Chapter 3
COMMISSIONING AND WORK SHARING

COMMISSIONING FEDERAL, STATE, AND LOCAL OFFICIALS; ACCEPTING A STATE'S COMMISSION; WORK SHARING INITIATIVES

This chapter contains the following sections on commissioning Federal, state, and local regulatory officials, accepting a State's commission, and on cooperative work sharing initiatives:

3-1 INTRODUCTION; OBJECTIVES

This chapter describes the Food and Drug Administration's (FDA) policies, procedures, and responsibilities for commissioning other government officials. This chapter also sets out the circumstances for FDA consumer safety officials to accept state commissions.

FDA developed its commissioning program to make inter-Agency cooperation more effective thereby increasing the amount of protection afforded to the American consumer. FDA achieves its goal by: (1) permitting commissioned Federal, state and local officials to operate under the Act, and (2) enabling those commissioned officials to effectively carry out their responsibilities by reviewing FDA information, such as draft policies, that is protected from disclosure to the public by a Freedom of Information Act (FOIA) provision.

FDA has two procedures for commissioning a state or local official--the variation that the agency typically has used (e.g., issuing credentials or a certificate), and another variation that is "streamlined" because it involves less paperwork. The "streamlined" variation arises in the context of FDA contracts with state government agencies. This chapter focuses on commissioning of state and local officials, with most of the attention devoted to the first variation of the commissioning procedure.

However, this chapter also briefly sets out references to FDA's authority to commission officials from other Federal government Departments and agencies (Federal officials) under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002) (The BT Act).

FDA's Office of Regulatory Affairs' Division of Federal-State Relations (DFSR) (HFC-150) has

primary responsibility for overseeing the implementation of FDA's Commissioning Program. For state or local officials, ORA Regional Food and Drug Directors (RFDDs) have primary responsibility for carrying out the Program. For Federal officials the interagency Memorandum of Understanding (MOU) that is required by the BT Act should include provisions regarding the implementation of the commissioning procedures. For that reason, this chapter will only briefly refer to those provisions.

3-2 AUTHORITIES

Title 21, U.S.C. Section 702(a) (Federal Food, Drug, and Cosmetic Act (The FD&C Act)), as amended by Public Law 107-188, (The Public Health Security and Bioterrorism Preparedness and Response Act of 2002) (The BT Act)). The BT Act was signed into law on June 12, 2002. Section 314 of the BT Act included language for insertion into Section 702(a) to authorize the FDA to commission other Federal officials to conduct investigations under the FD&C Act pursuant to a memorandum of understanding (MOU) between the Secretary and the head of the other Federal Department or Agency.
21 C.F.R. § 5.35 (Authority delegated to the Commissioner of Food and Drugs by the Secretary of Health and Human Services).

3-3 CONSIDERATIONS BEFORE COMMISSIONING

3-3-1 Initiating the Process

(1) Introduction. Either an FDA official or the director of a state or local program, can initiate the process for commissioning by sending a written recommendation to DFSR. Recommendations from the field offices should be sent to the RFDDs through district directors. Recommendations from the state or local program should be sent to the RFDDs through the director of state programs. The commissioning of Federal officials generally begins at the time specified in the MOU that FDA and the other agency signs.

(2) "Streamlined" procedure for commissioning state or local officials. In a contract situation, FDA may rely on a variation of streamlining that, in part, depends on the state Agency head certification that the state or local official:

a. met the requirements the state has established to credential its own official to carry out state government regulatory or enforcement responsibilities; and,

b. has provided written assurances regarding conflict of interest and prohibited financial interests, and maintaining the confidentiality of non-public information provided.

3-3-2 Qualification; Eligibility

The RFDD determines the eligibility of a state or local official for a commission.

(1) State and local Agency heads. FDA considers all Agency heads of state regulatory agencies appointed by the governor of the state to be qualified and eligible for commissioning. Agency heads of state regulatory agencies not appointed directly by the governor, and Agency heads of local agencies are eligible to receive a commission if they are qualified. Factors include the individual's educational achievements, subsequent training, and career experience.

FDA usually suggests that the head of the Agency in which one or more officials will be or currently are commissioned by FDA, also hold a FDA commission. This is advisable, but not mandatory, to avoid any situations in which a commissioned official refuses to share with their non-commissioned supervisor, confidential information obtained under their commission. If the Agency head declines to accept a FDA commission, the deputy commissioner, center director, etc., may be designated by the Agency head to act in his place when a commissioning issue arises. If this is not possible, FDA may commission one or more of the operating personnel but this would be infrequent and would be done only if needed to achieve program goals.

(2) Other state and local officials. A program director or subordinate official is eligible to receive a commission if qualified. The RFDD may request pertinent information on the official, including a *curriculum vitae* (CV) (see Exhibit 3-1 for examples of questions usually answered by information recorded on a CV). Factors include: (1) the recommendation of the head of the Agency in which the individual works; and, (2) the training and experience of the candidate; and (3) reports of appropriate FDA field personnel and State Program Specialists who have worked with the candidate.

(3) Federal officials. The MOU may specify procedures regarding the commissioning of designated Federal officials, e.g., who determines whether all commissioning requirements under the BT Act, such as training, have been met.

3-3-3 Background Check

(1) General. FDA will not commission any official, if FDA determines that there is conflict of interest regarding that individual. Commissioned officials must be citizens of the United States. For Federal officials, the MOU may contain provisions about a background check. FDA, in its discretion, may conduct a background check on a state or local government official, as described below.

(2) State or local official. Prior to commissioning, in the unusual event that a state or local official has not had a background check by his or her own Agency, the RFDD may decide: (a) not to offer a commission; (b) to offer a commission on the basis of other information on the candidate; or, (c) to require a background check. If FDA decides to conduct a background check, the RFDD or other designated official should inform the state or local official of FDA’s authority conduct that activity.

If an RFDD determines that a background check should be made, the RFDD has the option of issuing the commission prior to receiving the results of the check, or waiting until the background check has been made. If the RFDD requires a background check, he/she will

compile a package of all information gathered on the candidate, including the candidate's CV, and send it to DFSR, which will obtain the background check through the Office of the Inspector General of the Department.

Obtaining a FDA commission is a privilege FDA extends to a select and limited number of regulatory officials. If the candidate objects to the process, or challenges the right to make such a check, FDA considers the individual as having withdrawn his or her candidacy and FDA will not conduct the background check.

3-3-4 Program Areas; Commissioning Activities 1-4

(1) The FDA will commission a government official only in program areas in which the official is qualified. FDA will commission a state or local official to act in specific program areas that correspond to the laws administered by FDA. Program areas may include the following: Foods, Drugs, Medicated Feeds, Shellfish, Medical Devices, Radiological Health, Biologics, and Cosmetics.

(2) Commissioning activities #1-4. In addition to considering the appropriate program area for an individual, FDA will also consider the scope of the activity. FDA may commission a state or local official to perform one or more of the following four activities in a specific state:

#1. Conduct examinations, inspections, and investigations.
#2. Collect and obtain samples.
#3. Copy and verify records.
#4. Receive and review official FDA documents.

Because of their knowledge and or training, some state or local officials may be commissioned to act in all program areas, but only for the purpose of receiving and reviewing official FDA documents (Activity 4).

(3) Federal officials. The BT Act authorizes FDA to commission a federal official to act in areas "jointly regulated by the Secretary and the other Department or Agency." The MOU should include provisions to address the types of program areas covered by the commission, the extent of activities 1-4 covered by the commission, and training for those activities.

3-3-5 Reasons for Commissioning

After review of the necessary information regarding a state or local official, an RFDD might conclude that offering a commission to a state or local government employee is in the interest of the Agency. The following examples are some reasons why FDA might decide to offer a commission to a State or local official:

(1) The individual is by position, training, and/or experience a person whose advice and counsel on confidential or sensitive matters is desired on the district, regional, or national level.
(2) The individual is, by position, a person who would have to review the recommendations of a commissioned subordinate in order to assure FDA that the recommendations represent the official views of the state or local Agency. Since only holders of FDA commissions can review certain FDA documents, it would be

necessary that the supervisory individual be commissioned.
(3) The individual is engaged in joint state/FDA investigation operations.
(4) The individual is engaged in carrying out a contract issued by FDA for which the application of federal law is required for successful completion of the contract.
(5) It is necessary to have access to FDA information of an investigation or otherwise confidential nature.
(6) The state or local official is helping FDA in a special manner for which FDA credentials are required. For example, an FDA district may require samples to be collected on a routine basis from a plant that is located about a half-day's journey from the closest FDA post. However, a state employee, located near the plant, could, if commissioned, pick up the samples at a tremendous savings in time and money to FDA (it is assumed that FDA would make arrangements for this with the state Agency that are satisfactory to that Agency).

3-3-6 Contacting the Candidate

(1) General. FDA must contact all state and local officials who have been nominated for a FDA commission before a commission is prepared. This is to ensure that the individual understands the terms and conditions attached to holding a commission and is willing to accept the commission when presented. Specific points to cover include:

a. General description of the commissioning program;
b. Purpose for which this particular commission is offered;
c. The importance of maintaining confidentiality of FDA non-public information shared (see “Confidentiality” for detailed information);
d. FDA’s expectations of the candidate;
e. Conflict of interest safeguards and what they mean (see “Conflict of Interest” for detailed information);
f. The requirement of American citizenship;
g. FDA’s right to conduct a background check at any time; and,
h. Appreciation of the individual's willingness to serve.

