit, indicate that it was read aloud in the presence of the respondents, and include in the dictation only information concerning the points discussed for clarification.

Each respondent may present any information bearing upon the issues. This may consist of proposed or revised labeling, letters, laboratory data, sanitation contracts, etc. Identify each exhibit submitted by respondents at the meeting with the related sample number, date received, and the Compliance Officer's initials. Place the identification at the top right hand corner of the exhibit, if it is possible to do so without obscuring any material.

Respondents may request that the Compliance Officer comment on the adequacy of the proposed corrections. Unless headquarters provided specific instruction, refrain from commenting, and explain that comments may be provided after careful consideration of the submitted material and that it may involve headquarters review. Advise the respondents that the information will be included in the record as an exhibit.

ASSURE SCOPE OF RESPONDENTS' RESPONSIBILITY

Usually respondents demonstrate their responsibilities while expressing their views with respect to the alleged violations. Normally, they express responsibilities in the form of comments such as "I hired extra men for sanitation" or "I ordered the destruction of the merchandise" etc.

If there are any doubts about the responsibility of any of the respondents, ask questions to assure that you are not including individuals in a criminal proceeding who lack the authority to detect, prevent or correct violations. For example, ask who had the authority to change pest control firms or consulting laboratories, who hires or discharges employees for sanitation or quality control work, who directs labeling changes, who expends monies for structural repairs and the purchase of new equipment, etc.

In addition to the responsibility of those who appear, the Compliance Officer may need to make inquiries regarding the responsibilities of an individual listed in the Section 305 Notice who does not appear. This could be particularly important in cases where officials of a company at a location other than the one inspected have been cited, but do not appear at the meeting.

GUARANTIES

Unless a respondent voluntarily includes as part of his presentation a guaranty related to the violations, explore thoroughly the question of whether one exists. Otherwise, the respondent may overlook the fact that he had a guaranty, until he or his attorney eventually presents it as a defense at trial.

If a respondent requests information regarding guaranties so that he may obtain them in the future, furnish a copy of 21 CFR 7.13.

If the respondent presents a guaranty at the meeting, do not comment upon its validity. Tell the respondents that the validity of the guarantee will be reviewed after the meeting.

SUMMARY

At the conclusion of the meeting, the Compliance Officer will dictate an accurate summary of the meeting in the presence of the respondents, or at their option, immediately after their departure. The respondents, for a variety of reasons, may wish to leave the meeting before the summary is dictated, and should be afforded that option. In that event, a draft copy of the summary should be forwarded to the respondents, requesting their comments within 10 days, and explaining that without benefit of comment the record will stand as drafted. In the event respondents remain during the dictation, they should be offered an opportunity to provide additional comments or corrections. Inform the respondents that if they disagree with, or wish to clarify, any of the statements they may do so after dictation of the summary.

If respondents undertake to have long or irrelevant statements included in the dictated summary, tactfully suggest that they may wish to submit a statement after the meeting, and that the statement will be included as an attachment to the Record. (21 CFR 7.85(g)).

Required Statements

The Summary should always contain statements to the effect that:

1. The purpose of the meeting was discussed with the respondents and they understood that it was being held pursuant to Section 305 of the Act.
2. The charges were discussed with the respondents and they understood them.
3. The respondents indicated that the shipments had been made, or received, as alleged. (If not admitted, or they have reservations, this information should be included).
4. Information concerning the statements each respondent made concerning his scope of authority (responsibility) at the firm.
5. The respondents were asked if they had any corrections or comments to make (followed by their statements or a comment in the record that they had none).
6. Copies of the Summary will be forwarded to the respondents.
7. The final section of the record should consist of a statement indicating that the Summary was dictated in the presence of the respondents and when asked if they felt that the dictation accurately and fairly summarized the discussion they indicated that it did (or did not in the following respect). If the respondents elected not to remain during the dictation of the summary, the final section of the draft should reflect that fact.

A copy of the typed summary should be provided to each respondent, and should be accompanied by a cover letter, which states that the firm and individuals have an opportunity to make any additions or corrections in writing within 10 days after receipt.

Addendum to the Summary

Occasionally after the respondents have left the premises, the Compliance Officer will realize that significant information was omitted from the Summary. In such a case, an addendum to the Summary should be dictated and mailed to the respondents along with the Summary

dictated in their presence. A cover letter should accompany the Summary and addendum pointing out the inadvertent omission. Request a letter from the respondents within 10 days indicating that the additional information had been discussed as recorded in the addendum.

A respondent may request that the meeting be reopened in order to submit new information for the record. Such a request must be timely, in writing, state the nature of the new information, the reason it was not previously available at the time of the original meeting and why the information cannot be submitted in documentary form. If the District concludes that the meeting should be reopened to receive the new information, it may do so.

On occasion, respondents will request an additional meeting at headquarters to discuss the matter further. Such meetings are an extension of the Section 305 meeting and are governed by the procedures of this chapter.

Verbatim Transcript of Meeting
The respondent has the right to a verbatim transcript, at his expense. If exercising this right, the respondent must provide the necessary person or equipment to make the transcript. The respondent must submit a copy of such transcription to the District at no cost with an opportunity to make corrections and obtain agreement as to its accuracy. Under these circumstances, the Compliance Officer need dictate only a brief in-house summary after departure of the respondents, explaining the circumstances under which the verbatim transcript was made, who was present, etc. In this case, FDA does not prepare a "Summary".

The Compliance Officer may also order the meeting transcribed at FDA's expense. In this case, a copy of the transcription is provided to each respondent (21 CFR 7.85(e)).

Handling of Electronic Recording
If the meeting statement has been recorded, after transcribing, appropriately identify the recording medium with the date of the meeting, the name of firm cited, the sample numbers, and the transcriber's name. File the recording in the lead sample jacket and retain it until the 10-day period for review by the respondent has expired, then remove and destroy, or erase the recording.

Preparation of Summary
Method of Preparation - Prepare the summary as a separate document, using the format in Exhibit 5-11 as an example.

Include the following statement at the bottom of the copy provided to each respondent:

"Copy of this Summary (or transcript) furnished to (respondent)."

Include the transmittal letter advising respondents of the 10-day period for additions or corrections.

Number of Copies - Make sufficient copies for the following distribution:
Original + 1 copy for Center
(hold for submission with case)
One copy for HFA-224
One copy for District case file

One copy for District establishment file on firm
One copy for Resident Investigator, if desired
One copy for District reading file
One copy for each respondent

MULTI-SESSION MEETINGS
The intent of the regulations is to limit multi-session meetings. Requests for changes in time and place of the meeting must be made in accordance with 21 CFR 7.84(e). New evidence may be submitted in accordance with 21 CFR 7.85(g). Nevertheless, a respondent may appear for a meeting, but claim he has further evidence to submit. If the request is reasonable, recess the meeting until a mutually agreeable date. Prepare only one Record covering both meetings.

When the respondent merely requests an opportunity to submit supplemental documentary evidence without further personal appearance, he may do as provided in 21 CFR 7.85(g). Mark additional information and/or documentation that is received within ten calendar days after respondents' received their copy of the summary or transcription of the meeting as an exhibit and add it to the Record.

RESPONSE BY MAIL
Frequently, respondents elect to respond in writing in lieu of making a personal appearance. It is not necessary to acknowledge receipt of a written response. However, it may be desirable to acknowledge a written response when you also need to clarify some point of misunderstanding or oversight on the part of the respondent.

Hold correspondence to a minimum to avoid "holding a meeting by mail."

5-2-6 Procedures After Meeting

After the meeting (or written response, if any), a decision must be made as to disposition of the charges for each sample involved. The charges are disposed of by one or a combination of the following actions: Permanent Abeyance, Temporary Abeyance, or Prosecution.

REPORTING PERMANENT ABEYANCE AND TEMPORARY ABEYANCE CASES
The District should process cases designated as in abeyance within seven days after the meeting, with notification to the appropriate Center, as described below.

Permanent Abeyance
Prepare a memorandum to the appropriate Center(s) compliance office, headed "PA after CITATION" which provides the reason for placing the case in permanent abeyance (PA) and the planned District follow-up. Attachments should include a copy of the Section 305 Notice endorsed "PA (date and initials)", a copy of the Charge Sheet, a copy of the Summary, and any relevant information. Hold all copies the above documents in the District case file.

Forward a copy of the memorandum to the Center(s), an endorsed "PA (date and initials)" copy of the Section 305 Notice, and a copy of the Charge Sheet to the district establishment file and to the Records Section (HFA-224).

The Home District's Compliance Branch should update the Sample Disposition record(s) in

FACTS with the appropriate information about the status of the samples.

Temporary Abeyance
Prepare assignments for necessary follow-up and forward copies to the appropriate Center(s) compliance office. Hold the file in the District Compliance Branch. Send a copy of the Charge Sheet and Section 305 Notice endorsed temporary abeyance (TA) "TA (date and initials)" to Records Section (HFA-224). A case in TA is not considered closed.

NOTIFICATION OF NON-PROSECUTION
When the Agency makes a final determination that prosecution will not be recommended for any of the persons named in a notice (i.e., the case is closed), the district that issued the 305 Notice will advise each person in writing of that fact (21 CFR 7.85(h)(1)).

After the Agency decides to decline prosecution, that decision must be communicated to the office (generally a District Office) that originated the citation recommendation to assure that notification of non-prosecution issues in accordance with regulations. The FDA unit to which the recommendation was made, e.g., Center, OE, OCC, is responsible for issuance of the declination to the originating office/District. Upon receipt of the declination, and absent a request for reconsideration of the recommendation, the originating office/District should issue the notification of non-prosecution within 10 working days.

When it is determined that one of several persons named in a notice will not be included in a recommendation for criminal prosecution, the Office of Chief Counsel (OCC) will determine when that person will be notified (21 CFR 7.85(h)(2)). The Office of Chief Counsel will notify the district of this fact, and the district will issue the letter. The latter procedure applies when the Department of Justice declines to proceed with the entire case (21 CFR 7.85(h)(3)) or declines to proceed against an individual (21 CFR 7.85(h)(4)). See Exhibit 5-12 for the model letter to use.

5-3 DETENTION OF FOODS

5-3-1 Purpose

This section contains the procedures for exercising FDA's authority to detain meat, poultry and egg products as delegated to FDA under the provisions of the Federal Meat Inspection Act (MIA), the Poultry Products Inspection Act (PPIA) and the Egg Products Inspection Act (EPIA).

FDA was granted authority to administratively detain foods under Subtitle A of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and is in the process of preparing regulations to implement this new authority. Current information on the status of these regulations may be found on http://www.fda.gov/oc/bioterrorism/bioact.html.

For the purpose of this section only, the following definitions are applicable:

MEAT AND MEAT PRODUCTS - The carcasses of cattle, sheep, swine, goats, horses, other equines, parts of such carcasses, and products made wholly or in part from such carcasses.

POULTRY AND POULTRY PRODUCTS - The carcasses of domesticated birds, parts of such carcasses, and products made wholly or in part from such carcasses.

EXCEPTION - In the case of both meat and poultry products, certain products are exempted from the Acts by U.S.D.A. because they contain a relatively small portion of meat or poultry or historically have not been considered meat or poultry products.
EGGS - The shell eggs of the domesticated chicken, turkey, duck, goose or guinea.

EGG PRODUCTS - Dried, frozen or liquid eggs, with or without added ingredients, except products exempted by U.S.D.A. because they contain a relatively small proportion of eggs or historically not considered egg products.

5-3-2 Authority

The Federal Meat Inspection Act (MIA) as amended by Public Law (P.L.) 90-201 and Sections 19 and 20(b) of the Poultry Products Inspection Act (PPIA) as amended by P.L. 90-492 and Sections 19 and 23(d) of the Egg Products Inspection Act (EPIA) provide certain detention powers.

The detention authority under the MIA and the PPIA provide that FDA representatives may detain articles subject to these acts if they are outside a U.S.D.A. inspected plant and there is reason to believe that the products are adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (the Act).

The detention authority under the EPIA provides that FDA representatives may detain products subject to that act if the products are found outside a U.S.D.A. inspected plant and there is reason to believe that the products are in violation of the EPIA. .

NOTE: Interstate Commerce is not a requirement for FDA jurisdiction over eggs and egg products because authority is based on violation of the Egg Products Inspection Act rather than the Federal Food, Drug, and Cosmetic Act (the Act).

The detention process is another regulatory tool to achieve compliance with the Act. It should be considered when such products are encountered during regular District operations, on assignment, or as a follow-up to complaints. This procedure becomes most appropriate when no immediate arrangements can be made for local or state authority to take control of the product, and/or it appears that the product will not be held voluntarily.