At the conclusion of this discussion it must be clear that the individual sees no obstacle to holding a commission and will accept the commission when it is formally offered.

(2) Eligible. If there is reasonable assurance that the state or local candidate for commissioning is eligible and will accept the commission(s), the "commissioning packets" discussed in the next section may be prepared in advance and brought to the meeting. The FDA official may remain and be available to answer questions while the forms in the commission package that have to be returned to FDA are filled out and handed back.

(3) Not eligible. If FDA determines that the state or local candidate for commissioning is not eligible, a letter must be issued to the candidate and his/her supervisor informing them of the reasons for the withdrawal of the offer of a commission.

3-4 DOCUMENTATION; CREDENTIALS

3-4-1 Request or recommendation for commissioning a state or local official

The request or recommendation for commissioning a state or local official should contain:

(1) The full name, title, and Agency of the individual for whom the commission is being requested;
(2) The reasons for which the commission is requested;
(3) The program area or areas for which the commission will be issued (see item 3-3-4.);
(4) Which of the four activities the individual will be authorized to perform (see item 3-4-4-4.);
(5) Whether the individual is to be issued a certificate, credentials, or both (see item 3-4-3.);
(6) The nature of the assignment, when possible; and,
(7) A concurrence or non-concurrence line for the RFDD.

3-4-2 Written Assurances

FDA will commission a state or local government official only if the official provides a written assurance, e.g., by signing the "Acceptance of Commission" that includes provisions about conflict of interest and confidentiality matters (see Exhibit 3-2). For Federal officials, the MOU may set out provisions about written assurances.

3-4-3 Credentials

(1) FDA issues credentials for State and local officials who are commissioned for activities other than activity 4, "Receive and review official FDA documents." (see item 3-3-4.; see Exhibits 3-3 and 3-4). The credentials will show:

a. The program area or areas (see Exhibit 3-4) covered.
b. The state where the official may operate.
c. Other information, such as the credential number and expiration date.
d. The picture of the individual.

(2) No credentials. FDA generally does not issue credentials for:

a. State and local officials that FDA commissions for activity 4, "Receive and review official FDA documents." Those individuals usually receive a Certificate of Commission (Exhibit 3-5).
b. State and local officials that FDA commissions under FDA's "streamlined" commissioning program. For additional information, contact DFSR.
c. Federal officials that FDA commissions. Since FDA confers the "Commission Authority" under the MOU with the collaborating federal agency, typically FDA will not issue a separate set of commissioning credentials. The Federal officials will have identification/ credentials from their Agency.

(3) Lost credentials. FDA considers the loss of credentials to be a serious matter. FDA asks commissioned state and local officials to report the loss of their credentials immediately to the RFDD or designated official. The RFDD or designee should provide detailed information on the loss of the credentials to DFSR for transmittal to the Federal Bureau of Investigation (FBI). Also, FDA should clearly inform commissioned state and local officials who receive credentials that they may not retain the credentials as mementos or souvenirs. The Certificate of Commission may serve this purpose.

3-4-4 Commissioning Package

(1) State or local official. Upon confirmation to the RFDD that a commission will be accepted by a state or local employee, FDA will deliver a "commissioning package" to each candidate. This package generally contains:

a. A letter signed by the RFDD offering the candidate a commission.
   (i) In the case of an Agency head, the letter will cite the Commissioner's desire that the candidate have a FDA commission (see Exhibit 3-6).
   (ii) In the case of a program director or an individual subordinate to the program director, the letter goes to the Agency Head, but these letters will not mention the Commissioner (see Exhibit 3-7).
b. A copy of the most recent edition of the brochure “The FDA Commission”
c. Acceptance of Commission form (see Exhibit 3-2).
d. One blank Identification Card, FDA Form 200A (see Exhibit 3-3). (If copies are needed contact DFSR)
e. A request for a CV (only at RFDD's specific instructions) (see Exhibit 3-1). If the candidate or commission holder has not completed a CV, FDA may request one from the individual. Failure of that individual to supply a CV to the RFDD upon request may be considered grounds for withdrawing the offer of a commission, or revoking a previously issued commission.
f. "Basic Information from a Candidate" form (see Exhibit 3-8).
g. "Instructions to Candidate” form (see Exhibit 3-9).
h. Any other information that DFSR deems relevant.

Upon receipt of the requested portions of the commissioning package, FDA will check the material for accuracy and completeness. Forms that have been partially completed or apparently completed incorrectly will be returned to the candidate with a request for correction(s).

(2) For Federal officials, the MOU may contain provisions about documentation for the commissioning process. FDA expects that there will be minimal paperwork for a Federal official.

3-4-5 Commission Documents

(1) For state and local officials, after FDA checks the information from the candidate, it generally will prepare and send the following materials to the newly commissioned state or local official:

a. A letter, signed by the RFDD, thanking the individual for accepting a commission.
b. If issued, laminated credentials in a credential case (see Exhibits 3-3 and 3-4).
c. A "Certificate of Commission," signed by the Commissioner (see Exhibit 3-5). A small stock of "FDA Form 1990A" and "Certificates of Commission" pre-signed by the Commissioner may be obtained from DFSR (HFC-150) and should be kept in a locked file or desk
d. A form to be returned to the RFDD on which the Commissioned Official can order certain FDA material without charge (see "Relationship with Commissioned Officials"and Exhibit 3-10).
e. Any other information that DFSR deems relevant.

(2) For Federal officials, the MOU may contain provisions about documentation for the commissioning process. FDA expects that there will be minimal paperwork for a Federal official.

3-5 CONFLICT OF INTEREST

3-5-1 Written Assurances

State or local officials seeking commissioning and Commissioned Officials considered for renewal are asked to attest in writing, e.g., through the Acceptance of the Commission form (Exhibit 3-2), that they do not have certain personal financial interests or financial or business relationships with firms operating in the specific fields where authority would be granted to the official under the Commission.

For Federal officials, the MOU may contain provisions about the conflict of interest standard, e.g., the standard that is imposed by that other Federal agency.

3-5-2 Conflict of Interest Considerations before Commissioning

(1) General. FDA will not commission any official if he/she is determined to have a conflict of interest. All issues affecting candidate's financial interests must be resolved prior to granting a commission.

(2) State or local official. A state or local government employee recommended for a commission may discuss questions about the conflict of interest with his/her sponsoring FDA official. If the candidate becomes aware of a potential financial interest that would affect participation under the FDA Commissioning Program, the sponsoring FDA official will summarize the issues and submit it along with other documentation to the FDA Regional Office and DFSR for resolution. DFSR will discuss the matter with the RFDD and a decision will be reached as to whether or not the individual can be commissioned. DFSR may contact the FDA's Ethics and Integrity Staff (HFA-320). This discussion should be conducted in person by the RFDD in the case of a state Agency head. If circumstances make this impractical, a district director, director of state programs, or assistant regional director may make a visit for this purpose for intergovernmental affairs. Agency heads who are already familiar with the program and for whom this information need not be duplicated may be contacted by telephone to get the assurance that the commission, when offered, will be accepted.
In the case of a program director or a subordinate official, a district director, assistant regional

director for intergovernmental affairs, or the director of state programs should conduct this discussion. However, in situations where the commissioning program is ongoing and well understood by the program director, the discussion may be held with a supervisory investigator with whom the program director already works. Since it is not always practical to meet with each subordinate, the program director may vouch for his or her subordinate.

3-5-3 Conflict of Interest Considerations after Commissioning

(1) General. The FDA commissioned official must remain free from financial interests that may affect the specified authorities in the FDA commission. If the official acquires a financial interest after receiving a commission, he/she must notify FDA and not participate in any assignment affected by the financial interest.

(2) For state and local officials, if problems arise about conflict of interest, the sponsoring FDA official will summarize the issues and submit them along with other documentation to the FDA Regional Office and DFSR for resolution. If problems arise about the commissioned status of any official, FDA's resolution may range from disqualification from participating in any commission related activities pertaining to the firm, to revocation of the commission and return of the FDA credentials. FDA may revoke a commission for good cause. If FDA determines that the problem is resolved, it may consider commissioning the official again.

3-6 CONFIDENTIALITY

3-6-1 Written Assurances

State or local officials seeking commissioning and Commissioned Officials considered for renewal are asked to attest in writing, e.g., through the Acceptance of the Commission form (Exhibit 3-2), that they understand that any non-public information FDA provides for review is entitled to significant protection under Federal law. The official further understands that if they makes any unauthorized disclosures of non-public information they may be committing a criminal violation under Federal Law (21 U.S.C. § 331(j) and 18 U.S.C. § 1905).

3-6-2 "Receive and Review;" Activity 4

FDA may provide a state or local official, who is commissioned to receive and review FDA information, with information that is protected from disclosure to the public by the Freedom of Information Act (see 21 CFR § 20.84). Examples of non-public information include confidential commercial information, trade secrets, and other non-public information, such as personal privacy information. Whenever FDA provides a commissioned official, in accordance with the Act and FDA regulations, with non-public information, FDA should indicate that the information is non-public, e.g., by affixing a transmittal letter which cautions the recipient against further disclosure. The document's envelope should be identified "To Be Opened By Addressee Only." See Exhibit 3-11 for a Model letter used to transmit non-public information.

3-6-3 Personal Privacy Information

The Privacy Act of 1974 has an impact on cooperating officials because FDA:

(1) might ask the candidate for a commission to supply personal information;

(2) might conduct a background check of the candidate;

(3) will maintain a personnel file on the commissioned official in the FDA Regional Office and DFSR; and

(4) if permitted by the Privacy Act, might give the commissioned official personal privacy information protected by that law. Files maintained on commissioned officials are subject to the Privacy Act. A commissioned official may review his or her own file by requesting a copy of it from RFDD under the Privacy Act. All other questions about a commissioned officials file should be addressed to FDA's Division Freedom of Information (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

3-6-4 Sharing Non-public Information under 21 C.F.R. § 20.88 (State)

For state or local officials, if the Agency head (or other management) cannot or will not accept a commission, FDA may consider using the "Confidentiality Commitment Form," under 21 CFR § 20.88, to enable the Agency to share non-public information with the state. This form and its use are covered under the current "Information Disclosure Manual" section entitled "FDA Information Disclosure Procedures - Sharing Non-Public Information with State or Local Government Officials," dated November 6, 2001.

3-6-5 Sharing Non-public Information under 21 C.F.R. § 20.85 (Federal)

For Federal officials, the MOU should contain provisions about the sharing of non-public information. If FDA determines that it is unable to share non-public information with a particular Federal official, because that individual is not commissioned, FDA is not precluded from considering whether to disclose non-public information to the other Federal agency under 21 C.F.R. § 20.85 (Disclosure to other Federal government departments and agencies). Contact ORA's Division of Compliance Policy (HFC-230) for further details, and refer to the Information Disclosure Manual section entitled "FDA Information Disclosure Procedures - Sharing Non-Public Information with Federal Government Officials," dated November 6, 2001.

3-7 CONSIDERATIONS AFTER COMMISSIONING

3-7-1 Duration

Generally, each state or local commission is issued for a period of three years. For Federal officials, the MOU should include the duration of commission, which might be a term other than three years.

3-7-2 Background check

In its discretion FDA, may conduct a background check on a state or local government official after FDA commissions that official if substantive questions subsequently arise, and should inform the official of FDA's authority to do so. For Federal officials, the MOU may contain provisions about a background check.

3-7-3 Legal restrictions

FDA considers the commissioned state or local official to be an official of the Department of Health and Human Services. However, accepting a commission does not subject the state or local commissioned official to the restrictions on political activity set forth in the Hatch Act, except on days in which the Federal service under the commission is actually rendered.

The United States is liable for torts of its employees under the Federal Tort Claims Act as further clarified by the Federal Employees Liability Reform and Tort Compensation Act of 1988. The definition of employee includes persons acting on behalf of a Federal Agency in an official capacity, temporarily or permanently in the service of the United States, with or without compensation. This definition would include all individuals commissioned under this Program. However, the Federal Tort Claims Act would only apply if the individual holding a commission were performing Federal duties.

For Federal officials, the MOU may contain provisions about legal restrictions, such as those imposed by the Federal Tort Claims Act. If legal restrictions arise, contact DFSR, who may consult with the Office of Chief Counsel.

3-7-4 Renewal of Commission

Commissions of state or local officials are valid for three years. The region will review the commissioned official's record approximately two months prior to expiration of the commission. This review considers all pertinent aspects the commission including inspections, collection of samples, consultation extended, cooperation in routine and emergency situations, and any breaches of confidentiality.

For state or local officials, a memorandum recommending whether or not to renew the commission, with details, should be sent to the RFDD by a district director, assistant regional director, executive official, director of state programs, or other official specifically charged with oversight of the commissioning program.

If the RFDD agrees to a renewal, a new Form FDA 1990A and Form FDA 200A (Exhibits 3-3 and 3-4) is prepared and exchanged for the ones about to expire. This exchange may be handled in any convenient way, provided the old Form FDA 1990A and Form FDA 200A are returned to the RFDD for cancellation. The RFDD also may send the commissioned official a new Acceptance of Commission form (Exhibit 3-2) to be completed and sent back to the Regional Office.

For Federal officials, the MOU should contain provisions about the duration of the commission and procedures about renewal of a commission.

3-7-5 Non-renewal of Commission

FDA will not renew a commission for any official if the person who holds it has changed positions, resigned, or retired. FDA's decision not to renew a commission may be made at any time if the conditions so warrant. If the commission is not renewed, FDA should send a letter to that effect to the supervisor of the individual. This letter should briefly cite the reason. Examples of reasons include: "change of position," "resigned," "retired," "no longer involved in FDA contract work," "inactive," or "at holder's request."

For state or local officials, commissions for which only a certificate was issued may be allowed to expire without correspondence indicating that the commission will not be renewed. Instead, send a letter thanking the commission holder for their service. For state or local officials who received credentials, FDA collects the credentials as soon as a decision is made that a commission will not be renewed. These credentials are cancelled by cutting them in two pieces and placing the pieces in the regional file record of that commission. Notify DFSR.

Non renewal of a commission is done without prejudice. That is, FDA might commission that official later should conditions change.

For Federal officials, the MOU may contain provisions about non-renewal of a commission.

3-7-6 Revocation of commission

FDA may revoke a commission for cause. A reason for revocation could be the abuse or misuse of the commission, including transmittal of FDA's confidential information from a commissioned state or local official to individuals who are not employees of the Department of Health and Human Services. Other appropriate causes for revocation include a conflict of interest, arrest and conviction for a felony, substance abuse, and behavior that may discredit the Agency.

For state or local officials, a memorandum recommending such action, with details, should be sent to the RFDD by a district director, assistant regional director, executive official, director of state programs, or other official specifically charged with oversight of the commissioning program. If the RFDD concurs, a letter signed by the RFDD should be sent to the Agency head stating the details of the revocation and requesting that the certificate of commission, credentials (if any), and any documents belonging to FDA be collected and returned to the RFDD by registered mail. Notify DFSR.

Revocation of a commission is done with prejudice. That is, the official is no longer eligible for an FDA commission.

For Federal officials, the MOU may contain provisions about revocation of a commission.

3-7-7 Relationship with Commissioned Officials

FDA's relationship with state and local agencies is very important, because close coordination and cooperation provides a high level of consumer protection. Having state and local officials hold FDA commissions helps promote FDA's efforts to foster better understanding of FDA's mission and functions. Having an FDA commission is, for most holders, both a tangible and

intangible benefit. Not only can the commission help the holder get his or her job done, but FDA considers a commission as its recognition of the individual's competence, experience, and training in the subject area.

To encourage closer ties with cooperating state and local officials who hold FDA commissions, to inform them about FDA, and to let FDA benefit from their knowledge and experience, the RFDD should consider the following steps:

(1) Regional Meetings. Plan to hold a yearly one-day meeting for all commissioned Agency heads. This event may include a discussion on FDA priority decisions, presentations by senior Agency officials on new developments, policy matters, state contracts, and training. Spend as much of the meeting as possible in soliciting participant views and suggestions. Include examples of effective state-federal cooperation and individual recognition to those who performed outstanding work on joint projects. If the meeting cannot be held due to travel restrictions on out-of-state Agency heads, or lack of funds, consider visiting the offices of each commissioned Agency head, or invite the Agency head to a closer FDA facility for a meeting.

(2) Recognition from the Commissioner. Prepare a letter for the Commissioner's signature recognizing outstanding efforts by a state or local commissioned individual, his or her unit, division, or Agency. If used, send the letter to DFSR to arrange for signing and mailing.

(3) Awards. Nominate commissioned individuals, or groups of commissioned individuals, for FDA awards, medals, or commendations similar to those awarded to FDA employees.

(4) Binders. Give each commissioned official a binder(s) appropriate for the material FDA provides them.

(5) Literature and Publications. Offer subscriptions/copies to selected FDA publications and reports to commissioned officials. Share only those publications that are appropriate for the commissioned official to meet their particular needs. The commissioned officials may request publications from FDA using a Request for FDA Materials form (Exhibit 3-14). Examples of publications to offer are:

a. FDA Investigations Operation Manual (also available on the Internet)
b. FDA Compliance Policy Guides Manual (also available on the Internet)
c. FDA Regulatory Procedures Manual (also available on the Internet)
d. Catalog of Courses and Training Materials (ORA/DHRD)
e. Annual Directory of State & Local Officials (only available on Internet)
f. Laboratory Information Bulletin (LIB)
g. Approved Drug Products With Therapeutic Equivalence Evaluations (and cumulative supplements)(also available on the Internet)
h. Special reports in the area in which the commission is held

(6) Training. Provide headquarter-initiated training bulletins. Announce training courses sponsored or held within a commissioned official in the area for which the course is intended. Give priority to commissioned officials for attendance when possible.