5-3-3 Criteria For Effecting And Terminating Detentions

Use the following procedures in detention situations:

EXERCISE OF DETENTION AUTHORITY

Meat and Poultry Products
Detentions may be made when all of the following criteria are met:

The article meets the jurisdictional requirement of interstate commerce in Section 304 of the Act and the article is in commercial channels.

The article is located in an establishment that does not have U.S.D.A. meat or poultry inspection service.
The article is intended for human food or could readily be diverted into use for human food.
The article is adulterated or significantly misbranded under the Act. (NOTE: Detentions based solely on misbranding or on adulteration involving Section 402(b) of the Act must be cleared by the Center for Food Safety and Applied Nutrition (CFSAN) before detention.)
Eggs and Egg Products
Detentions may be made when all of the following criteria are met:

The article is in commercial channels. (NOTE: Interstate commerce is not a requirement for jurisdiction under the Egg Products Inspection Act.)
The article is located in an establishment that does not have U.S.D.A. egg products inspection service.
The article is intended for human food or could readily be diverted into use for human food.
There is reason to believe the article is in violation of the Egg Products Inspection Act.

TERMINATION OF A DETENTION ACTION
Detention should be continued until one of the following criteria is met:

State, county or municipal authorities have exercised jurisdiction and control of the article; or, in the case of meat or poultry, U.S.D.A. has assumed control.
It has been determined that there is no significant violation of the Federal Food, Drug, and Cosmetic Act, or the Egg Products Inspection Act, and the U.S.D.A has been notified that we intend to terminate the detention action.
The detained article has been denatured, destroyed or reconditioned under appropriate supervision.
The detention period of 20 consecutive days, counting the day the detention was executed as the first day, has expired.
Seizure has been accomplished.

NOTE: Forward seizure recommendation as soon as possible after detention is accomplished, because the detention cannot be reinstated after the 20 day detention period expires.

PROCEDURES
The Investigations Operations Manual (IOM), Chapter 7, subchapter “Detention Activities” contain specific inspectional instructions including initial reporting requirements, detention initiation, reconditioning, and termination.

5-4 ADMINISTRATIVE DETENTION OF DEVICES

5-4-1 Purpose

This section provides the procedures and defines responsibilities for the Administrative Detention of Devices.

5-4-2 Detention Of Devices

Background

Section 304(g) of the Act authorizes the FDA to detain devices intended for human use for a period of up to 30 calendar days if, during an inspection, the FDA has reason to believe the devices are adulterated or misbranded. The intent of administrative detention is to protect the public by preventing distribution or use of violative devices until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action. The action of choice, in most cases, is a seizure. Detention of devices requires prior approval from the district director in which the devices are located and the concurrence of the appropriate center's director for compliance.

Any person entitled to claim the devices, if seizure occurred, may appeal the detention and may request a hearing on the appeal. The decision to affirm or revoke the detention must occur within five (5) working days of receipt of the appeal if there is no request for a hearing or if the request for a hearing is within 5 working days after filing the appeal. If requesting the hearing for a date more than 5 working days after receiving the appeal, the decision must occur within 5 working days after the conclusion of the hearing.

The Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH) are responsible for administering the medical device amendments.

REFERENCES

The regulatory authority for administrative detention and associated operations appears in Sections 304(g) and 201(x) of the Act, and in 21 CFR 800.55, 21 CFR Part 16, 21 CFR 5.47, and 21 CFR 10.19. The IOM Subchapter 750 contains the instructions for implementing the detention authority.

DETENTION POLICY

At a minimum, prior to approving the detention order, the district director contacts the senior compliance official in the appropriate center to assure that the Agency supports an administrative detention based on the violations observed. This assures that the Agency considers recent policy developments or changes not yet communicated to the field. In addition, the district director notifies headquarters of the impending seizure recommendation.

Contacts are:

Director, Office of Compliance (HFZ-300), CDRH (301) 594-4692 or, if a biological device: Director, Office of Compliance and Biologics Quality (HFM-600), CBER (301) 827-6190.

Concurrence is by telephone. The field or headquarters does not require written concurrence except for cause, for example, for issues of science, policy, or law involving precedent or questionable facts.

If the district director concludes that the person in possession of the device(s) will voluntarily hold the product, will provide assurance that integrity and security will be maintained over the devices on hand, and agrees to correct the violation(s) prior to shipment, there isn't any need to detain the goods.

Approval of Detention Order By The District Director

The district director approves a detention order, before issuance, either orally or in writing. If

the approval is oral, it should be placed in writing as soon as possible.

Detention Order Issuance
An investigator or other authorized agent signs the order. Issue the order in writing to the owner, operator, agent, or other responsible person in charge of the place where the device is located.

When issuing the order, the FDA investigator informs the owner, agent or other responsible person that they have the opportunity to appeal and have a hearing on the detention as noted on the order. If the order is not issued to the owner or agent of the owner of the device, then the district sends, as soon as possible, copies of the detention order and 21 CFR 800.55(g)(1)& (2) to the owner, via certified mail return receipt requested.

Form of Order
Issue the detention order on Form FDA 2289 Detention Notice.

Subchapter 751 of the IOM contains instructions for completion of the form.

The detention order frames the issues for appeal or informal hearing, which may result from the detention. Therefore, the information on the order concerning the reason for detention is very important.

There is no requirement that the order include all of the reasons for believing that the product is adulterated or misbranded. Only list the more significant violations. However, if a violation is not identified in the order, it may not be relied on to support the detention. State the charge in the order in factual, non-statutory language. For example, if the investigator finds a sterile, individually packaged syringe with holes along the seams of the packaging, black greasy spots on the needle, and the label lacks the Zip Code of the manufacturer, describe the apparent violation in the reason for detention as "there is reason to believe the device is:

Adulterated per Section 501(a)(2)(A) of the Act because there are holes in the package and black spots on the needles. The firm prepared, packed, or held the product under insanitary conditions whereby it may have been rendered injurious to health.
Misbranded per Section 502(a) because the label states that it is sterile and the integrity of the package is compromised by holes. The labeling is false or misleading."

Note: Use a "continuation sheet" if all of the charges will not fit on the form.
Note: Charges used in the detention order do not necessarily limit the charges that may be identified in a subsequent complaint filed in court.

Length of Detention
According to statute, a detention is for 20 calendar days unless the district believes that additional time is required to accomplish a legal action. In such cases, the detention is for 30 calendar days at the time of issuing the order. When extending a detention from 20 to 30 days, issue another detention order and place new tags on the devices.

By statute, the detention cannot last for longer than 30 calendar days.

Movement, Use, etc. of Detained Devices

Except as noted below, without the written permission of the Agency, detained devices cannot be moved, used, altered, or tampered with in any manner. Therefore, if possible, the investigator should segregate the detained devices from other devices or products at the time of the detention so they remain undisturbed.

With the approval of the district director, the investigator who detained the devices or any other responsible district official may authorize, in writing, the movement of detained material. Whoever moves the devices must immediately notify (orally) the authorizing official of the new location.

The only exception to the prohibition on movement without written permission is when the goods are not in final form for shipment and the manufacturer wants to complete work on them. The manufacturer may move them within the facility where detained to complete manufacture, but must orally notify FDA of the movement as it occurs. When completing manufacturing, the manufacturer must immediately segregate the detained devices from other products and orally notify FDA of their new location.

However, the manufacturer may not move the devices from the establishment without prior written approval of the district director as referenced above.

Note: 21 CFR 800.55(h)(2) prohibits further movement even within the establishment without FDA approval.

Legal Actions Against Detained Devices

The district should expedite the preparation and processing of a seizure recommendation involving the detained devices. The recommendation should be flagged to indicate that it involves detained devices and show the date the detention expires, and should be forwarded to the responsible center by overnight delivery service.

The center compliance office, ORA, and OCC should likewise expedite their reviews to accomplish the legal action prior to expiration of the detention. If the detention expires prior to the seizure, the person who owns the devices may move the goods and the violative product may find its way into commercial distribution.

The district is responsible for monitoring the length of the detention and the progress of the recommendation. If a 20-day detention expires prior to accomplishing the legal action, the district should extend the detention for an additional 10 days.

The district is responsible for coordination with the U.S. Attorney's office and the Marshal's Service, ensuring prompt filing of the complaint, and seizure of the goods.

The district is also responsible for immediately providing oral notice to the appropriate center compliance office, OCC, and the presiding officer of the accomplishment of the seizure or of any appeal of a detention order.

Recordkeeping Requirements

At the time of issuance of a detention order, or as soon as possible thereafter, the district informs the owner, operator, or agent in charge of the establishment where the devices are detained of their responsibility to establish and maintain records as required by 21 CFR

800.55(k).

Termination of Detention Orders
The reasons for termination of Detention orders:

1. FDA determines that the device(s) is (are) not violative.
2. FDA approves voluntary destruction or compliance by reconditioning or other means (e.g., relabeling).
3. FDA revokes the detention on appeal.
4. FDA accomplishes a regulatory action against the product. Actual seizure or entry of TRO or an order by consent or otherwise of preliminary injunction is necessary. The filing of a complaint does not necessarily terminate a detention order.
5. The detention period expires.

The district director, within whose district the devices are detained, must approve termination of detention orders. Approval is oral or written, and if oral, confirmation is in writing. The district issues the Detention Termination Notice (Form FDA 2291) to the person(s) who received the Detention Notice, or his representative and, if movement of the devices occurred prior to the termination, to the person possessing the devices. Issuance of the notice is in person or by mail. If the termination notice is issued by mail, request that the Detention Tags (Form FDA 2290) be returned. If the termination notice is issued in person, see IOM 751 for instructions. Per 21 CFR 800.55(k)(2), the district issues a statement advising the owners, operators, or agents in charge to keep the records concerning the detention for the remainder of the two year period from the date of detention or such shorter period as FDA directs.

DISTRICT RESPONSIBILITIES
As referenced above, the district is responsible for:

1. Assuring support from the senior compliance official of the appropriate center before issuing a detention order.
2. Issuing the detention order.
3. Notifying the Director of the Division of Compliance Management and Operations (DCMO) by phone of the detention and supplying that person with a copy of the detention order by the most expeditious means available (fax, express mail, etc.) immediately after issuance.
4. Approving and monitoring the movement of detained devices.
Notifying the regional director that the district issued a detention order. NOTE: Keep the Regional Food and Drug Director (RFDD) insulated from detention proceedings after the detention is in place in order to avoid even the appearance of bias or prejudice.
5. Pursuing the follow-up legal action as discussed under the heading, "Legal Actions Against Detained Devices."

CENTER COMPLIANCE OFFICE RESPONSIBILITIES
District contact with the center, for concurrence, is a routine procedure. If the director of compliance for the center will not support a proposed detention, do not issue the order. Communication of the director’s decision to the district is by phone, e-mail, or other expedited communication. Generally, a formal submission of documents supporting detention is not necessary.

The compliance office will quickly review any information provided by the district, through DCMO, alert the district, DCMO, and OCC of any problems, and forward to the district all requested documents. The compliance office will provide expert witnesses and other support, as appropriate.

Office of Chief Counsel Responsibilities
OCC will quickly review any information provided by the district, and through DCMO, alert the district, the center office, and DCMO, of any problems, prior to the detention being put in place.

The Deputy CC for Litigation or the Deputy CC for Regulations and Hearings shall make staff assignments in OCC and notify the center and DCMO of the attorney assigned to the case. OCC will begin preliminary preparations for any appeal. OCC will determine whether the district and the RFDD require legal counsel.

DCMO RESPONSIBILITIES
Upon notification that a detention has been affected or a subsequent appeal received by the district:

DCMO will immediately notify the center compliance office and OCC, and deliver to them copies of the detention order, request for hearing, and other supporting documents. DCMO will coordinate the detention to ensure that all Agency and OCC components receive notification and prepare for a hearing in a timely manner.

RFDD RESPONSIBILITIES
The RFDD must insulate himself/herself, after the detention is in place, from all aspects of a detention except those relating to his/her responsibilities as a presiding officer. Responsibilities at that time are in the next section, "Appeal of a Detention Order."

5-4-3 Appeal Of A Detention Order

GENERAL INFORMATION

Background
Section 304(g) of the Act permits anyone who is entitled to claim the goods, if seized, to appeal a detention order.