(7) State Activity Information Letter (SAIL). Assist, when requested, in providing material for SAIL.

(8) Visibility. Consider notifying commissioned state and local officials when disseminating information to the public about FDA activities. For example, Public Affairs Specialists who have radio or television programs, or who write columns for newspapers or magazines, should report interesting and meaningful activities of commissioned officials. Regional and district officials compiling material for the FDA Consumer magazine should include stories concerning the activities of commissioned officials.

(9) District Meetings. Invite commissioned officials to all or part of annual district meetings.

(10) Laboratory Support. When possible, permit commissioned officials to use FDA laboratories to run state samples, and state personnel to use laboratory facilities.

3-8 ADMINISTRATIVE CONSIDERATIONS

The following sections set out some of the responsibilities of the regional office management and the DFSR personnel regarding management review and record keeping. For Federal officials, the MOU should specify who will conduct management review and the scope of the review of an individual's commission, and who will submit reports to the House of Representatives and the Senate of the details of that year's accomplishments (see Subparagraph C, Section 314, of the BT Act). The following information relates to commissioning state or local officials:

3-8-1 The RFDD or Designee Should:

(1) ensure that the regional office has established a file on each commissioned state or local official within the region. This record shall include:

a. credential number, date issued, and expiration date. This information, along with other data, may be entered on (optional) Form FDA 2081 (Exhibit 3-12);
b. data on commission holder contained on the Basic Information from Candidate for an FDA Commission form (Exhibit 3-8);
c. copy of naturalization papers if the official was not born in the United States;
d. official's CV, if the RFDD specifically requested that one be furnished;
e. signed Acceptance of Commission form (Exhibit 3-2);
f. all correspondence including awards;
g. photocopies of credential forms (FDA 1990A and FDA 200A);(Exhibit 3-3 and 3-4)
h. one color photograph of commission holder; and,
i. any other information relevant to the commission.

(2) maintain a record of the annual validation of all credentials issued in the region (Exhibit 3-13), and send DFSR copies of the validation forms, and relevant information on the official (full name, credential number (if any) or certificate only designation, state, Agency, program area(s), and expiration date;

(3) annually validate credentials issued to state or local personnel to maintain strict accountability for FDA credentials and to make sure that the list of credential holders is up-to-date;

(4) notify the appropriate district director of the issuance of the commission;

(5) electronically send DFSR (cvassar@ora.fda.gov) information for the national inventory maintained by that office;

(6) periodically review each state or local commission to determine whether it should be renewed or revoked;

(7) review the commissioned official's record approximately two months prior to expiration of the commission;

(8) send DFSR a written decision to revoke a commission or to not renew a commission;

(9) send an accounting letter (see Exhibit 3-14) to each State or local Agency head, together with a form listing the members of that Agency holding credentials (Exhibit 3-13), and send DFSR a copy; and,

(10) notify DFSR about the results of an assignment issued to a commissioned state or local official.

3-8-2 DFSR Should:

(1) maintain a current national inventory of Federal, state and local officials holding commissions issued by FDA and periodically review the inventory for currency;

(2) periodically review the inventory of commissioned officials and advise the appropriate regional commissioning contact of any commissions that have expired;

(3) notify the regional commissioning contact person for resolution if commissions have expired, and have not been renewed, of if there are other issues;

(4) when requested by a RFDD, arrange for initiation of special checks, e.g., background check, of a candidate for a FDA commission, if the field manager has determined such an eligibility review is necessary;

(5) notify the FBI of lost state or local commissioned official’s credentials;

(6) provide copies of commissioning forms if needed, upon request;

(7) facilitate resolution of matters arising about conflict of interest, confidentiality, legal restriction, and other areas related to the commissioning process, and notify appropriate agency personnel;

(8) facilitate the signing of letters by the Commissioner, and other headquarters management regarding commissioning of state or local officials; and,

(9) stop subscriptions and routine mailings of information to an individual whose commission will not be renewed or has been revoked, and close the file.

3-9 ACCEPTING A STATE'S COMMISSION

Sometimes an FDA investigator may find it valuable to exercise state powers. For example, an FDA investigator may wish to obtain a state commission to have the ability to place an embargo in those cases when a state official, who has the authority to do so, is not available an FDA investigator may hold a state commission provided that:

A. the commission is offered by a state Agency whose Agency head holds an FDA commission; and,

B. the commission is not used unless a state official, authorized by the state regulatory Agency, has given prior permission to use the state commission in each specific contemplated use. The supervisor of the FDA investigator should agree to the contemplated use of the commission.

3-10 WORK SHARING

3-10-1 Purpose and Policy

This section sets out FDA's authority, policy, format, and responsibilities to establish collaborative efforts with state and local agencies, whether or not those efforts are formalized in work-sharing agreements. On a case-by-case basis, the information in this section may be applicable to work-sharing agreements with other Federal government agencies.

FDA initiates and enters into cooperative work-sharing programs with other government agencies whenever such cooperation ensures overall consumer protection and effectively utilizes the expenditure of resources. The efforts may be written or unwritten. FDA should routinely evaluate whether unwritten working arrangements between districts and state or local government agencies, should be formalized in writing.

3-10-2 Authorities

(1) FDA and state or local cooperative efforts.
Section 702(a) of the Federal Food, Drug, and Cosmetic Act (the FD& C Act) (Authorizes the Secretary to commission state and local officials to conduct examinations and investigations for purposes arising under the Act. 21 U.S.C. Section 702(a).
Section 311(a) of the Public Health Service Act (states that the Secretary "…shall cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations ..."). 42 U.S.C. Section 311(a).

(2) FDA and other Federal government cooperative efforts.
Section 702(a) of the Federal Food, Drug, and Cosmetic Act (the FD& C Act) as amended by Public Law 107-188, (The Public Health Security and Bioterrorism Preparedness and Response Act of 2002) (The BT Act)) FDA is authorized to commission other Federal officials to conduct investigations under the Act pursuant to a memorandum of understanding (MOU) between the Secretary and the head of the other Federal Department or Agency.)

3-10-3 Confidentiality

FDA's preference is that information shared during the cooperative effort be in a form appropriate for public dissemination under FOIA, but that is not always possible or efficient. Regardless of whether the cooperative effort is set out in writing, FDA should not share non-public information with a state or local government Agency unless that sharing is carried out under the procedures for 21 CFR §20.88 or a written agreement that contains provisions that included or refer to those procedures. (For sharing non-public information with non-HHS Federal government agencies, consider 21 C.F.R § 20.85.) A written agreement should refer to the provisions of FDA's laws and procedures regarding the sharing of non-public information. The sharing of non-public information pursuant to an informal arrangement should also be conducted according to FDA's laws and procedures for such sharing, and FDA should notify the receiving party of that information.

3-10-4 Work Sharing Agreements

FDA may formalize work-sharing agreements by entering into Partnership Agreements, Inter-Agency Agreements, and Memoranda of Understanding (MOU's) between (FDA), and other federal or state, and foreign government agencies. Some work-sharing agreements are covered under Staff Manual Guides (SMG) 2810, 2820, and 2830. FDA shares non-public information under an agreement with FDA regulations and procedures by FDA must follow its laws and procedures to share non-public under an agreement.

3-10-5 Alternatives to Work Sharing Agreements

Where a work-sharing agreement between FDA and a federal, or state authority is not in effect, FDA should promote cooperation between state and federal authorities to the greatest extent possible. To this end, FDA regional management can use an "Exchange of Correspondence," which is essentially an exchange of letters/memoranda in which each Agency (FDA and state) sets forth those selective program areas where each believes a cooperative work-sharing effort is appropriate. FDA also may enter into contracts with state government agencies to carry out its mission.

3-10-6 Agreement Format and Content

(1) Format
To insure that there is a relatively uniform national approach in the development and implementation of these agreements, consider using the basic format in Exhibit 3-15. On a case-by-case, FDA may adapt this model for use as an agreement with a non-FDA Federal government agency.

The model offers some "boilerplate" language that may be used in developing the terms of agreement. Contact DFSR if you are interested in adding to, deleting, or modifying the provisions in the model form, especially if the changes involve FDA policy or enforcement of statutes(s), the sharing of non-public information, or continued maintenance of confidentiality of non-public information. Some variations may require headquarters' or OCC concurrence. DFSR also might consult with Contact ORA's Office of Resource Management (ORM) (HFC-10).

(2) Content

a. Subject of agreement. The subject matter of an agreement may vary, but must be within the regulatory jurisdiction of the Parties. Each Party should comply with its legal responsibilities under such an agreement, e.g., it may be appropriate for the agreement to provide that the Parties retain independent responsibility over some aspect of the work covered by the agreement. The Parties should decide how they will apportion work. For example, under an agreement, one Party might agree to collect product samples for analysis by the other Party.

b. Goals. Each agreement should describe significant, mutually beneficial, realistic, and practical goals (anticipated outcome) and related activities necessary to accomplish the goal(s) and indicate whether a time frame applies. To measure the extent to which goals are met, each agreement may include a mechanism to monitor in-process activities (output measurement) and contain a means by which the Parties may conduct a final evaluation. It is helpful to set out the anticipated benefits (ultimate outcomes) of reaching the goal. The extent of description may vary.

c. Resource commitments. An agreement might have provisions about resources because both Parties must be able to contribute a portion of the resources necessary to accomplish the terms of the agreement. For those reasons the Parties should discuss prior to entering into an agreement the expenditure of resources likely to be required for the division of labor agreed upon, the priorities each Party expects to assign to the tasks, and if any, competing regulatory considerations.

d. Confidentiality provisions.

e. Quality assurance provisions. A work-sharing agreement should provide that a quality assurance evaluation might be performed at the request of either Party to ensure that the agreement is being carried out efficiently and effectively in the interest of each Party. To this end, the Parties should meet periodically (annually or semi-annually) to conduct such an evaluation. See Exhibit 3-15, Attachment A – Model Agreement Format Joint Planning, Option a or b. While no formal reporting format is required, the agreement should include and the parties should agree to the method of exchange (e.g., by memorandum, discussion during program review and planning conference(s), etc.).

f. Duration of the agreement.

g. Designation of agency official authorized to sign the agreement. For agreements with state or local government agencies, either the Regional or District Food and Drug Director, at the option of the RFDD, may sign the agreement for FDA. The Federal MOU under the BT Act will indicate the signatory.

3-10-7 Record Keeping

(1) Copies. The FDA component that is taking the lead in developing the work sharing agreement should prepare two copies of the work-sharing agreement for FDA, in addition to a copy for the non-FDA Party. When the Parties sign the agreement, the sponsor will submit a

signed original under cover memorandum to DFSR. For state and local government agreements, the regional office will maintain one original signed copy of the agreement. Any subsequent modification or renewal to the agreement should be documented and an original signed copy forwarded to DFSR, see Exhibit 3-16, Attachment B–Model Addendum. For agreements with other Federal government agencies, contact ORM for advice on the number of copies, etc.

(2) Official repository. The Division of Contracts and Grants Management, Office of Administration, State Contracts and Assistance Agreements Branch (HFA-520) (DCGM/SCAAB) is designated as the official repository for agreements with state or local agencies. DCGM/SCAAB maintains a current listing of all MOU's and agreements. One original, plus one copy will be transmitted by DFSR to DCGM/SCAAB. The signed original will be the official repository copy. Send an electronic file of the agreement, preferably in Word, to DFSR. DCGM/SCAAB will assign a control I.D. number (prefix 225) to the agreement and return the copy document to DFSR with the assigned control number denoting the official repository's receipt of the agreement. For agreements with other Federal government agencies, contact ORM for advice on the official repository for those agreements.

3-10-8 References

For further information related to Partnership Agreements and Contracts with states, other federal agencies, industry, educational institutions and associations see ORA's websites:

Partnership Agreements: http://www.fda.gov/ora/partnership_agreements/default.htm.

State Contract: http://www.fda.gov/ora/Partnership_Agreements/contracts/default.htm.

3-11 ATTACHMENTS AND EXHIBITS

ATTACHMENTS:
A – MODEL AGREEMENT FORMAT
B – MODEL ADDENDUM

EXHIBITS:
3-1 SAMPLE QUESTIONS LISTED ON A CURRICULUM VITAE
3-2 FORM: ACCEPTANCE OF COMMISSION
3-3 FORM FDA 200A: IDENTIFICATION CARD
3-4 FORM FDA 1990A: AUTHORITY CARD
3-5 FORM FDH 2088: CERTIFICATE OF COMMISSION
3-6 MODEL LETTER OFFERING A COMMISSION TO AN AGENCY HEAD
3-7 MODEL LETTER OFFERING A COMMISSION TO NON-AGENCY HEADS
3-8 FORM: BASIC INFORMATION FROM CANDIDATE
3-9 FORM: INSTRUCTIONS TO CANDIDATE
3-10 FORM: REQUEST FOR FDA MATERIALS
3-11 MODEL LETTER TRANSMITTING NON-PUBLIC INFORMATION
3-12 FORM FDA 2081: COMMISSIONED OFFICER'S RECORD (OPTIONAL)
3-13 FORM: ANNUAL VALIDATION OF FDA CREDENTIALS
3-14 MODEL ANNUAL VALIDATION LETTER

Attachment A – Model Agreement Format

WORK - SHARING AGREEMENT

(INSERT TITLE, e.g., MEMORANDUM OF UNDERSTANDING)

BETWEEN

(INSERT NAME OF STATE AGENCY)

AND

(DISTRICT/REGION)

FOOD AND DRUG ADMINISTRATION

FORMAT

I. Purpose

II. Background

III. Substance of Memorandum of Understanding

- A. General Provisions
- B. Confidentiality
- C. FDA Agrees To:
- D. State Agency Agrees To:
- E. Conflict of Interest (if applicable)

IV Name and Address of Participating Agencies

V. Liaison (Designees from each Agency)

Name, Title

Address

Telephone

VI. Period of Agreement (Limited or Indefinite)

VII. Approval - Acceptance (Signatures, Title, Date)

(MOU TITLE)

I. PURPOSE: This agreement establishes a cooperative program between the (State Agency) and the (FDA region/district). This agreement sets forth the working arrangements between the agencies concerning: (e.g., the inspection or investigation of: [insert type inspection or products or name the program area]) in the State of _____.

II. BACKGROUND: (Briefly describe why the cooperative agreement is needed including phrasing; overall consumer protection will also be enhanced through joint planning and coordination efforts, thereby reducing duplication and providing for more efficient use of combined resources.)

III. SUBSTANCE OF AGREEMENT (This section delineates the work and responsibilities of the agencies.)

A. General Provisions (i.e., the agencies agree to):
B. Confidentiality
C. FDA Agrees To:
D. (State Agency) Agrees To:
E. Conflict of Interest (if applicable)

The following list of elements may be used to derive the areas applicable to this agreement. One or more of the "elements" may be used as appropriate. You may add more elements.

Elements

1. Joint Planning
2. Joint Inspections
3. Compliance Activities
4. Disasters
5. Recalls
6. Training
7. Sharing of Inspectional and Analytical Information (with a cross reference to the confidentiality provision)
8. Pesticide and Mycotoxin Data Exchange
9. Investigation of Foodborne Illnesses
10. Consumer Complaints

Suggested Term(s) of Agreement - (choose one or more option(s), except that all agreements will contain a provision addressing the sharing of non-public information, the maintenance of confidentiality of non-public information shared (see item III.E.), and a statement about the extent to which conflict of interest provisions apply.

1. **JOINT PLANNING** (Examples of Options include, are not limited to those set out below.)

   Option a.
   The Parties will meet (e.g., annually, semi-annually), to discuss and plan to assure that resources are efficiently and effectively used. The listing and scheduling of establishments to be inspected by each Agency will be completed at these planning meetings.

   Option b.
   The Parties will meet periodically to review working arrangements, evaluate accomplishments, maintain program uniformity, and plan future operations.

   Option c.
   The Parties intend to develop a Plan of Work describing specific activities to be carried out under this agreement. The Parties intend to meet at least once a year to review and revise the plan of work.

2. **JOINT INSPECTIONS**

   Either Party may, for training or compliance follow-up purposes, request a joint inspection. The implementation of joint inspections will depend on the availability of personnel and Agency priorities.

3. **COMPLIANCE ACTIVITIES** (Examples of Options include but are not limited to, those set out below.)

   Option a.
   The Parties will coordinate enforcement actions against persons, firms, or products subject to both Federal and State statutes and inspections.
   Option b.
   The Party that discovers a violation associated with an inspection will have the primary responsibility to follow through with appropriate compliance activity. Either Party may propose to refer a compliance matter to the other when it appears resolution can best be achieved under the authority of the other Party.
   Option c.
   Copies of Warning Letters issued to firms will be exchanged in a timely fashion.
   Option d.
   The Parties will coordinate and maintain close communication on all compliance activities associated with inspections of (type; e.g., food, drug, devices, etc.) establishments in the State of _____.

4. DISASTERS

Disaster Investigation: Each Party will cooperate in the resolution of problems involving contamination caused by such disasters as floods, fires, tornadoes, common carrier wrecks, chemical spills, etc. Each Agency may request assistance from the other on an as-needed basis. Much traceback and recall information is to be considered to be confidential information.

5. RECALLS (Examples of Options include, but are not limited to, those set out below.)

Option a.
(Insert name of State Agency) will assist FDA in monitoring recalls of products manufactured or distributed in the State of _____. This assistance will be limited to recalls involving products considered by FDA to represent significant health hazards.
Option b.
The FDA region/district will notify (insert name of State Agency) of all "hazard to health" recalls involving (food, drug, or devices) manufacturers or repackers within the State of _____. Such notification will generally be made through the Federal-State communications system.

6. TRAINING

Either Party may request training with the understanding that the ability to respond to such a request will depend on the availability of personnel and resources as well as the priorities of the responding Party.