If appealing the detention, Section 304(g) requires that the Agency afford the appellant with an opportunity for an informal hearing. If the appellant does not request an informal hearing, the decision to affirm or revoke the detention must be rendered within 5 working days after the filing of the appeal. The appellant may request the holding of an informal hearing either within 5 working days after filing the appeal or at a later date, but not later than 20 calendar days after receipt of the detention order (21 CFR 800.55(g)(1)). If the appellant requests a hearing within 5 working days after filing the appeal, the presiding officer holds the hearing and renders a decision within 5 working days of the filing of the appeal. In the event of a request for a delayed hearing, the scheduling of the hearing must occur after the fifth working day following the appeal, and a decision must be issued within 5 working days of the hearing's conclusion.

Regardless of the scheduling of the hearing, there is no extension past the 30-calendar day detention period without the consent of the appellant. (The provision for extension of the

detention found in 21 CFR 800.55(g)(6) is incorrect and should not be followed.)

Time to Appeal
The regulations allow an appellant 5 working days from the receipt of the detention order (which also serves as a notice of opportunity for a hearing) to appeal the detention, with or without a request for an informal hearing. The appeal must be in writing, must be addressed to the district director of the district office within whose area the goods are detained, and must contain a statement asserting that interest (e.g., ownership) in the detained goods would qualify the appellant to claim the goods if they were to be seized. The postmark on the appeal letter will determine the date of the appeal.

The district director will allow 1 day of additional time for the receipt of an appeal request. Allow additional time if the appellant shows that it was impossible to appeal earlier.

Presiding and Deciding Official
The RFDD for the region where the district is located and in which the goods were detained must be the presiding and deciding official unless he/she disqualifies him/herself (21 CFR 800.55(g)(4), 21 CFR 16.40 and 16.42, and 21 CFR 5.47). In the event of disqualification, the RFDD will immediately arrange for another RFDD to preside and provide immediate notification of any such change to the district director and the appellant.

Communications Between Parties to the Hearing And the Presiding Officer
Avoid any off-the-record communication between parties to the hearing and the presiding officer. If any such communication occurs, reduce it to writing and make it a part of the record. The presiding officer must supply a copy of any memoranda of such communication, which would affect his or her decision, to the other party, giving them an opportunity to respond (21 CFR 16.44(b)).

The person who originates any written communication between a participant in the hearing and the presiding officer must send a copy of any such communication to all of the participants (21 CFR 16.44(c)).

APPEAL PROCESSING DISTRICT RESPONSIBILITIES
Preparation for an appeal should begin when the district decides to detain a device(s), in case a hearing is requested within 5 working days of the filing of the appeal.

1. When the district receives an appeal, the director:
   a. Dates and time stamps the appeal, and notifies the appellant of receipt of the appeal. If the appeal does not specify that a hearing is or is not requested, does not demonstrate ownership or proprietary interest as required in 21 CFR 800.55(g)(1) and (2), or does not specify the time period within which to hold a hearing (see “Appeal of a Detention Order-Background"), contact the appellant and clarify this information. Make any declaration of ownership or proprietary interest in writing.
   b. Orally notifies the RFDD and the Director, DCMO of the appeal immediately and forwards a copy of the appeal to them as soon as possible. Requests assistance of OCC and the appropriate center for completing the next item.

2. When the appeal includes a request for a hearing:
   a. Prepare (1) a general summary of the information that supports the detention and (2) a

comprehensive statement of the basis for the action. The Detention Order (notice) may serve as the comprehensive statement only if the reason for detention is described in sufficient detail. See Exhibits 5-6 and 5-7 for an example of a general summary and a comprehensive statement respectively. See Exhibit 5-8 for examples of reasons detailed enough for the FDA 2289 to serve as a comprehensive statement.

b. Forward the general summary and comprehensive statement to the appellant (21 CFR 16.24(f) and Section 201(x)(3) of the Act), the RFDD, and any office and OCC representatives to the hearing. Send the documents immediately so that they arrive as soon as possible, but at least 1 day prior to the hearing.

c. At least 1 day before the hearing, provide the appellant, the RFDD, and any office and OCC representatives to the hearing, written notice of, or copies of, if they could not reasonably be expected to obtain copies, any published articles or written information to be presented at or relied on at the hearing (21 CFR 16.24 (g)).

3. When the appeal does not include a request for a hearing, the district forwards all the information that supports the detention to the RFDD acting as the deciding official. The district includes the referenced general summary and comprehensive statement and any additional information provided by the appellant. It must arrive within sufficient time to be reviewed and for a decision to be rendered within 5 working days after receipt of the appeal.

APPEAL PROCESSING PRESIDING RFDD RESPONSIBILITY
When notified of an appeal, the RFDD must:

1. if a hearing is requested,

a. rally contact the parties as soon as possible. Depending on the time period within which the appellant requests a hearing, either set a hearing date and time to allow for a decision within 5 working days after the date of receipt of the appeal by the district, or set a hearing date and time later than 5 working days after receipt of the appeal by the district, but not later than 20 calendar days after issuance of the detention order. The hearing normally takes place at the district office where the goods are located.

b.Provide all parties with written notification of the time, date, and location of the hearing.

c.Provide the appellant with oral and written notification (see form letter as Exhibit 5-9) of the following:

Notification of those portions of 21 CFR Part 16 that are excluded or modified under 21 CFR 800.55(g)(3) and waived or modified for hearings on appeal of administrative detentions (see "Informal Hearing on Appeal of a Detention Order.")
Notification that the informal hearing is not a public hearing per 21 CFR 16.60(a), in order to protect investigatory records compiled for law enforcement purposes that are not available for public disclosure under 21 CFR 20.64, or trade secret material under 21 CFR 20.61.
Notification that the appellant should provide, at the hearing, a brief summary of any lengthy documents for presentation at the hearing (e.g., volumes of computer printouts).
Notification that if feasible, at least 1 day before the hearing, the appellant should provide the district director written notice of, or a copy of (if the district director could not reasonably be expected to obtain a copy), any published articles or written information for presentation at or relied on at the hearing as required by 21 CFR 16.24(g).
Notification of the requirements under 21 CFR 16.44(c) (see "Communications Between Parties to the Hearing and the Presiding Officer.")

2. If an appeal is made but no hearing is requested, the presiding officer must immediately

orally notify the parties to submit information supporting their positions as soon as possible so that the information can be reviewed and a decision reached within 5 working days of the receipt of the appeal. We will accept additional information submitted prior to the decision. The presiding officer orally notifies the appellant of the requirement under 21 CFR 16.44(c) (see "Communications Between Parties to the Hearing and the Presiding Officer.")

3. When advice of the CC is needed, contact the Deputy CC for Litigation.

5-4-4 Informal Hearing On Appeal Of A Detention Order

Section 304(g) of the Act states that upon appeal of a detention order, the Agency will afford the appellant with an opportunity for an "informal hearing." Section 201(x) of the Act defines an informal hearing and lists specific provisions. 21 CFR 800.55(g)(3) provides that 21 CFR Part 16, Regulatory Hearing, establishes the procedures for conducting the informal hearing. 21 CFR 16.5 of the regulations advises that Part 16 procedures apply to the extent that they are supplementary to and not in conflict with other procedures specified for the hearing. 21 CFR 16.60(h) gives the presiding officer the power to suspend, modify, or waive provisions under Part 16.

WAIVERS, MODIFICATIONS, ETC. TO 21 CFR PART 16
21 CFR 800.55(g)(3) waives the following sections of 21 CFR Part 16:

1. §16.22(a) concerning the issuance of a separate notice of opportunity for hearing because the detention notice FDA 2289 serves that function under 21 CFR 800.55(g)(3)(i).

2. §16.22(b) concerning the forwarding of the appeal to the presiding officer because 21 CFR 800.55 (g)(1) requires sending the appeal to the district director.

3. §16.24(e) concerning not permitting the hearing to be held within 2 days of the receipt of the appeal because time constraints cannot allow for such a restriction.

4. §16.42(a) regarding those persons who may act as the presiding officer because 21 CFR 800.55(g)(4) only allows RFDDs to be presiding officers.

The presiding officer has the authority to waive, suspend, or modify any of the provisions under Part 16 (21 CFR 10.19 and 21 CFR 16.60(h)). The presiding officer must waive the following other provisions:
1. §16.60(f) which requires the hearing officer to make a recommended decision with statement of reasons to the deciding official because the RFDD performs both functions.

2. §16.95(b)(1) & (2) which state that the Administrative Record of a Regulatory Hearing (21 CFR 16.80(a)(1)-(5)) is the exclusive record and basis for the decision, are modified as follows: FDA bases the decision, in most cases, on all information presented to the presiding officer prior to or during the hearing. The decision is not to be based on the following information or documents, if they are not received or completed by the presiding officer within the time necessary for the presiding officer to review or complete them prior to making the decision as required by the Act or regulation:

   a. Information and views submitted to the presiding officer after the hearing are not part of the official record unless the presiding officer permits post-hearing submissions and

submittal of information occurs within the period specified by the presiding officer (21 CFR 16.80(a)(2)).
b. Any transcript of the hearing (21 CFR 16.80(a)(3)).
c. The presiding officer's report of the hearing and comments on the report under 21 CFR 16.60(e) and 16.80(a)(4).

FDA waives that part of 21 CFR 16.60(b) which provides that all parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing. There is an allowance for reasonable questions instead. Reference Congressional intent: House of Representatives Report no. 94-853. Also, see 21 CFR 16.5 and 16.60(h).

CENTER RESPONSIBILITIES
The center will provide documents, witnesses, or office representatives for the hearing if requested by the district or the OCC attorney counseling the district.

OFFICE OF CHIEF COUNSEL RESPONSIBILITIES
OCC will provide for the district and/or the presiding officer, as appropriate, for the hearing.

DISTRICT AND PRESIDING RFDD RESPONSIBILITIES
The section “Conducting the Hearing” includes individual responsibilities of the district and the presiding RFDD.

CONDUCTING THE HEARING – GENERAL PROCEDURES/RESPONSIBILITIES
At the onset, the presiding officer reminds the parties of the modifications to Part 16 that apply and explain the purpose or issue of the hearing. The issue at the hearing is whether FDA had reason to believe the devices were adulterated or misbranded at the time of the detention and as charged in the detention order. The issue is not whether the law has been violated. That question is properly left to the court trial, if one is held.

The FDA representative(s) is present to explain the bases for the detention and answer reasonable questions from the appellant.

The appellant then presents relevant information and reasons why he believes the Agency did not have reason to detain the product.

The FDA representatives may then ask reasonable questions (see Section 201(x)(4) of the Act).

The presiding officer assures that the material presented and the questions asked are relevant to the issue of the hearing.

The appellant may request a transcript of the hearing. However, the appellant must pay the cost of it and furnish the presiding officer a copy for the record. The Agency can also request a transcript of the hearing and the costs are borne by the government.

If the appellant wishes a copy of the government transcript, he/she may obtain it via a Freedom of Information (FOI) Act request. 21 CFR Part 20 applies to the release of the transcript.

The presiding officer notifies the parties that his decision will not await transcription or correction of the transcripts so ordered.

5-4-5 Requirements After A Hearing On Appeal Of A Detention Order

PRESIDING RFDD RESPONSIBILITY

Confirming or Revoking the Detention Order

(1) Time Period for Rendering Decision
As referenced in "Appeal of a Detention Order - Background," the presiding officer must by order, confirm or revoke the detention order within 5 working days of the receipt of the appeal by the district director, if there is no hearing requested or if the appellant requests a hearing within 5 working days. However, if the appellant requests a hearing later than the referenced 5 working day time frame, but not later than 20 calendar days after issuance of the detention order, then the presiding officer must, by order, confirm or revoke the detention order within 5 working days after the close of the hearing (21 CFR 800.55(g)(5) and (6)). The detention may not be extended past the otherwise applicable 30-day period (see "Appeal of a Detention Order - Background") without the consent of the appellant.

(2) Basis for Rendering Decision
If the Agency can show that it had a reason to believe that the devices were adulterated or misbranded at the time of the detention under one or more of the charges in the detention order, the presiding officer will affirm the detention order. If not, the presiding officer will revoke the detention order.

(3) Issuance of the Order
The decision is issued in the form of an order. (See Exhibit 5-10 for model order.) The parties to the appeal should be orally notified of the order immediately. Copies of the order should then be mailed to them via certified mail return receipt requested.

FDA must order the decision rendered on the detention within the above time frames; however, the completion of the written decision and report of the hearing (discussed below) cannot delay the order. Normally, the order is consolidated with the written decision and report of the hearing. However, there are cases when the Agency needs additional time to complete the written decision and report of the hearing. In that case, it is separate from and will shortly follow the order.

Written Decision and Report of Hearing
The presiding officer must prepare a written decision to include the reasons and basis for his decision (§ 16.95(b)(2)). The written decision must include the report of the hearing required by Section 201(x)(5) of the Act and 21 CFR 16.60(e). All written material submitted during the hearing must be attached to the written decision and report of the hearing (Section 201(x)(5) of the Act and 21 CFR 16.60(e)). Any transcripts of the hearing must be included. Whenever time permits, the participants will be given the opportunity to review and comment on the written decision and report of the hearing. However, the presiding officer should set a time limit for the participants to comment. (As previously noted, whenever possible, the written decision and report of the hearing should be issued with the order as a single document).

Administrative Record of the Hearing
The presiding officer must prepare the Administrative Record of the Hearing, which consists of the following items:

The detention order and the appeal.
All written information and views submitted to the presiding officer in conjunction with the hearing.
Any transcript of the hearing.
The presiding officer's written decision, report of the hearing, order, and any comments on the written decision or report of the hearing permitted under Section 201(y) of the Act and 21 CFR 16.60(e).
All letters and memoranda of meetings and communications between participants and the presiding officer referred to in 21 CFR 16.44(c).

File the original Administrative Record of the Hearing with the firm's official file at the district office after completion of the report. A copy should be forwarded to the center involved for its information, and then filed in the administrative files (HFA-224). Another copy should be maintained in the office of the RFDD that held the hearing.

FOI REQUESTS
21 CFR Part 20 applies to all requests for documents involved in administrative detentions

5-5 LICENSE REVOCATION OR SUSPENSION

5-5-1 Purpose

This section contains procedures for revoking and suspending biologic licenses issued under the Public Health Service Act. These procedures are applicable to actions recommended by the field or by CBER.

"Revocation" is the cancellation of a license and the withdrawal of the authorization to introduce or deliver for introduction, biological products into interstate commerce, at either the request of the manufacturer or when grounds exist for the Agency to initiate such an action.

"Suspension" is a summary action taken by the Agency and may be an initial or intermediate step in the revocation process. Suspension provides for the immediate withdrawal of the authorization to introduce or deliver for introduction, biological products into interstate commerce when the Commissioner has reasonable grounds to believe that any of the grounds for revocation exist and that by reason thereof there is a danger to health.

5-5-2 General

Licenses issued for the manufacture of specific biologic products under the provisions of Section 351(a) of the PHS Act, may be: 1) revoked upon request of the licensee or by initiative of the Commissioner when sufficient grounds exist; or 2) suspended if one or more of the grounds for revocation exists and presents a danger to health (see 21 CFR 601.5 and 601.6).

CBER's Office of Compliance and Biologics Quality (OCBQ), Division of Case Management (DCM) reviews recommendations for license revocation and suspension proposed by the field offices or the appropriate unit within CBER. If DCM concurs with the recommendation, it is forwarded to the Office of Chief Counsel (OCC) for review. If OCC concurs, the recommendation and action letter are sent to the Director, CBER for concurrence and signature. Pursuant to 21 CFR 5.202, the Commissioner has delegated the authority to issue notices of revocation and suspension to the Director and Deputy Director, CBER.

OCBQ ensures that recommendations for license revocation or suspension are supported with evidence of violations of the applicable statutes and regulations. License suspensions and revocations are significant enforcement actions with possible far-reaching consequences. As such, it is important to consider the impact that the action may have on product supply as part of the Agency's review of a proposed license suspension or revocation action.

When the license relates to multiple locations, revocation may be limited to one or more of the locations, if inspectional findings support that approach.

In the absence of willful noncompliance or a history of violations of a significant nature, the district or CBER inspection review unit considers issuing a Warning Letter or conducting a meeting with the firm, rather than recommending revocation as a first choice remedy.

Part V of the Compliance Program Guides for inspections of CBER-regulated products contains information on deviations that may warrant regulatory or administrative action. These inspection programs are located at: www.fda.gov/cber/cpg/cpg.htm.

5-5-3 General Considerations For Revocation

The Agency may consider revocation of a biologic license when any of the conditions specified in 21 CFR 601.5 exist. In establishing that the grounds for revocation in 21 CFR 601.5 are met, the recommending unit considers the two courses of action provided in the regulations: 1) notice of intent to revoke with the possibility of demonstrating or achieving compliance, or 2) in cases involving willfulness, notice of FDA's intention to move directly to revocation without providing an opportunity to demonstrate or achieve compliance.

Notice of Intent to Revoke
Inspectional findings must demonstrate a current history of repeated or continuous significant deviations that represent a breakdown of process controls, rather than isolated incidents. Ordinarily, a demonstration of prior warning to the firm is via Warning Letter and/or a meeting or other contact with the firm before consideration of license revocation. If a past Warning Letter issued and one or more non-violative inspection(s) follows it, a recommendation for license revocation based on current significant deficiencies must document whether the deficiencies are of a continuing nature and how the current inspection relates to any previous inspection which resulted in the Warning Letter or other communication with the firm that provided the firm notice of such deficiencies. Issuance of a Warning letter in the past may not preclude issuance of an additional Warning Letter, especially if the nature and cause of the violation has changed. For example, a firm issued a Warning Letter three years ago for viral marker testing violations may warrant issuance of another Warning Letter or other action,

rather than proceeding to license revocation, if the current inspection shows violations in different areas of the operation or manufacturing practices, e.g., computer validation.

In addition, FDA may proceed to revocation upon suspension of a license, as provided by 21 CFR 601.6(b).

Upon issuance of a "Notice of Intent to Revoke" letter (except in cases involving willfulness), we provide the licensee an opportunity to demonstrate or achieve compliance before instituting proceedings for revocation of the license.

Direct Revocation
FDA may proceed directly to revocation in cases involving willful conduct.

Willful conduct is established by showing that an individual 1) knowingly committed a prohibited act, such as records falsification or concealment; or 2) acted with careless disregard of the regulatory requirements, as exemplified by repeatedly failing to correct violations. In cases involving willfulness, FDA ordinarily does not provide the licensee with the opportunity to demonstrate or achieve compliance, in accordance with 21 CFR 601.5(b). In all cases, FDA notifies the licensee of the opportunity to request a hearing pursuant to 21 CFR 12.21(b).

5-5-4 Issues Not Supporting License Revocation

CBER ordinarily will not support license revocation when the following issues are the basis for the recommendation to revoke:

Biological Product Deviation Reports
Biological product deviation reports, in and of themselves, ordinarily may not form the basis for a license revocation unless the firm failed to recognize the error, failed to investigate and properly document the investigation, and/or failed to implement corrective action to prevent its recurrence, or failed to notify FDA if so required under 21 CFR 600.14. In addition, in order to meet the grounds for license revocation, the deviation must be of such a nature or extent as to represent a firm's failure to establish or maintain control over one or more of the systems employed for the manufacture of biological products.

Isolated Incidents
Isolated occurrences do not ordinarily establish grounds for license revocation, unless there is documentation to demonstrate that the occurrences represent a pattern of violative activity.

Past Violations
Violations that occurred prior to the current FDA inspection (and for which implementation of appropriate corrective action prevents reoccurrence) ordinarily do not form the basis for license revocation. However, FDA must document previous violations even with correction, or no repeats, because they may demonstrate a pattern or history of non-compliance. If violations persist, such a pattern is pertinent to a future decision to proceed to revocation.

5-5-5 Revocation Procedures

If the inspection review unit is considering revocation as an enforcement option, contact CBER, DCM, during the inspection or soon after issuance of the FDA 483. Discussions with

CBER prior to submission of a recommendation will facilitate the processing of the recommendation.

If the inspection review unit believes license revocation is appropriate, that office submits a recommendation to DCM for revocation with supporting documentation. Include the district director's concurrence on recommendations for revocation. In addition to forwarding documentation of the violations, the recommending unit submits a detailed summary of the firm's inspectional and compliance history over the past five years. The recommending unit also assesses the impact of license revocation on the supply of the biological products involved. The initial CBER contact is DCM, HFM-610, (301) 827-6201, FAX: (301) 594-0940. CBER assigns a consumer safety officer from HFM-610 to each revocation recommendation. If using express delivery, send to:

Food and Drug Administration
Center for Biologics Evaluation & Research
Attn: Division of Case Management (HFM-610)
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448

CBER personnel review the information received and determine whether the inspectional findings support revocation of the firm's license.

If CBER does not concur with the revocation recommendation, it communicates its decision to the recommending unit. CBER sends a memorandum confirming the reasons for the disapproval and provides other enforcement options, if appropriate.

If CBER concurs with the district's recommendation, it prepares an Action Memorandum with supporting documentation to the Director, CBER, and a letter notifying the licensee of the Agency's intention to initiate proceedings to revoke the license. This package is forwarded to the Office of Chief Counsel (OCC) for review. If OCC concurs, the recommendation and action letter are sent to the Director, CBER for concurrence and signature. Recommendations that CBER has initiated are also routed to the Director of CBER for clearance. Prior to doing so, however, the CBER initiating office contacts the appropriate district office to advise the district of the action proposed by CBER.

After the Director signs the letter, the Director, DCM verbally advises the most responsible person at the firm of the Agency's intention to revoke the license. DCM then transmits a copy of the letter to the firm via facsimile and mails the original letter as Certified/Return Receipt Requested.

CBER's OCBQ advises the district office and/or recommending unit within CBER of the action concurrently. In addition, they transmit copies of the Action Memorandum and the revocation letter to the recommending unit via facsimile or electronic mail.

Both CBER and the recommending unit review the establishment's response to the letter of revocation expeditiously. The recommending unit provides CBER with its conclusions and comments regarding the adequacy of the firm's response.

The Agency usually gives an establishment the opportunity to demonstrate or achieve

compliance. If the establishment has not waived its opportunity for a hearing by voluntarily requesting revocation, CBER's OCBQ and the firm continue to correspond until all corrective actions appear satisfactory. CBER will distribute copies of all correspondence between CBER and the firm to the recommending unit for review. When the recommending unit and CBER's OCBQ agree that all corrective actions appear satisfactory, CBER will ask the district office to conduct a follow up inspection expeditiously.

The district will advise CBER of the approximate date of reinspection and notify CBER by telephone or electronically of its findings and recommendation. Afterwards, the district sends a written recommendation either to move toward revocation or to discontinue proceedings for license revocation.

In some instances, the firm may have made significant progress in demonstrating or achieving compliance, but after review of the FDA 483 and the firm's response(s), the district and/or CBER may view a limited follow-up inspection as necessary prior to making a final determination on the matter of revocation.

Following reinspection, if CBER and the district determine that the firm demonstrated or achieved compliance, CBER will notify the firm of this determination.

In cases involving willfulness, ordinarily the establishment has 10 days from the date of the revocation letter to waive the opportunity for hearing by requesting voluntary revocation in writing. If the establishment does not waive the opportunity for a hearing by surrendering the license within the ten-day time frame, DCM forwards a request to the Division of Regulations and Policy, HFM-17, to prepare the Federal Register Notice of Opportunity for Hearing.

FDA publishes the Notice of Opportunity for Hearing on a proposal to revoke a license in the Federal Register together with an explanation of the grounds for the proposed action. A person subject to the notice has 30 days after its issuance to request a hearing. There is no extension of the 30-day period. A request for hearing must set forth specific facts showing that there is a genuine and substantial issue of fact that justifies a hearing, and may not rely upon mere allegations or denials.

5-5-6 General Considerations For Suspension

Pursuant to 21 CFR 601.6, the Commissioner may suspend a license if the Commissioner has reasonable grounds to believe that any of the grounds for revocation exist and that by reason thereof there is a danger to health. Investigators obtain documentary evidence to support revocation and danger to health, and CBER conducts an evaluation of the danger to health.

Once CBER determines that a danger to health exists, the recommending unit immediately contacts the appropriate state health authorities. In addition, the district considers legal actions such as injunction or seizure, particularly if a given state health department lacks regulatory authority over intrastate operations or if the license suspension does not result in immediate corrective action. The recommending unit provides CBER with any information obtained regarding the state health department authority and the likelihood it may take regulatory action based on FDA's findings.

If a blood establishment is involved, the recommending unit determines the approximate

number of annual collections and the percentage of blood products distributed in interstate commerce. The recommending unit, together with CBER, examines supply issues and considers contacting the large national blood organizations to assure that a license suspension will not adversely affect the public health.

As in the case of revocation, when there are multiple locations encompassed by one license, suspension may be limited to one or more of the locations, if inspectional findings warrant that approach.

5-5-7 Suspension Procedures

If the inspecting unit believes a danger to health exists, it should contact CBER's DCM, HFM-610, 301-827-6201 immediately, during the inspection, and provide specific, substantive information relating to the grounds for suspension. It must not wait until the conclusion of the inspection to make contact. At that time, DCM assigns a consumer safety officer from HFM-610 to the suspension recommendation who will work with the investigators in case development.