7. SHARING INSPECTIONAL AND ANALYTICAL INFORMATION

The Parties may share will exchange information regarding firms subject to the jurisdiction of each Agency. Information to be exchanged may include: official establishment inventory (OEI); establishment inspection reports (EIR's); and analytical information and compliance activities, which include copies of correspondence with the regulated trade such as warning letters. EIR's and sample reports will not normally be exchanged when there are no adverse findings. However, a Party may provide this information if needed to assist the other Party and reduce any duplication of effort.

8. PESTICIDE AND MYCOTOXIN DATA EXCHANGE (Examples of Options)

Option a.
Pesticide and/or Mycotoxin Program: The Parties may exchange pesticide and (or) mycotoxin analytical results on (insert appropriate term such as all violative, etc.) samples collected within the State of _____.
Option b.
(_____) may provide (_____) with results of analyses of food, feed, and related samples, that are examined for pesticides, industrial chemicals, or mycotoxins.

9. INVESTIGATION OF FOODBORNE ILLNESS (Examples.)

Option a.
The Parties may, as necessary, conduct joint inspections of foodborne disease outbreaks. The Parties intend to share exchange copies of all investigational and analytical results.
Option b.
The (insert name of State Agency) intends to promptly inform FDA of foodborne illnesses involving commercially prepared food products subject to the Federal Food, Drug, and Cosmetic Act.
Option c.
FDA intends to promptly inform (name State Agency) of foodborne illnesses involving commercially prepared food within the State subject to State or Federal statutes.
Option d.
The Parties intend to promptly inform each other of foodborne illnesses involving commercially prepared food.

10. CONSUMER COMPLAINTS

The Party receiving the initial complaint intends to investigate consumer complaints regarding (insert description; food and drug related products). The investigating Party may refer the matter to the other Party if the situation indicates that the other Party has a greater interest in the matter. Joint inspections also may be conducted. Sharing will be done in accordance with the Confidentiality provisions.

IV. NAME AND ADDRESS OF PARTIES AGENCIES

A. State Agency
B. Food and Drug Region/District

V. LIAISON OFFICIALS

A. For State Agency
Name, Title
Address
Telephone

EXAMPLE:
Director, Compliance Division
(Currently, Joe Doe)
State Department of Health
Room 101, State Office Building
Tel. (Commercial)

B. For FDA same format as (A.) above. Insert Federal liaison information.

VI. SETTLEMENT OF DISPUTES

The Parties will strive to resolve by mutual agreement any disputes that arise from the interpretation or application of this agreement.

VII. PERIOD OF AGREEMENT

Option a. (Indefinite)
This agreement will become effective upon acceptance by each Party and shall remain in effect indefinitely. It may be modified by mutual written consent or may be terminated by either Agency upon a 30-day advance written notice to the other Party.
Option b. (Limited)
The agreement, when signed by each Party, will be effective from date of last signature and will expire one year from that date. It may be renewed or modified by mutual written consent or may be terminated by either Party upon 30-day advance written notice to the other Agency.

VIII.

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR _____ (NAME THE STATE AGENCY)
BY: _____	BY: _____
TITLE:_____	TITLE:_____
DATE:_____	DATE:_____

Attachment B –Model Addendum

AGREEMENT (INSERT NAME, E.G., MEMORANDUM OF UNDERSTANDING)

Between

(Insert Name of State Agency)

and

(Insert Name of FDA Region)
U. S. Food and Drug Administration

ADDENDUM

This addendum authorizes the renewal of the agreement developed by the above two Parties for the (insert purpose, for example. coordination of food processing, storage and service, and interstate carrier support inspectional activities) with (insert state or county) without revision for the period ending (insert date).

Approved for the (state Agency) by:

_____ _____
Name and Title Date

Approved for the (Region, FDA) by:

_____ _____
Name and Title Date

Exhibit 3-1

SAMPLE QUESTIONS LISTED ON A CURRICULUM VITAE

The following questions are the ones for which answers are usually found on a routine curriculum vitae (CV) prepared by an individual seeking employment. However, few, if any, CVs would contain answers to all the questions on this checklist.

1. Title (Mr., Mrs., Ms., Dr.)
2. Name (first, middle, last)
3. Home address (apartment no., street, city, state, Zip)
4. Home telephone number (including area code)
5. Office telephone number (including area code)
6. Date of birth
7. Place of birth (city, state or other country)
8. Citizenship
9. Marital status (married, widowed, divorced, single, separated)
10. High school (name, location, and date of graduation)
11. Colleges attended (names, locations, and dates)
12. Major field(s) of study at highest level of college work
13. Degrees confirmed (dates)
14. Honors, awards, fellowships, or scholarships received in schools
15. Honors and recognition received in professional life
16. Employment history. Starting with current position and working backwards, preferably to completion of education, give: name and address of employer, title of position held, name and telephone number of immediate supervisor
17. Three references (other than current employer or family - include their addresses and telephone numbers)
18. Licenses or certificates held (cite type and issuing Agency)
19. Military or civilian federal service (branch, department, Agency, rank or rating at separation, date of separation)

Exhibit 3-2

FORM: ACCEPTANCE OF COMMISSION

(Regional letterhead)

ACCEPTANCE OF COMMISSION

In accepting a commission as an official of the Department of Health and Human Services as authorized by law, I have read and understand the provisions of 21 U.S.C. § 331(j) [Section 301(j) of the Federal Food, Drug, and Cosmetic Act (the Act)] which contain this specific prohibition:

> "The using by any person to his own advantage, or revealing, other than to the Secretary or official or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of sections 404, 409, 412, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 708, or 721 concerning any method or process which as a trade secret is entitled to protection..."

Section 520(c) of the Act also prohibits the release of information exempt from disclosure pursuant to 5 U.S.C. § 552(b)(4) of the Freedom of Information Act that is obtained under sections 513, 514, 515, 516, 518, 519, 704, or under section 520(f) or 520(g) of the Act.

I understand that any non-public information I receive from the Food and Drug Administration, including trade secret and commercial confidential information, is protected from disclosure under Federal law. I further understand that if I make any unauthorized disclosures of trade secret or confidential commercial information I will be committing a criminal violation under Federal Law, such as 21 U.S.C § 331(j) and 18 U.S.C. § 1905.

I shall not use this information to further my private interests or the interests of any other person. I attest that I do not have any personal interests (stocks, bonds, etc.) and have no financial or business relationships in firms operating in the specific fields where authority has been/will be conferred on me as a commissioned official.

_____ _____

signature date

Certification of the Recommending Agency Head

I certify that, to the best of my knowledge, this candidate for a FDA Commission is an individual of good character, ability, and work habits and is capable of carrying out the responsibilities of a commissioned official of the Department of Health and Human Services, Food and Drug Administration.

_____Signature of Agency Head

Exhibit 3-3

FORM FDA 200A: IDENTIFICATION CARD

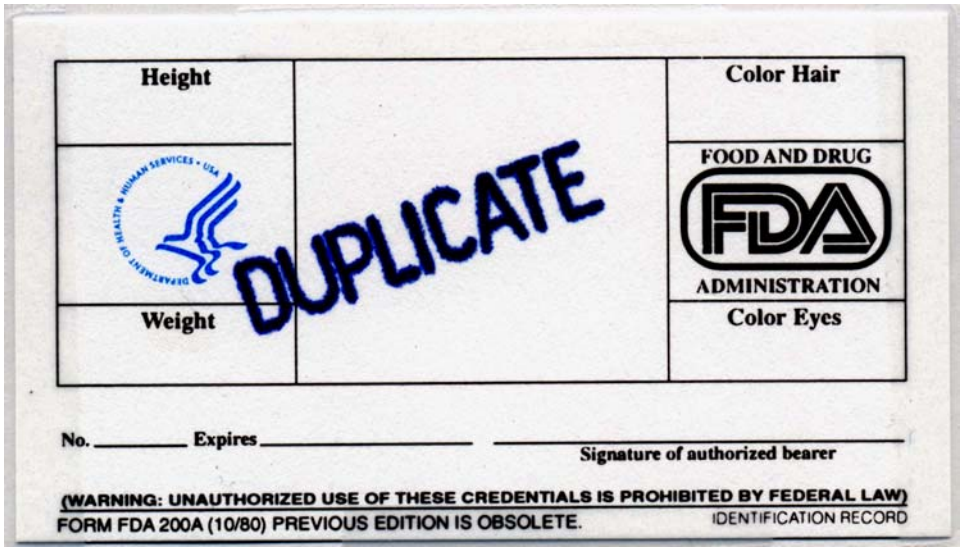
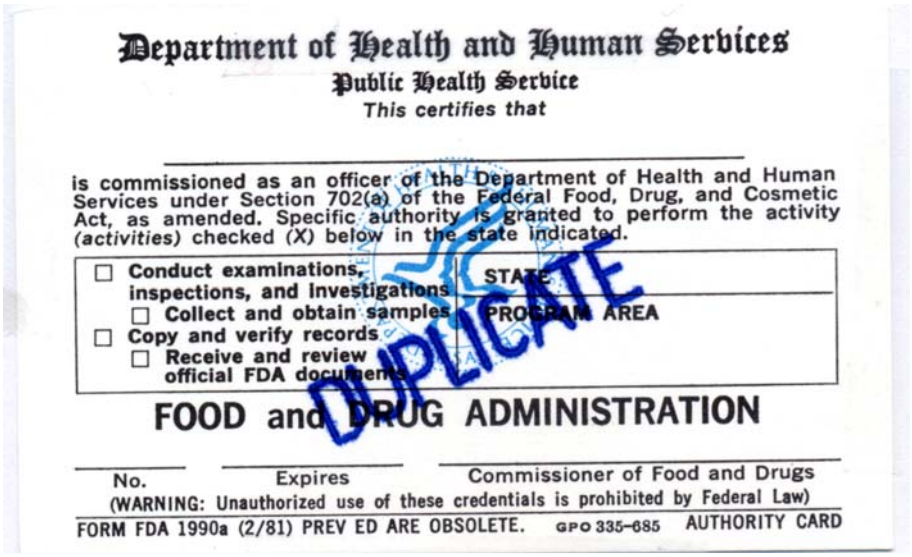


Exhibit 3-4

FORM FDA 1990A: AUTHORITY CARD



Department of Health and Human Services
Public Health Service
This certifies that

_____

is commissioned as an officer of the Department of Health and Human Services under Section 702(a) of the Federal Food, Drug, and Cosmetic Act, as amended. Specific authority is granted to perform the activity *(activities)* checked (X) below in the state indicated.