The inspecting unit should transmit a copy of the FDA 483 (draft or final copy) as quickly as possible to DCM by facsimile, electronic mail, or express delivery, along with any additional requested preliminary information and/or documentation. To avoid delay, do not send supporting documentation through the regular mail system if other means of transmission are available. If using overnight express delivery, send to:

Food and Drug Administration
Center for Biologics Evaluation & Research
Attn: Division of Case Management (HFM-610)
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448

DCM will consult, as necessary, with the appropriate scientific/medical staff to determine if a danger to health exists. If a danger to health exists, the inspecting office will be advised and should submit a recommendation in a brief memorandum that includes the basis of the recommendation. Transmit the recommendation by facsimile (301 594-0940) or by electronic mail. Recommendations for suspension are given a high priority and supervisors are to act promptly. Recommendations for suspension should have the concurrence of the district director. The district will make every effort to expedite the submission of a recommendation to CBER to suspend operations under license at an establishment whose practices present an imminent danger to health.

Frequently DCM may concur with a suspension recommendation after receiving the FDA 483 but before receiving the Establishment Inspection Report (EIR). In cases involving complex issues, DCM may need to review the completed EIR before reaching a decision. In either event, write the EIR promptly and forward by express mail service to DCM.

Depending upon the products involved, CBER may ask the recommending unit to obtain a complete inventory of the products on the firm's premises.

If DCM concurs with the suspension recommendation, it will prepare an Action Memorandum

and a letter of suspension within three working days of receipt of the recommendation. Documents will be sent to OCC for review as soon as available. Upon OCC concurrence, the Director, CBER, who notes the date and time of signature, signs the Action Memorandum and letter of suspension. The Director, OCBQ or DCM will immediately telephone the firm and advise it of the suspension of its biologics license. DCM will then send the letter to the firm by facsimile and certified mail.

CBER may concurrently advise the recommending unit of FDA's action. In some situations, CBER may arrange to transmit a copy of the suspension letter to the district for hand delivery to the firm.

If CBER does not concur with a suspension recommendation, it communicates its decision to the recommending unit. DCM will prepare a memorandum explaining the reasons for the disapproval. If CBER disagrees with the suspension recommendation based on the absence of a danger to health, and any of the conditions specified in 21 CFR 601.5(b) exist, DCM considers whether it is appropriate to revoke the license or send a Warning Letter and will discuss these options with the recommending unit.

DCM and the recommending unit concurrently review the reply to a letter of suspension and continue to correspond with the firm until both agree that all corrective actions appear satisfactory. At this point, DCM notifies the firm, ordinarily by telephone (later confirmed by letter), that limited operations may resume for the purpose of a reinspection to determine that the corrective actions implemented are effective. CBER requests that the district office conduct a follow up inspection expeditiously, generally within 30 days of resumption of limited operations.

The district office advises CBER of the approximate date of reinspection. As soon as possible upon its conclusion, the district notifies CBER by telephone of its findings and recommendation (CBER contact is DCM, HFM-610, 301-827-6201). The district follows-up by sending a written recommendation on the last day of the inspection or shortly thereafter. If issuing a FDA 483, the district forwards a copy of the firm's response, if any, to CBER. In addition, the district sends a written copy of the establishment inspection report to CBER as quickly as possible to support continued suspension, revocation or reinstatement.

In some instances the firm may have made significant progress in achieving compliance, but after review of the FDA 483 and the firm's response(s), the district and/or CBER may view a limited follow-up inspection as necessary prior to making a final determination as to whether to recommend reinstatement of the license.
If the follow-up inspection indicates inadequate corrective actions and continued deviations, the district obtains additional documentation and notifies CBER as soon as possible. CBER decides whether to allow the firm to continue in limited operations or to cease all operations. In addition, CBER considers the possibility of proceeding toward license revocation.

If the firm is achieving compliance, CBER prepares an Action Memorandum and letter of reinstatement for the signature of the Director, CBER. After the letter is signed, the Director OCBQ or DCM telephones the firm and advises it that the Agency has lifted the suspension of the firm's activities and they may now ship products collected or manufactured since the date they resumed limited operations. Also, DCM advises the district by telephone and sends a copy of the reinstatement letter, which, if appropriate, may contain instructions to the firm for

filing a request to use products in inventory at the time of suspension.

On a case-by-case basis, CBER evaluates written requests for release of products in inventory at the time of suspension. Communicate in writing all decisions regarding the disposition of products to the firm (copy to the district). CBER may request that the district monitor the disposition of the inventory.

Send copies of all correspondence, verbal and written communications, and EIRs relating to suspensions of operations under license, to the attention of:

Food and Drug Administration
Center for Biologics Evaluation & Research
1401 Rockville Pike, Suite 200N
Rockville, Maryland 20852-1448
ATTN: Division of Case Management, HFM-610

5-6 ORDER FOR RETENTION, RECALL, AND/OR DESTRUCTION OF HUMAN TISSUE

5-6-1 Purpose

This section contains procedures and guidance for issuing an Order for Retention, Recall, and/or Destruction (Order) of human tissue pursuant to 21 CFR Part 1270.43, Human Tissue Intended for Transplantation, promulgated under Section 361 of the Public Health Service Act (PHS Act).

5-6-2 Background

In the fall of 1993, following extensive surveillance of the tissue industry, FDA learned of the uncontrolled importation of foreign tissue into the United States, and that the testing and screening of the donors were not acceptable (e.g., FDA had evidence that one of the foreign donors had tested repeatedly reactive for hepatitis). In the interest of protecting the public health, FDA acted quickly to gain control over an unregulated industry by promulgating under the authority of Section 361 of the PHS Act the Interim Rule for Human Tissue Intended for Transplantation (21 CFR Part 1270). The Interim Rule was finalized on July 29, 1997, and became effective January 26, 1998.

At that time, FDA established a single regulatory program that encompassed both foreign and domestic sources of tissue. The regulation requires certain infectious disease testing, donor screening, and record keeping to prevent the transmission of HIV and hepatitis through human tissue intended for transplantation. Section 1270.43 of the regulation includes a provision for ordering the recall and destruction of human tissue when FDA deems it unsuitable for transplantation. This regulation further provides that a firm or individual receiving such an Order be given the opportunity to request a hearing pursuant to 21 CFR Part 16.
Tissues subject to the provisions of this regulation include bone, ligaments, tendons, fascia (muscle-enclosure tissue), cartilage, ocular tissues (corneas and sclera), blood vessels, pericardium, amniotic membrane, and skin. The regulation does not apply to human tissue currently regulated as a human drug, biological product, or medical device under the Act. For example, we currently regulate dura mater as a medical device.

FDA conducts inspections of human tissue establishments in accordance with the guidance included in CP 7341.002, Inspection of Tissue Establishments. Imported tissue is subject to the specific guidance provided in Import Alert #57-08 regarding the importation of human tissue intended for transplantation.

The Agency allows firms the opportunity to achieve compliance voluntarily prior to initiating legal and/or administrative sanctions in situations not raising significant questions as to the source of the tissue or the adequacy of testing or donor selection. Consistent with this practice, district management considers the appropriateness of voluntary corrective action by firms before recommending an order to CBER.

5-6-3 General Considerations

FDA will consider an Order when there is documentation of deviations from 21 CFR Part 1270 that raise significant questions as to the suitability of the tissue for transplantation.

Before making a recommendation to issue an Order, the District first determines the specific situation that exists at the firm and decides whether an Order is the appropriate action or whether to provide the firm an opportunity for voluntary corrective action. FDA may subject tissue not present at the firm, but distributed after December 14, 1993, without adequate testing and donor screening or with significant deviations from 21 CFR Part 1270, to an Order for recall and destruction. In addition, human tissue in storage at a firm is subject to this regulation regardless of when harvested or collected.

We may issue orders to either domestic firms/individuals or importers. FDA uses the same criteria to evaluate imported tissue and domestic products for the issuance of an Order. The requirements are the same for all tissue regardless of its origin (foreign or domestic). Make a recommendation to issue an Order to CBER's Division of Case Management (DCM).

5-6-4 Procedure

In those circumstances where the District concludes that it is appropriate to offer the firm an opportunity to achieve compliance prior to the issuance of an Order, the District may modify a model (Opportunity for Voluntary Corrective Action) letter and hand-deliver it to the tissue establishment (see Exhibit 5-13 for model letter). Send a copy of the letter to CBER's DCM. Issue this at the close of the inspection or as soon as possible thereafter. This action affords the establishment the opportunity to bring the tissue into compliance voluntarily by making a prompt written commitment to take specific corrective actions within specific and appropriate timeframes. In addition to a corrective action plan, the letter requests that the firm place all non-compliant tissue in inventory at the firm in a quarantine status until it corrects the deficiencies. The letter also requests notification of customers and asks that tissue in their possession be returned or retained (not transplanted). If the firm fails to make a written commitment or proposes an inadequate corrective action plan, the district should contact CBER, DCM to discuss the possible issuance of an Order and additional inspectional follow-up. Promptly and thoroughly monitor all written commitments to correct. This monitoring ensures fulfillment of the commitments.

Districts may choose to recommend an Order to CBER following the inspection rather than

considering voluntary compliance in certain circumstances. For example, if there is a significant question as to the source of the tissue, the adequacy of the testing of the donor, the adequacy of donor selection, or failure to meet stated commitments to the Agency to gain control over or properly determine suitability of non-compliant tissue, it is appropriate to issue an Order specifying a recall and/or destruction of the tissue.

Before issuing an Order to tissue establishments or importers, obtain concurrence from CBER. Part V of CP 7341.002 provides examples of violative conditions that may warrant issuance of an Order.

As soon as the investigator encounters what he/she believes is violative tissue, make contact with the supervisor/team leader and the responsible district management. If there is confirmation of significant deficiencies, the district notifies CBER of a possible Order recommendation. Early contact with CBER helps to ensure collection of all necessary documentation.

After obtaining complete documentation of the violative conditions, a documentary sample, and an inventory of products on the premises as well as those products distributed (including names and addresses of consignees and tissue(s) shipped to consignees) as of the last day of the inspection, the investigator follows the established procedures for informing district management.

If the District believes an Order is appropriate, the District prepares and submits a written recommendation, including a draft Order, to CBER (see Exhibit 5-14 for model order). At that time, present specific substantive information relating to the violations. The initial CBER contact is DCM, HFM-614, Chief, Blood and Tissue Compliance Branch at 301-827-6201or fax 301-594-0940.

Transmit the Order recommendation by electronic mail or fax. Also, send the FDA 483 via electronic mail or fax immediately. Forward a packet including the recommendation, the FDA 483 and copies of all supporting documentation to HFM-614 via express delivery at the following address:

Food and Drug Administration
Center for Biologics Evaluation & Research
Office of Compliance and Biologics Quality
DCM/HFM-614
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448

All districts must identify Order recommendations as high priority and make every effort to expedite submissions to CBER.

CBER (and OCC) may concur with issuance of an Order after reviewing the FDA 483 and supporting documentation, but before receiving the EIR, if the violations are serious and if the potential for continued distribution of unsuitable tissue exists. Complete the EIR expeditiously and forward it along with the exhibits and additional supporting documentation by express delivery to CBER. In some cases, CBER may need to review the completed EIR before deciding whether to concur with the District recommendation to issue an Order.

If CBER concurs with the recommendation, DCM prepares a brief concurrence memorandum. In addition, HFM-614 assists the District in finalizing the Order.

5-6-5 Nonconcurrence

If CBER does not concur, CBER notifies the district compliance review personnel regarding the decision by telephone and then forwards a memorandum to the responsible district official explaining the reasons for non-concurrence with the Order. The Agency then considers the appropriate action, if any, to take. Such actions include a letter for Voluntary Corrective Action allowing for voluntary correction of the deficiencies observed, a Warning Letter, or a request for a meeting with the firm.

5-6-6 Delivery Of The Order

Once CBER concurs with the recommendation to issue an Order, the District Director signs the Order, and the District issues it. It is preferable to have the original signed Order hand-delivered to the tissue establishment by the FDA investigator. Under certain circumstances, however, it may be more efficient to fax the signed Order to a Resident Post for immediate delivery while mailing the original signed Order to the firm. If mailed, send the package by certified mail with return receipt requested.

Networking and contracting of tissue bank operations to other firms occurs often, such that there may exist shared responsibility for certain violations of the interim rule. In such cases, CBER and the District may agree to send a copy of the Order to parties affiliated with the firm/individual that will receive the Order.

5-6-7 Follow-Up

Following receipt of the Order, it is expected that action to recall or destroy the violative tissue will be taken within five working days of receipt of the Order. Alternatively, the firm/individual may respond to the Order making other arrangements for assuring the proper disposition of the violative tissue. Such arrangements may include providing FDA with documentation that adequately assures that recovery, processing, storage and distribution of the tissue is in compliance with the regulations. The District and CBER should review the reply concurrently. The tissue establishment must retain the the violative tissue in quarantine status until implementing the appropriate corrective actions and providing documentation to FDA to address the issues identified in the Order. The firm must notify its consignees to return or retain affected tissue in their inventories until resolving the issues. If, however, the firm/individual agrees to retain, recall and/or destroy the unsuitable tissue, the District should promptly verify that the recall and/or destruction is carried out expeditiously and monitored or witnessed by an FDA investigator. Manage recalls as provided for in Chapter 7. It is the firm's responsibility to destroy all violative/unsuitable tissue. However, the regulation provides the Agency with the authority to take possession of and/or destroy the violative tissue. It is rare, however, for FDA to do so, and it must only be done as a last resort. The District does not take possession of any tissue without first notifying CBER. CBER will provide guidance on procedures for handling and destroying the tissue safely.

The district monitors the destruction of unsuitable tissue and obtains destruction records.

Incineration is the recommended method of destruction of biohazardous substances, but there are a limited number of sites in the United States. There are services that specialize in the removal and destruction of biohazardous substances. These firms provide their clients with the appropriate records documenting the destruction of such materials.

The district will schedule a follow-up inspection as appropriate. If the District observes continued deviations, the District and CBER will jointly consider what action to take.

5-6-8 Part 16 Hearing

Upon receipt of an Order, a firm/individual may request a hearing by submitting a written request in accordance with 21 CFR Part 16 as described in the information provided with the Order. CBER, the Office of Enforcement, and the OCC should be notified promptly by both telephone and electronic mail upon receipt of a hearing request. A request for a Part 16 hearing places that portion of the Order requiring destruction of the violative tissue in abeyance, pending the outcome of the hearing. The portion of the Order requiring recall and retention of violative tissue, however, is not placed in abeyance or affected in any way by the hearing request.

If a hearing is granted, DCMO will determine the availability of a Presiding Officer (usually an RFDD), and will prepare a memorandum for the signature of the Associate Commissioner for Regulatory Affairs (ACRA) designating the Presiding Officer and the deciding official (usually the Deputy Commissioner for Operations) for each particular case. The Presiding Officer has administrative responsibility for the conduct of the hearing. OCC will appoint counsel for the District and CBER, and counsel for the Presiding Officer. OCC will inform DCMO so that it can identify such attorneys in the memorandum prepared for the ACRA. The District and the Center will provide documents, witnesses, and other support for the hearing if requested by the District or the OCC attorney counseling the District.

5-7 CIVIL MONEY PENALTIES

5-7-1 Reduction Of Civil Money Penalties For Small Entities

The Small Business Requlatory Enforcement Fairness Act of 1996 (SBREFA) (Public Law 10-121) was enacted on March 29, 1996, and seeks to improve the regulatory climate for small entities by, among other things, requiring agencies to establish small entity penalty reduction policies.

The Food and Drug Administration (FDA) has issued final guidance for the reduction of civil money penalties (CMPs) for small entities (penalty reduction guidance) as mandated by the SBREFA and the Presidential Memorandum of April 21, 1995 (60 FR 20621, April 26, 1995). This guidance can be obtained on FDA's internet site at http://www.fda.gov/OHRMS/DOCKETS/98fr/010049gd.pdf

FDA currently enforces the following amendments to the Federal Food, Drug, and Cosmetic Act (21 U.S.C.) and the Public Health Service Act (42 U.S.C.), which authorize CMPs under the referenced sections:

Radiation Control for Health and Safety Act of 1968 (21 U.S.C. 360pp)

Safe Medical Devices Act of 1990 (21 U.S.C. 333(f))

Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Reauthorization Act of 1998 (42 U.S.C. 263b(h))

National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 262(d)(2) and 42 U.S.C. 300aa-28)
Prescription Drug Marketing Act of 1988 (21 U.S.C. 333(b))

Generic Drug Enforcement Act of 1992 (21 U.S.C. 335b)

Food Quality Protection Act of 1996 (21 U.S.C. 333(f))

5-8 EXHIBITS

5-1 Model Section 305 Notice
5-2 Model Charge Sheet
5-3 Model Charges
5-4 Legal Status Sheet
5-5 Information Sheet
5-6 Model General Summary of Information
5-7 Model Comprehensive Statement
5-8 Examples of Detailed Statements
5-9 Model Hearing Confirmation Letter
5-10 Model Order
5-11 Summary Format - Section 305 Meeting
5-12 Notification of Non-Prosecution
5-13 Model Letter for Voluntary Corrective Action
5-14 Model Order For Retention, Recall, And/Or Destruction

Exhibit 5-1
MODEL SECTION 305 NOTICE

SECTION 305 NOTICE

.....In reply refer to:
.....Sample No.
.....Product

Firm Name and Individual
Street Address ....Date
City, State, Zip

Investigation by this Administration indicates your responsibility for violations of the Federal Food, Drug, and Cosmetic Act, and other Federal Laws, as described in the attached Charge Sheet, with respect to the following:

> Shipment of an article labeled in part "Cream Style White Sweet Corn Net Weight 5 lb 10 oz" by (Firm, Location), to (Firm, Location), on or about (date).

A meeting has been scheduled for (day, date, time) at (location), to give you an opportunity to present your views on this matter. The enclosed **INFORMATION SHEET** explains the purpose and nature of the meeting, and how you may reply. If no response is received on or before the date set, our decision on whether to refer the matter to the Department of Justice for prosecution will be based on the evidence in hand.

By direction of the Secretary of the Department of Health and Human Services:

Compliance Officer

(IMPORTANT: NOTE ALL ENCLOSURES CAREFULLY)

Enclosures:
Legal Status Sheet (3)
Charge Sheet
Information Sheet
Regulations

Exhibit 5-2
MODEL CHARGE SHEET

CHARGE SHEET

(In Connection with Enclosed Section 305 Notice)

Sample Nos.	Sample Nos.
Sample #, Product	Sample #, Product
Sample #, Product	Sample #, Product
Sample #, Product	Sample #, Product
Sample #, Product	Sample #, Product
Sample #, Product	Sample #, Product
Sample #, Product	Sample #, Product

PROHIBITED ACT: Section 301(a) of the Federal Food, Drug, and Cosmetic Act. The introduction or delivery for introduction into interstate commerce of any food that is adulterated.

CHARGES: The articles are adulterated in the following respects:

Sample #)
Sample #)
Sample #)
Sample #) They contain insect fragments and rodent hair fragments.
Sample #)
Sample #)
Sample #)
Sample #)
Sample #)
Sample #) It contains insects, insect fragments, and rodent hair fragments.
Sample #) It contains insect fragments.
Sample #) It contains insect larvae, insect fragments, and rodent hair fragments.

All Samples) The factory in which the articles were prepared was infested with insects and rodents which may have contaminated the articles.

Exhibit 5-3
MODEL CHARGES

SPECIMEN CHARGE

(Do not quote the section of the Act listed below on the Charge Sheet)

Adulterated Foods
402(a)(1)
(1) The soybeans contain an added poisonous or deleterious substance, namely, crotalaria seeds, which may render them injurious to health.
(2) The frozen eggs contain added salmonella microorganisms, pathogenic bacteria, which may render them injurious to health.
(3) The article contains selenium, a poisonous or deleterious substance, in a quantity that would ordinarily render it injurious to health.
402(a)(2)(A)
(1) The articles contains an added deleterious substance, namely, metal fragments, which is unsafe since it is not required in the production of this food and can be avoided by good manufacturing practices.
(2) The cod fillets contain oxytetracycline that is unsafe, since oxytetracycline is not required in the production of this food and can be avoided by good manufacturing practices.
NOTE: Generally, the use of Section 402(a)(2)(A) as a basis for charges should be limited; other sections, such as 402(a)(1), are usually preferred.
402(a)(2)(B)
(1) The berries contain heptachlor, which is not generally recognized as safe, and for use of which a tolerance has not been prescribed by regulation.
(2) The cabbage contains excessive Toxaphene.
402(a)(2)(C)
(1) The article contains a food additive, namely lead, which is unsafe within the meaning of Section 409(a) since its use and intended use are not in conformity with a regulation or exemption in effect.
402(a)(2)(D)
(1) The meat intended for human food contains a new animal drug, namely MGA, which is unsafe in that there is no approved new animal drug application in effect for this use.
402(a)(3)
(1) The article contains insect parts and insect excreta.
(2) The article contains rodent excreta pellets.
(3) The nuts are rancid.
(4) Some of the cans contain decomposed salmon.
(5) The catsup contains decomposed tomatoes.
(6) The peanut butter contains grit.
402(a)(4)
The factory (warehouse) in which it was prepared and packed (held) was infested with rodents and insects, which may have contaminated it.
402(a)(5)
(1) Some of the boxes contain emaciated and diseased birds.
(2) Some of the boxes contained birds that were not slaughtered but that died from other causes.

402(a)(7)
The article has been subjected to radiation, not provided for by the Food Additives Regulations.
402(b)(1)
(1) The article is deficient in Vitamin B.
(2) The butter contains less than 80% milkfat.
402(b)(2)
(1) Mineral oil has been used to replace part of the vegetable oil.
(2) Chicory has been used in part instead of coffee.
402(b)(3)
Blemished, old potatoes have been colored and waxed to resemble new potatoes and to conceal the blemishes.
402(b)(4)
(1) The ground pepper contains ground olive seeds.
(2) The poppy seeds are brown and have been artificially colored to appear to be blue poppy seeds.
402(c)
(1) The article contains a color additive, namely, "butter yellow," not permitted by regulation for use in food.
(2) The article contains a color additive, namely, FD&C Purple Number 8, for which no tolerance has been established.
402(d)
(1) Some pieces of the candy contain a metallic toy.
(2) The candy is filled with alcohol.
402(e)
(1) The article contains vegetable oil that is rancid.
(2) The milk used to manufacture the butter contained flies and manure.

Misbranded Foods
403(a)
(1) The label falsely represents it to contain a significant amount of honey but the amount present, if any, is inconsequential.
(2) The label bears statements that falsely represent, in the setting in which they are presented, that the article will supply an unusually large amount of protein in a quantity which is low in calories, and that the article is therefore of significant value for weight reducing.
(3) The labeling falsely represents that the product contains copper, folic acid, cobalt and calcium pantothenate.
(4) The label falsely represents the article to be canned peas, whereas the article is canned spinach.
403(b)
It was offered as lemon extract by the price list sent to the consignee on or about May 2, XXXX, but it is in fact an extract of lemon grass oil.
403(c)
(1) The word "Imitation" on the label is in type of smaller size and less prominence than the type in which the words "Vanilla Extract" appear.
(2) The label fails to bear the name "Imitation Strawberry Preserves."
403(d)
(1) The can has a depressed top and bottom and contains a thick corrugated inner liner,

which give the container the appearance of containing more nuts than it does.
(2) The container is slack-filled.
403(e)(1) ....
The label fails to bear the name of the manufacturer, packer, or distributor.
403(e)(2) ....
(1) The label statement "net weight 4 oz." is inaccurate.
(2) The article is short weight.
403(f)
(1) The statement of ingredients on the label is inconspicuous.
(2) The name and address of the manufacturer is printed on the cellophane bag in white ink and lacks contrast with the white candy mints contained therein.
403(g)(1) ....
(1) The article is represented as raspberry preserves but contains less fruit than the standard of identity
requires.
(2) The article purports to be French dressing but contains less fat than specified in that standard.
(3) The egg noodles are deficient in egg solids content.
403(g)(2) ....
(1) The article is bleached flour but the label does not state that it is bleached.
(2) The article purports to be enriched macaroni, and its label fails to bear the name of that food.
(3) The article purports to be Fruit Butter, but its label fails to bear the name of the optional ingredient, lime juice, present in the food.
403(h)(1) ....
(1) The article contains excessive blemished fruit but its label does not bear the statement of substandard quality prescribed for canned peaches.
(2) Its quality falls below the standard for canned tomatoes, since it contains excessive peel.
403(h)(2) ....
The cans are underfilled but the label does not bear the statement of substandard fill prescribed for
canned peas.
403(i)(1)
The article is ground cinnamon but its label does not bear the name "ground cinnamon."
403(i)(2) ....
(1) Flour is present but is not named in the label listing of ingredients.. ....
(2) The label fails to bear a statement of ingredients of the article by their common or usual names.
403(j) ....
(1) Its label fails to bear a statement of the percentage of the USRDA for the vitamins B(1), B(2),
niacinamide and the mineral iron, as required by the special dietary regulations. ....
(2) The label fails to state the percent by weight of methylcellulose present; and in juxtaposition with name of such constituent, the word "non-nutritive," as required by the special dietary regulations.
403(k) ....
(1) The labeling fails to state the fact that a chemical preservative has been added. .....
(2) The article is artificially colored, but its labeling fails to state that fact.
403(1)

The oranges contain biphenyl (diphenyl applied post harvest), but its shipping container fails to bear labeling declaring the name and function of the pesticide chemical.
403(m)
The article is a color mixture but its label does not declare the name of the color components contained therein.