☐ Conduct examinations, inspections, and investigations ☐ Collect and obtain samples ☐ Copy and verify records ☐ Receive and review official FDA documents	STATE PROGRAM AREA

DUPLICATE

FOOD and DRUG ADMINISTRATION

No. Expires Commissioner of Food and Drugs

(WARNING: Unauthorized use of these credentials is prohibited by Federal Law)

FORM FDA 1990a (2/81) PREV ED ARE OBSOLETE. GPO 335-685 AUTHORITY CARD

Exhibit 3-5

FORM FDA 2088: CERTIFICATE OF COMMISSION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Certificate of Commission

DUPLICATE

IS COMMISSIONED AS AN OFFICER OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES UNDER AUTHORITY CONFERRED BY SECTION 702(a) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO CONDUCT SPECIFICALLY AUTHORIZED ACTIVITIES IN DESIGNATED PROGRAM AREAS IN THE STATE OF _____ FOR THE PURPOSE OF THE ACT. THIS COMMISSION EXPIRES _____.

_____
COMMISSIONER OF FOOD AND DRUGS

FORM FDA 2088 (12/96)

Exhibit 3-6

MODEL LETTER OFFERING A COMMISSION TO AN AGENCY HEAD

(Regional letterhead)

State Health Commissioner
State/Local Agency
123 Elms Street
Somewhere, US 00000

Date

Dear (NAME):

It is my distinct pleasure to offer you a commission in the Department of Health and Human Services, Food and Drug Administration (FDA). Commissioner (NAME) recently made a particular point of his desire to have you serve with us.

The commission will enable you to receive and review official FDA documents. This will permit us to benefit from your review and recommendations on policy matters that are still confidential. We are anxious to get your input on current public health issues, not only as they affect your State, but the nation as a whole.

Enclosed with this letter is a packet of informational materials and some forms that need to be filled out so that we can finish processing your commission. In particular, please review the booklet, "The FDA Commission." If you have any questions on this material, please give me a call.

Our agencies have a good record of working closely together to protect the citizens of (name of state). Your acceptance of this commission is a continuation of this important cooperation and coordination.

Best personal regards,

Sincerely,

Regional Food and Drug Director

Enclosure(s)

Exhibit 3-7

MODEL LETTER OFFERING COMMISSION TO NON-AGENCY HEADS

(Regional letterhead)

State Health Commissioner
State/Local Agency
123 Elms Street
Somewhere, US 00000

Date

Dear Commissioner:

I am pleased to offer, with your concurrence, FDA commissions to the following individuals on your staff:

NAME, AGENCY {for (name program areas)}

These commissions will authorize these individuals to (select one or more) conduct examinations, inspections, and investigations; collect and obtain samples; copy and verify records; and receive and review official FDA documents. Unless limitations are noted in their commissions they will have the same authority that FDA officials have. These individuals will, of course, continue to serve under your direction.

Enclosed with this letter are packets of informational material and forms for each candidate. Please note that your signature will be required on the "Acceptance of Commission" form and, if "Application for Commission" forms are included, in section 19 of that form. When these forms are completed, please ask the individuals to return them to my office, attention: (name of FDA official).

We will be most happy to have these members of your staff join the ranks of FDA commissioned officials, and I personally appreciate your willingness to permit them to serve with us.

Sincerely yours,

Regional Food and Drug Director

Enclosure(s)

Exhibit 3-8

FORM: BASIC INFORMATION FROM CANDIDATE

(Regional letterhead)

BASIC INFORMATION FROM A CANDIDATE FOR AN FDA COMMISSION

This information is necessary to process your commission. Please complete this form and return it to the FDA Regional Office. Accuracy is essential.

Last or Family Name:
_____

First or Given Name:
_____

Middle Name(s) or Initial(s)
_____

(if you do not have a middle name or a middle initial, enter "not applicable" [N/A])

Other Names or Aliases Used:_____
_____

Date of Birth:_____ Place of Birth:_____
(If not born in the United States, please attach photocopy of naturalization papers or other document attesting to citizenship)

Home Address: _____
City, State, and Zip: _____
Job Title: _____
Agency: _____
Division or Department: _____
Address: _____
City, State, and Zip: _____
Data for Credentials:
Height:_____Weight:_____Color Eyes:_____
Color Hair: _____

I affirm that I am an American citizen.
Date: _____ _____
(signature)

Exhibit 3-9

FORM: INSTRUCTIONS TO CANDIDATE

(Regional letterhead)

INSTRUCTIONS TO CANDIDATE FOR AN FDA COMMISSION

You have been offered a commission as an official of the Department of Health and Human Services, U.S. Food and Drug Administration (FDA). Congratulations! However, before the actual commission can be conferred, some processing is necessary. This information sheet is designed to help you with the paperwork.

- **The FDA Commission (brochure)**. This booklet contains information about the FDA commission that you need to know. Please read this material carefully and retain for future reference.

- **Acceptance of Commission**. You must sign and date this form. If you have questions about possible conflict of interest, please talk to your FDA advisor. Note that this form also requires a certification signed by the head of your Agency. Please obtain this signature and return the form.

- **Basic Information From a Candidate for an FDA Commission**. This form asks for some basic information needed to complete processing of your commission. Please answer each question, sign, and return. Accuracy is essential.

- **Identification Card (Form FDA 200A).** If you are to be issued credentials, we need your signature on this card. Please sign in black ink. **Do not fill in** any other part of the card; this will be done later. Return this card.

- **Photographs**. We need three color pictures of your face, including a portion of your upper shoulders. The pictures will be trimmed to 1 3/8" high x 1 1/2" wide. In addition -- and this is optional -- we would appreciate a black and white photograph of you that could be used for promotional purposes. Photos in JPG format on a diskette, digital, or as an email attachment are also acceptable.

If you have any questions about this material, please contact _____, Commissioning Coordinator, FDA _____ Region at (xxx) xxx-xxxx or by email at _____.

Exhibit 3-10

FORM: REQUEST FOR FDA MATERIALS

(Regional letterhead)

REQUEST FOR FDA SUBSCRIPTIONS, LITERATURE, AND MANUALS

As a FDA commissioned official, I would appreciate receiving the following materials. I understand that manuals and some directories require frequent updating. It should also be noted that some of the following are, or in the future may be, only available on the Internet. Please send the material marked "H" to my residence, and the material marked "O" to my office.

Name: _____Title: _____

Office Address
Department number.:_____
Street: _____
City:_____
State and Zip:_____

Home Address _____
Apartment number _____
Street:_____
City: _____
State and Zip:_____

(mark an "H" or an "O" within the brackets next to the material you want)

[ ] FDA Investigations Operation Manual (also on internet at:www.fda.gov//ora/inspect_ref/iom/iomtc.html)
[ ] FDA Compliance Policy Guides Manual (also on internet at:www.fda.gov/ora/compliance_ref/cpg/default.htm)
[ ] FDA Regulatory Procedures Manual (also on internet at: www.fda.gov/ora/compliance_ref/rpm_new2/contens.html)[ ] Broadcast information (List program areas of interest and list your email address)
[ ] Catalog of Courses & Training Materials (ORA/DHRD) [ ] Approved Drug Products With Therapeutic Equivalence Evaluations (also on the internet at http://www.fda.gov/cder/orange/adp.htm)
[ ] Laboratory Information Bulletin (LIB)
[ ] Directory of State Officials (also on internet at: www.fda.gov/ora/fed_state/directorytable.htm))
[ ] Other: _____

Exhibit 3-11

MODEL LETTER TRANSMITTING NON-PUBLIC INFORMATION TO COMMISSIONED FEDERAL, STATE, OR LOCAL OFFICIAL

(Remove the italicized information in brackets prior to sending the letter.)