Adulterated Drugs
501(a)(1)
The aspirin tablets contain rodent hairs.
501(a)(2)(A)
The plant in which the aspirin tablets were manufactured was infested with rodents which may have contaminated them.
501(a)(2)(B) ....
(1) The door of the sterile filling room was left open while filling bottles of an eye solution. ..
(2) The methods used in its packing do not conform to current good manufacturing practices in that
Isopropyl alcohol is labeled as Citrate of Magnesia.
501(a)(3) ....
Its container is composed in part of lead, which may render the contents injurious to health.
501(a)(4)(A) ....The color used is in excess of the limits prescribed in the regulations.
501(a)(4)(B)
FD&C Red #4 intended for use in a drug for internal administration, and such use is for coloring purposes only.
501(a)(5)
The article is a new animal drug and there is no approved new animal drug application in effect for this drug.
501(a)(6)
The cattle feed contains a new animal drug, namely Carbadox, which is unsafe in that there is no approved new animal drug application in effect for this use.
501(b)
(1) The article purports to be an official NF drug but fails to comply with the compendium's standard for strength.
(2) It contains cresol, a substance not permitted by the U. S. Pharmacopeial Monograph for Water for Injection, which the drug purports to be.
(3) Magnesium carbonate, which the NF formula requires in Solution of Magnesium Citrate, has been replaced by sodium carbonate.
501(c) ....
(1) The article contains Neomycin Sulfate which is below the potency declared on the label.
(2) The quality of the article namely, Rubber Prophylactics, falls below that which it is purported to possess.
501(d)(1)
The article has been mixed or packed so as to reduce its quality or strength.
501(d)(2) ....P-aminosalicylic acid has been substituted in part for conjugated para-amino salicylic ascorbate.

Misbranded Drugs
502(a) ....

(1) Its labeling represents it as a treatment for influenza and related diseases, but it is not an effective treatment for these diseases.
(2) The article falsely claims that it will remove ascarids from hogs.
502(b)(1)
Its label does not bear the name and place of business of the manufacturer.
502(b)(2)
Its label does not bear an accurate statement of the quantity of contents.
502(c)
The statement "24 tablets" appears on the back label and is on a pink label in red type.
502(e)(1)(A)(i)
The label does not show that the drug is aspirin.
502(e)(1)(A)(ii)
(1) The quantity of bromide per tablet is not stated on the label.
(2) Its label fails to list all of the active ingredients.
502(f)(1)
(1) The directions do not state the uses of the drug.
(2) Its (O-T-C drug) labeling does not contain directions adequate for the treatment of diabetes, for which use the drug is recommended in advertising (as distinguished from labeling).
(3) The prescription drug lacks adequate full disclosure information.
502(f)(2)
(1) The labeling does not warn against use of the drug in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis.
(2) The labeling gives no warning that use of the drug in excess of what the directions call for may result in nervousness and sleeplessness.
502(g)
It is not packaged in tight containers as required by the United States Pharmacopoeia.
502(i)(1)
The container is slack-filled.
502(i)(2)
It is an imitation of citrate of magnesia.
502(i)(3)
The article, namely argel leaves, is offered for sale as senna.
502(j)
(1) It is dangerous to health when one tablet is taken every three hours as recommended in the labeling.
(2) It is dangerous to health when taken in the dosage suggested in its labeling.
502(m)
The label fails to provide directions for use to preclude adding excessive color additive to the drug.
502(n)(1)
The advertisement for Miltown which appeared in the May 19, 20XX edition of the Pleasant Medical Journal did not show the established name.
502(n)(2) .... The advertisement for "Triple Sulfa" tablets which appeared ____ etc. ____ did not list the active ingredients by their established names.
502(n)(3) ....
The advertisement for "Triple Sulfa" tablets which appeared in the May 19, 20XX edition of _____ contained or recommended indications for use or a dosage

recommendation, but not the brief summary of side effects, contraindications, and effectiveness.

502(o) ..... The potassium chloride tablets were manufactured in an unregistered plant.

503(b)(4)(A) .....

The label for the article, namely chloralhydrate, does not bear the symbol “Rx only”.

503(b)(4)(B)

The aspirin tablet label bears the symbol “Rx only,” but the drug is not entitled to such designation.

505(a)

The article, namely, Meprobamate, is a new drug and was shipped in interstate commerce without an approved new drug application.

Cosmetics

601(a)

(1) The article contains paraphenylenediamine, a coal tar dye which is a deleterious substance, but its label does not carry adequate warnings or directions to make a preliminary patch test before use.

(2) It contains formaldehyde, a deleterious substance.

601(b) .....Some of its components contain rodent excreta pellets.

601(c) ..... The plant in which the article was prepared was infested with rodents.

601(d) .....Its container is composed in part of lead.

601(e) .....The color used is not authorized by the regulations (or is in excess of the limits prescribed in the regulations.)

602(a)

The article is represented as containing a substantial amount of lanolin, but lanolin is a minor constituent of the cream.

602(b)(1)

The label for the eye shadow does not bear the name and location of the manufacturer, namely, New York Pencil Co., Inc., New York, N.Y.

602(b)(2) ..... The article does not bear a statement of the quantity of contents.

602(c) .....The statement of the quantity of contents appears on the bottom of the container (oval jar).

602(d)

The nontransparent container is composed of an outer and inner wall with a 1/8 inch space between the walls.

602(e)

The label fails to provide directions for use to preclude adding excessive color additive to the cosmetic.

Title 42

351(a) .....

(1) The Source Plasma (Human) was drawn and shipped from an unlicensed establishment.

(2) The label fails to bear the expiration date and license number of the establishment.

351(b) ....
(1) The label states the blood is Hgb negative, but the records show the unit is Hgb positive.
(2) The donor number on the unit label is false.
(3) The product is pooled serum, but the label falsely states it was drawn from one donor.
351(c) .... Inspection of the establishment by a duly authorized investigator was refused.
351(e) ....Officers of your firm interfered with the investigator in the performance of his duties by refusing to provide necessary records for his review.

Title 18, Section 1001 ....
(1) The firm was aware that test animals had died, but concealed that fact.
(2) You advised FDA Investigators that you had no connection with the study, knowing the statement to be false.
(3) The study that was submitted with NDA 80-125 contains fictitious entries.
(4) The documents submitted in support of your application contain false statements.

Exhibit 5-4
LEGAL STATUS SHEET

SAMPLE NO: _____

A. STATUS OF FIRM AT TIME OF ALLEGED VIOLATIONS

_____ ....(date)

Full name of firm

_____

Please check and fill in appropriate section below:

1. Corporation ☐ Year Incorporated_____ Under laws of what state? _____

Names and Titles of principal officers

_____

(include first name and middle initial)

_____.....

_____.....

_____.....

2. Partnership ☐

Name of each partner _____.. ....

(include first name and middle initial)

3. Sole Ownership ☐

Name of Owner

_____

(include first name and middle initial)

B. STATUS OF FIRM AT PRESENT TIME

_____.....

(date)

☐ Same as above ☐..... Different

Full name of firm_____.... ....

1. Corporation ☐ Year Incorporated_____Under laws of what state? .....

Names and titles of principal officers_____

(include first name and middle initial)
2. Partnership

Name of each partner _____..... ....
(include first name and middle initial)

3. Sole Ownership

Name of Owner_____..... .....
(include first name and middle initial)

Signature_____

Title_____

Exhibit 5-5
INFORMATION SHEET

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

INFORMATION SHEET IN CONNECTION WITH ENCLOSED SECTION 305 NOTICE

OBJECT OF THE MEETING

This meeting is scheduled to give the person or persons who appear to be responsible for the violations of the **Federal Food, Drug, and Cosmetic Act**, and other Federal Laws, as specified in the attached Charge Sheet an opportunity to explain voluntarily any circumstances connected with the preparation, handling, shipment, or sale of the articles involved which would indicate that criminal action should not be taken. You are not compelled, however, to answer. Any civil action which may have been taken against the goods involved, such as seizure, does not preclude prosecution of those responsible for the violation: the meeting concerns the possible criminal action only. A copy of the Federal Food, Drug, and Cosmetic Act and regulations for its enforcement may be had upon request.

NATURE OF THE MEETING

This **meeting** is informal and confined to questions of fact. For your convenience in submitting required information concerning the status of your firm both on the date of response to this notice and on the date of alleged violation, the attached Legal Status forms may be filled out and returned with your answer, whether written or by personal appearance. Your answer may consist of the disclosure of any pertinent facts, letters, files, guaranties, shipping documents, analyses, arguments, etc., which you feel may present valid reasons why you should not be prosecuted.

GUARANTIES

In the case of articles that are adulterated or misbranded when introduced in interstate commerce the Federal Food, Drug, and Cosmetic Act (the Act) places responsibility on the interstate shipper, even though he may be only the distributor and not the manufacturer. Distributors may relieve themselves of responsibility if they hold a legal guaranty under Section 303(c) of the Act. If the articles were sold to you by a person residing in the United States and guaranteed by such person to comply with the provisions of the Act, you should submit:

Evidence of that fact, and

A statement as to whether the product at the time of the apparent violation by you was in the identical condition and bore the same labels as when received by you from the guarantor, and

The full name of the person who, if called upon, can identify the pertinent records and testify to the
facts as you present them.

HOW TO ANSWER

You may appear in person or by attorney or other designated representative, or you many submit your response in the form of a letter in lieu of personal appearance. If written response is made, please submit your letter and all accompanying documents in **triplicate.** Documents submitted at personal appearance should be in **triplicate. All documents should be conspicuously identified by the reference number shown on the upper right corner of the Section 305 Notice.**

RESULT OF THE MEETING

After the meeting has been held and all the facts considered, if it is the conclusion of the Secretary of the Department of Health and Human Services that prosecution should be recommended, the facts in the matter will be transmitted to the Department of Justice for appropriate action

FORM FDA 466a (7/80) PREVIOUS EDITION IS OBSOLETE.

Exhibit 5-6
MODEL GENERAL SUMMARY OF INFORMATION

District Director Letterhead

Date

Ace Plastic Company
11124 Railroad Street
Ogallala, Nebraska 69158

Dear Sir:

This is a General Summary of Information in Support of Detention DN 60011.

We intend to present the following information to support our action:

1. Form FDA 483 list of observations issued to Albert C. Edwards, owner of Ace Plastic Company.

2. Establishment Inspection Report dated February 20, 1980.

3. Collection Report for sample of syringes.

4. Pages from Quality Control Log of Ace Plastic Company dated February 18, 1980.

5. Testimony of Sidney H. Rogers, Investigator, reporting his observations and his discussion with Mr. Edwards.

Sincerely yours,

District Director

Exhibit 5-7
MODEL COMPREHENSIVE STATEMENT*

Date

Ace Plastic Co.
11124 Railroad Street
Ogallala, Nebraska 69150

Dear Sir:

The following is a Comprehensive Statement of the Basis for Detention Order DN 60011.

FDA Investigator _____ observations:

Black unidentified spots on the needles and holes in the individual protective packaging of the sterile 2cc syringe led him/her to believe that the devices are adulterated and misbranded resulting in issuing Detention Order number DN 60011.

_____made these observations during his/her (date) inspection of your establishment.

The black spots on the needles and holes in the packages lead us to believe the product is adulterated within the meaning of (1) Section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the device has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health; and (2) within the meaning of Section 501(c) of the Act in that its quality falls below that which it purports or is represented to possess. Further, these same observations lead us to believe that the product is misbranded per Section 502(a) of the Act because the label states the product to be sterile and the holes in the protective wrapper allow the product to be exposed to contamination.

*To be used when the detention order (FDA 2289 Detention Notice) may not serve as the Comprehensive Statement because the "reason for detention" is not described in sufficient detail. When the detention order may serve as the Comprehensive Statement, the letter need only include a copy of the detention order and reference the "reason for detention" as the Comprehensive Statement.

Exhibit 5-8
EXAMPLES OF DETAILED STATEMENTS

EXAMPLES OF STATEMENTS UNDER ITEM #15, "REASON FOR DETENTION" THAT PROVIDE SUFFICIENT DETAIL FOR THE FDA 2289 ORDER TO SERVE AS A COMPREHENSIVE STATEMENT:

1. 21 USC Section 351(c) charge.

   - Detention order cites adulteration within the meaning of Section 351(c) because the quality of the device falls below that which it claims to possess.

   - Comprehensive statement expands upon the charge in the detention order by adding: "...because the labeling specifies that the device measures "x" within ± 3 percent but tests conducted by FDA show that the device only measures "x" within ± 25 percent."

2. 21 USC Section 351(h) charge.

   - Detention order cites adulteration within the meaning of Section 351(h) in that the methods used in, etc. (tracking in plain language the applicable portion of the statute) are not in conformity with GMP requirements under 21 USC Section 360j(f) as set forth in 21 CFR Part 820.

   - Comprehensive Statement expands upon the charge in the detention order by adding: "...because (citing applicable sections of the GMP regulations and deviations from them, working directly from the FDA 483 but using common, non-statutory language."

3. 21 USC Section 352(a) charge.

   - Detention order cites misbranding within the meaning of Section 352(a) in that the labeling for the device, which states that the device will cure the common cold, is false or misleading.

   - Comprehensive statements expand upon the charge in the detention order by adding: "... because..."

The same approach should be followed in comprehensive statements where the detention order cites misbranding within the meaning of 21 USC Sections 352(f), (j), etc. The comprehensive statement simply summarizes the factual basis of district's case. If this kind of format is used for a comprehensive statement, the general summary of the information which the district will present in support of the detention (21 USC Section 321(x)(3)) need not consist of anything more than a list of documents (FDA 483~~,~~ EIR, CR, Analyst Worksheet), including affidavits (for example, where the charge is based on the absence of an approved PMA or an IDE - see 21 USC Section 351(f)).

Exhibit 5-9
MODEL HEARING CONFIRMATION LETTER

RFDD Letterhead

Date

Mr. Albert C. Edwards
President
Ace Plastic Company
11124 Railroad Street
Ogallala, Nebraska 69158

Dear Mr. Edwards:

I am confirming the information listed below discussed during our telephone conversation of today.

The hearing you requested on the appeal of the administrative detention of your devices will be held on ___at the Kansas City district office, 1009 Cherry Street, Kansas City, MO at 9:00 a.m.

The hearing will be a closed hearing because the proceedings constitute an open investigatory record. This means that only you, your counsel, witnesses, and employees as well as FDA representatives will be allowed to attend.

The regulations on administrative detention 21 CFR 800.55 states that 21 CFR Part 16 will be followed in conducting the hearing, however, the regulations make the following exceptions to Part 16:

1. 21 CFR 16.22(a), concerning the issuance of a separate notice of opportunity for a hearing, is not applicable since the Detention Notice also serves as that notice.

2. 21 CFR 16.22(b), concerning the appeal being sent to the Presiding Officer, is not applicable since the regulations require the appeal to be sent to the District Director of the district where the devices are located.

3. 21 CFR 16.24(e), concerning not holding the hearing within two days of the appeal, is not applicable because of the short time frames involved. We can hold the hearing within two days of your appeal.

4. 21 CFR 16.42(a), concerning those persons who may act as the Presiding Officer, is not applicable because I have been designated by regulations as the Presiding and Deciding Official.

I am authorized by 21 CFR 10.19 and 21 CFR 16.60(h) to waive, modify, or suspend any provision under 21 CFR Part 16. I am waiving or modifying the following provisions:

1. 21 CFR 16.60(f), which requires the presiding officer to make a recommended decision

with statements of reasons to the deciding official, is not applicable because I am the Deciding Official as well as the Presiding Officer in this instance.

2. 21 CFR 16.95(b)(1) and (2) which state that the Administrative Record of a Regulatory Hearing (21 CFR 16.80(a)) is the exclusive record and basis respectively for the decision. The decision will not be based on any material that is not part of the administrative record. I am modifying 21 CFR 16.95(b)(1) and (2), however, because the decision will be based in most cases, on all information presented to me prior to or during the hearing. The decision will not be based on the following information or documents if they are not received or completed by me within the time period necessary for me to review or complete them prior to making a decision as required by the Act or regulation:

a. Information and views I have permitted to be submitted after the hearing, are not part of the official record unless the post hearing submissions and information is submitted within the time specified by me.

b. Any transcript of the hearing.

c. My Report of the Hearing and any comments on the report.

3. That part of 21 CFR 16.60(b) is waived which provides that all parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing. Reasonable questioning will be allowed instead. Reference congressional intent: House of Representatives Report no. 94-853 and 21 CFR 16.5 and 16.60(h).

If feasible, at least one day before the hearing, you are to provide the District Director with written notice of, or a copy of if the Director could not reasonably be expected to obtain a copy, any published articles or written information you intend to present or rely upon at the hearing as required by 21 CFR 16.24(g).

Any written communication you forward or present to me must be sent by you to all other participants to the hearing as required by 21 CFR 16.44(c).

You are requested to provide at the hearing a brief summary of any lengthy documents you intend to present at the hearing.

If you have any additional questions on the procedures I will follow at the hearing, you may contact me prior to the hearing.

Sincerely yours,

Albert Smith
Regional Food and Drug Director

Exhibit 5-10
MODEL ORDER 1/

RFDD Letterhead

Date

Order

Ace Plastic Company
11124 Railroad Street
Ogallala, Nebraska 69158

Dear Sir:

Based on my review of the material (make brief reference to the documents used by the presiding officer, (e.g. FDA 483, analyst worksheet, published article, CR, EIR, etc. and testimony) presented in the appeal of Detention Order number _____, I hereby order that the Detention Order be confirmed (revoked) because there is (insufficient) reason to believe that the devices are adulterated (misbranded) within the meaning of Section _____ of the Federal Food, Drug, and Cosmetic Act in that _____. 2/

Albert Smith
Regional Food and Drug Director

1/ Short Form: To be used when separate written decision/report of the hearing must be prepared later, due to short time frame for the order.

2/ Delete "of section_____", and "in that _____" if the detention is revoked.

Exhibit 5-11
SUMMARY FORMAT - SECTION 305 MEETING

SUMMARY

FIRM AND INDIVIDUAL CITED:

SAMPLE NO. AND PRODUCT:

DATE OF MEETING:

WHERE HELD:

PRESENT:
(List attendees - name, title, etc.)

WRITTEN SUMMARY:

_____
Compliance Officer
_____District

(distribution)

Exhibit 5-12
NOTIFICATION OF NON-PROSECUTION

Dear_____:

Pursuant to 21 CFR 7.85(h), this is to advise you of the decision not to proceed with criminal prosecution of (firm name and/or individual name or names) based on the charges set forth in the Section 305 Notice dated_____.

This decision is based on the evidence we have at this time and does not preclude the initiation of criminal prosecution, based in whole or in part on any or all of the charges set forth in the Notice, should new evidence or subsequent violations of the law reveal the need for such action. In such case, a new Section 305 Notice will issue except as provided in 21 CFR 7.84(a)(2) and (3).

_____
District Director

EXHIBIT 5-13
MODEL LETTER OPPORTUNITY FOR VOLUNTARY CORRECTIVE ACTION

OPPORTUNITY FOR VOLUNTARY CORRECTIVE ACTION

Firm Name
Address
CITY, ST. ZIP

Dear [NAME] :

A Food and Drug Administration (FDA) inspection of your facility conducted on MMM DD, YYYY, resulted in the issuance of a FDA 483, Inspectional Observations (copy enclosed). FDA review of information and records collected during that inspection revealed that the banked human tissues listed below appear to deviate from Title 21, Code of Federal Regulations, Part 1270 (21 CFR Part 1270):

LIST SIGNIFICANT DEFICIENCIES AND IDENTIFY AFFECTED TISSUE

[FOR EXAMPLE: All bone tissues procured between December 14, 1993, and January 31, 1995, which were subsequently processed, seemed suitable for transplantation, and currently in inventory or distributed.]

The purpose of this correspondence is to provide you with the opportunity to implement voluntarily corrective action(s) to bring your tissue and operations into compliance with 21 CFR Part 1270 (copy enclosed). Such corrective action may include, but is not limited to, obtaining and evaluating additional relevant documentation such as medical reports, patient charts, laboratory records, medical examiner/coroner's report, autopsy report or police records, and when necessary, additional information from the donor's next of kin.

We also request that you quarantine and identify as unsuitable for transplantation the above referenced tissue in inventory at your firm until FDA informs you that your corrective action has adequately resolved the deficiencies. In addition, please notify your customers to quarantine affected tissue in their inventories until the issues are resolved.

If you choose to commit to this course of action, please promptly notify me in writing of your decision to quarantine inventory and your plan for corrective action within ten (10) days from your receipt of this letter.

The corrective action plan should specifically address those deficiencies listed on the FDA 483. This plan should allow you to bring the referenced tissue into compliance with the interim rule within 30 days. The plan for corrective action should also include proposed revisions to your firm's standard operating procedures for processes and procedures used in the recovery, processing, record keeping, storage and distribution of banked human tissue for transplantation.

This office will be available to discuss with you the adequacy of your proposed corrective action plan. Based on our review of your plan of corrective action, FDA will evaluate the need for any further action.

Sincerely yours,

[Signature Block].....

DISTRICT DIRECTOR

Enclosures

cc: HFM-650
HFC-100
HFC-210
HFC-230
GCF-1

EXHIBIT 5-14
MODEL ORDER FOR RETENTION, RECALL, AND/OR DESTRUCTION

ORDER FOR RETENTION, RECALL, AND/OR DESTRUCTION

Date Issued: MMM DD, YYYY

Issued To: Name of Responsible Individual
Title
Establishment Name
Address
CITY, ST, ZIP CODE

The Food and Drug Administration (FDA) Inspection of your facility on [MM DD, YYYY], covering human tissue intended for transplantation which is subject to Title 21, Code of Federal Regulations, Part 1270 (21 CFR Part 1270), and our review of the information and records examined during the inspection show that certain human tissue received and distributed by your organization may be in violation of 21 CFR Part 1270, as indicated below:

[LIST VIOLATIONS]

- Between [DATE] and [DATE], [QUANTITY/TYPE] tissues from NNN donors were distributed for transplantation which were repeatedly reactive for HBsAg/HIV by EIA (21 CFR 1270.5(c)). (Example)

Pursuant to 21 CFR 1270.43, the above referenced tissue must be:

- Recalled (if distributed), within five (5) working days of receipt of this order, under the supervision of an authorized official of the FDA, and/or

- Destroyed by an acceptable method of disposition, within five (5) working days of receipt of this order, under the supervision of an authorized official of the FDA, or

- Retained until it is recalled, destroyed, the safety of the tissue is confirmed, or an agreement is reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA.

[NAME OF FIRM], its owners, employees, and agents shall not distribute or dispose of the tissue in any manner except to recall and destroy it consistent with the provisions of the Order. Any other arrangements for ensuring the proper disposition of the tissues must be agreed upon in writing by [NAME OF FIRM] and an authorized official of the FDA. Such arrangements may include assurance that the tissue has been recovered, processed, stored, and distributed in conformance with the attached regulations (21 CFR Part 1270).

All actions taken pursuant to this Order, or otherwise related to the tissue subject to this Order, shall be taken under the supervision of an authorized Official of the FDA.

Within five (5) working days from the receipt of this Order, the recipient of the written Order or

prior possessor of such tissue may appeal the Order to the District Director, [NAME], District, Food and Drug Administration, [ADDRESS, CITY, STATE, ZIP CODE] and request a hearing on the matter in accordance with 21 CFR Part 16 (copy attached). Such manner of appeal is described in 21 CFR 1270.43(e) of the attached regulations. Failure to request a hearing within the specified time period constitutes a waiver of the right to a hearing.

Please contact [NAME], Compliance Officer, at [TELEPHONE NUMBER], to arrange for supervision of the disposition of the tissue.

[SIGNATURE BLOCK]
District Director

Attachments (2)
21 CFR Part 1270
21 CFR Part 16

cc: Name and Address of any other tissue bank or organization with interest in/jurisdiction over this tissue.

HFM-360
HFM-100
HFC-210
HFC-230
GCF-1