(Regional letterhead)

FOR OFFICIAL USE ONLY

[Insert Date]

[Insert Name, Title, and Address of Commissioned Official]

Dear _____:

This letter accompanies agency records and information that the Food and Drug Administration (FDA) is sharing with you as part of the cooperative efforts with FDA relating to the _____ *[insert name of agreement, contract, etc.]* dated _____. *[If no formalized agreement, refer simply to the cooperative efforts under the commissioning status.]*

Please *[Insert the reason why you are sending the information, e.g., to request review and comments, etc.]*

The titles or descriptions of the non-public records and information are listed below: *[Insert title or brief description, date, etc. of record]*

The records contain one or more of the following categories of information that FDA considers to be non-public information:

[Check applicable items below.]
____ trade secrets *[Note: This category applies even if the company gave FDA consent to disclose its information to the Federal or State government official.]*
____ confidential commercial or financial information; *[Note: This category applies even if the company gave FDA consent to disclose its information to the Federal or Stat government official.]*
____ personal privacy information
____ deliberative process or pre-decisional information
____ open investigatory information
____ other
_____

This information is for official use only. As an FDA commissioned official, you must maintain the confidentiality of this material unless and until FDA determines that the information may be released to the public, and gives you written permission to disclose the information.

You may share this material only with members of your staff who hold FDA commissions specifying that they can receive and review official FDA documents. Divulging this material to others is not permitted. If you wish to share this information with individuals other than those just described, please contact the Director of FDA's Division of Federal-State Relations, for the appropriate procedures.

Thank you again for your assistance. If you have any questions, please contact me at: _____.

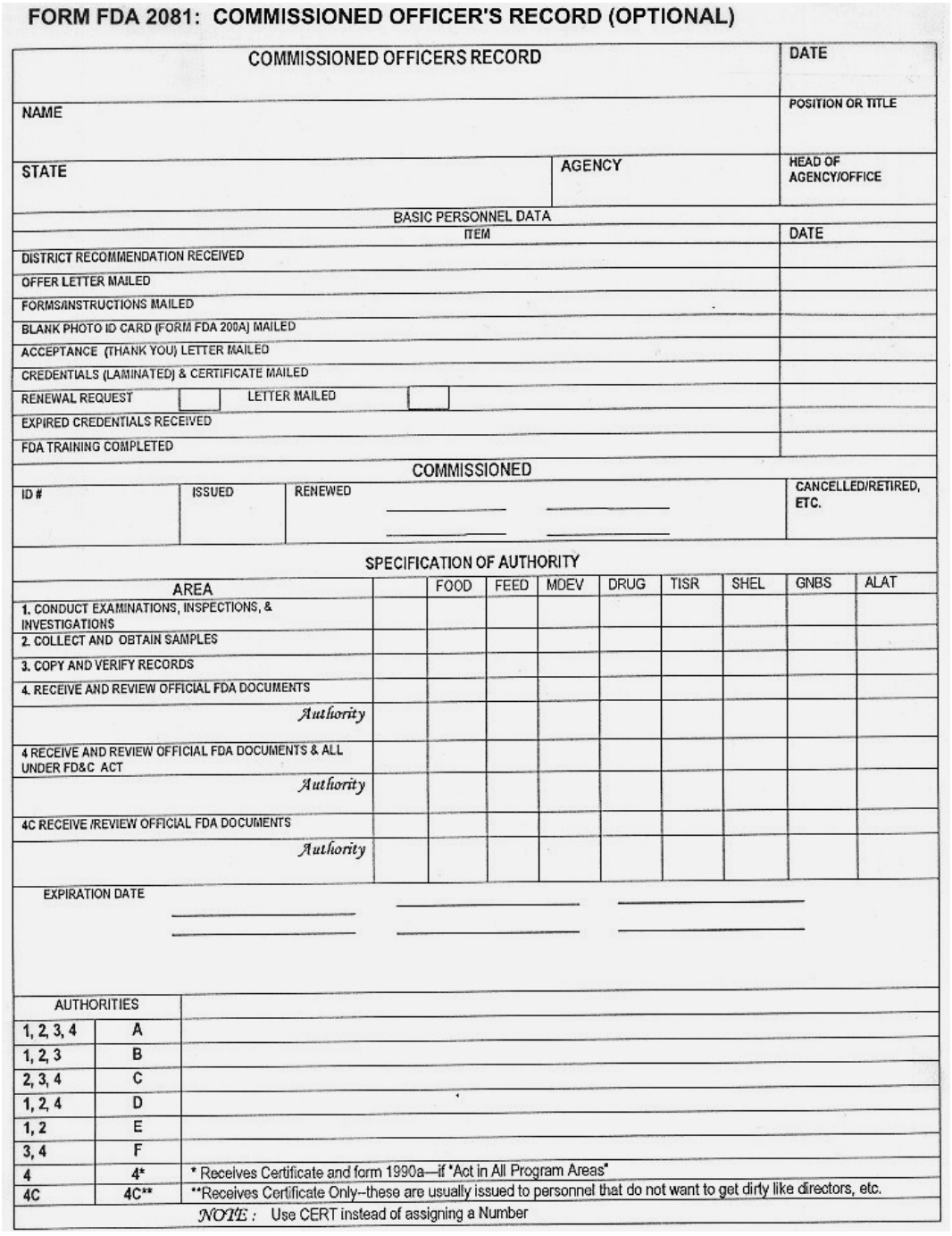
Sincerely,

Regional Food and Drug Director

Enclosure(s)

Exhibit 3-12

FORM FDA 2081: COMMISSIONED OFFICER'S RECORD (OPTIONAL)



FORM FDA 2081: COMMISSIONED OFFICER'S RECORD (OPTIONAL)

COMMISSIONED OFFICERS RECORD		DATE
NAME		POSITION OR TITLE
STATE	AGENCY	HEAD OF AGENCY/OFFICE

BASIC PERSONNEL DATA

ITEM	DATE
DISTRICT RECOMMENDATION RECEIVED	
OFFER LETTER MAILED	
FORMS/INSTRUCTIONS MAILED	
BLANK PHOTO ID CARD (FORM FDA 200A) MAILED	
ACCEPTANCE (THANK YOU) LETTER MAILED	
CREDENTIALS (LAMINATED) & CERTIFICATE MAILED	
RENEWAL REQUEST [ ] LETTER MAILED [ ]	
EXPIRED CREDENTIALS RECEIVED	
FDA TRAINING COMPLETED	

COMMISSIONED

ID #	ISSUED	RENEWED	CANCELLED/RETIRED, ETC.
		_____ _____ _____ _____	

SPECIFICATION OF AUTHORITY

AREA		FOOD	FEED	MOEV	DRUG	TISR	SHEL	GNBS	ALAT
1. CONDUCT EXAMINATIONS, INSPECTIONS, & INVESTIGATIONS									
2. COLLECT AND OBTAIN SAMPLES									
3. COPY AND VERIFY RECORDS									
4. RECEIVE AND REVIEW OFFICIAL FDA DOCUMENTS									
Authority									
4 RECEIVE AND REVIEW OFFICIAL FDA DOCUMENTS & ALL UNDER FD&C ACT									
Authority									
4C RECEIVE /REVIEW OFFICIAL FDA DOCUMENTS									
Authority									

EXPIRATION DATE _____ _____ _____ _____ _____ _____

AUTHORITIES		
1, 2, 3, 4	A	
1, 2, 3	B	
2, 3, 4	C	
1, 2, 4	D	
1, 2	E	
3, 4	F	
4	4*	* Receives Certificate and form 1930a—if "Act in All Program Areas"
4C	4C**	**Receives Certificate Only--these are usually issued to personnel that do not want to get dirty like directors, etc.

NOTE: Use CERT instead of assigning a Number

Exhibit 3-13

FORM: ANNUAL VALIDATION OF FDA CREDENTIALS

(Regional Letterhead)

Accounting for FDA Credentials for Calendar Year 20XX

Agency:

Name Credential Number

Validation Statement

I have personally viewed all the FDA credentials listed above and confirm that these individuals are employed by this Agency and that the credential you listed above exists and is used by that individual in his/her capacity as a commissioned official. Any exception to this statement is indicated below:

[ ] None, or:

Date: _____

Signature

Name: Title:

Exhibit 3-14

MODEL ANNUAL VALIDATION LETTER

(Regional letterhead)

State Health Commissioner Date
State/Local Agency
123 Elms Street
Somewhere, US 00000

Dear Commissioner:

As you are aware, the FDA credentials held by members of your Department have a high potential for misuse, particularly if lost. Because of their importance, we are conducting a review to make sure that each credential exists and is held by the person to whom it was issued.

Enclosed is our form "Accounting for FDA Credentials for Calendar Year 20xx" listing each member of your Department holding credentials and the identification numbers assigned to these credentials. We ask that you, or an official designated by you, make a personal examination of each credential, confirm that its number matches the number on our form, and then certify to FDA that the credential exists.

If anyone on the list is no longer an employee of your Agency, or will leave its employ before needing to use his or her credentials, please indicate this on the form by crossing off his or her name. I'd also appreciate it if the credentials could be collected from the individual(s) and returned to me via registered letter.

If any credentials cannot be located, please advise me immediately.

Thank you for your assistance.

Sincerely yours,

Regional Food and Drug Director

Enclosure(s)