

## Chapter 3 COMMISSIONING

### COMMISSIONING FEDERAL, STATE, AND LOCAL OFFICIALS; ACCEPTING A STATE'S COMMISSION

This chapter contains the following sections on commissioning Federal, state, and local regulatory officials; and accepting a state's commission.

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INTRODUCTION; OBJECTIVES

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

An FDA commission is a delegated authority from the Commissioner of Food and Drugs to an individual to act on his/her behalf. A health, food, or drug officer or employee of any State, Territory, or political subdivision thereof (herein referred to as “state and local officials”) may be commissioned to conduct examinations and investigations on FDA’s behalf for the purposes of the Act. For example, a commissioned official may work on behalf of the FDA under contract, partnership, or for the purposes of other worksharing agreements. It may be necessary for state or local officials to carry pocket credentials in cases where they are conducting assignments under FDA authority, such as conducting examinations, inspections, investigations or collecting samples, and copying and verifying records. In other cases, it may be necessary for them to only be commissioned with certificate to receive and review information.

FDA developed its commissioning program to make inter-agency cooperation more effective thereby increasing the amount of public health protection afforded to the American consumer. FDA achieves its goal by:

1.     Permitting commissioned Federal, state and local officials to operate under Section 702(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (hereafter referred to as the Act).
2.     Enabling those commissioned officials to effectively carry out their responsibilities by reviewing FDA information, such as draft policy, that is protected from disclosure to the public by the Freedom of Information Act (FOIA).

Each state or local official commissioned by FDA will receive a certificate of commission. In addition, certain commissioned officials who will be doing work in the field under FDA authority will be provided with a set of pocket credentials.

This chapter focuses on commissioning of state and local officials, and references FDA's authority to commission officials from other Federal government departments and agencies under important provisions regarding the safety and security of regulated products, including the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (hereafter referred to as the BT Act); and the Drug Quality and Security Act of 2013 (DQSA).

FDA's Office of Regulatory Affairs, Office of Partnerships (OP) has primary responsibility for overseeing the implementation of FDA's Commissioning Program. For state or local officials, ORA district directors (DDs) have primary responsibility for carrying out the program. For Federal officials, the inter-agency Memorandum of Understanding (MOU) that is required by the BT Act should include provisions regarding the implementation of the commissioning procedures. For that reason, those provisions are briefly mentioned.

## **3-2    AUTHORITIES**

Section 702(a)(1)(A) of the Act authorizes FDA "to conduct examinations and investigations for the purposes of this Act...through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department."

Section 702(a)(2) of the Act, as amended by the BT Act, authorizes FDA, pursuant to a memorandum of understanding, to "conduct examinations and investigations for the purposes of the Act through the officers and employees" of other Federal departments and agencies. Under this provision, FDA may commission other Federal officials pursuant to a memorandum of understanding between the Secretary and the head of the other Federal department or agency. Such a memorandum of understanding is only effective in the case of examinations or inspections at facilities or other locations that are "jointly regulated" by FDA and the other Federal agency or department.

Section 503A and 503B of the Act, as amended by the DQSA, requires the Secretary to establish a mechanism to receive submissions from state boards of pharmacy concerning certain actions taken against compounding pharmacies or expressing concerns that a compounding pharmacy may be acting contrary to section 503A. This section is to be implemented in consultation with the National Association of Boards of Pharmacy (NABP). In addition, state boards of pharmacy must be notified when the Secretary receives certain state submissions or makes a determination that a compounding pharmacy is acting contrary to section 503A.

### 3-3 CONSIDERATIONS BEFORE COMMISSIONING

Information for the public on considerations before commissioning Federal, state, and local regulatory officials; and accepting a state's commission now can be found on the following Office of Partnership's page, [For Federal, State, Local, Tribal, and Territorial Officials](#), including [Office of Partnerships Contacts](#) and [Communications & Outreach](#).

Procedures for FDA staff can be found on the Office of Partnerships and Operational Policy/Office of Partnership's Intranet page.

### 3-4 DOCUMENTATION; POCKET CREDENTIALS

Information for the public on documentation related to commissioning Federal, state, and local regulatory officials; and accepting a state's commission now can be found on the following Office of Partnership's page, [For Federal, State, Local, Tribal, and Territorial Officials](#), including [Office of Partnerships Contacts](#) and [Communications & Outreach](#).

Procedures for FDA staff can be found on the Office of Partnerships and Operational Policy/Office of Partnership's Intranet page.

### 3-5 CONFLICT OF INTEREST

#### 3-5-1 Written Assurances

##### 1. *State or local officials*

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.

## **2. Federal officials**

For Federal officials, the governing 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 officials**

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 them along with other documentation to the FDA Division and OP for resolution. OP will discuss the matter with the DD and a decision will be reached as to whether or not the individual can be commissioned. OP may contact the FDA's Ethics and Integrity Staff (HFA-320). This discussion should be conducted in person by the DD in the case of a state agency head. If circumstances make this impractical, a DD, director of state programs, or deputy 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 DD, deputy 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 related to the financial interest.

## **2. State or local officials**

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 division and OP 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 pocket credentials. 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 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 make 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 FDA Information**

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 Sharing Non-public Information under 21 CFR. § 20.88 (State)**

FDA may share certain non-public information pursuant 21 CFR 20.88 with state and local officials, including those officials who are not commissioned. For FDA to share confidential commercial information, there must be a written statement from the state agency establishing that the State government agency has the authority to protect confidential commercial information from disclosure and a written commitment that the State government agency will not further disclose any such information provided to it. This is called a 20.88 agreement. Trade secrets and information prohibited from disclosure under the Privacy Act may not be shared under 20.88 agreements.

OP has established a number of 20.88 agreements which provide a streamlined process for information sharing related to food (including animal feed) and cosmetics. For information on 20.88 agreements, contact Office of Partnerships and Operational Policy (OPOP) at [InfoShare-ORA@fda.hhs.gov](mailto:InfoShare-ORA@fda.hhs.gov).

### **3-6-4 Sharing Non-public Information under 21 CFR. § 20.85 (Federal)**

FDA may share certain non-public information to the other Federal agency under 21 CFR. §20.85 (Disclosure to other Federal government departments and agencies). For information on 20.85, contact OPOP at [InfoShare-ORA@fda.hhs.gov](mailto:InfoShare-ORA@fda.hhs.gov).

### **3-6-5 Privacy Act**

1. The FDA Regional Office and the Office of Partnerships maintain records on individuals who have applied to be commissioned (e.g., background investigation, commissioning package).
2. Any person may review his or her own file by requesting a copy of it from RFDD under the Privacy Act. All other questions about Privacy Act records should be addressed to:  
FDA's Division Freedom of Information (HFI-35),  
Food and Drug Administration, 12420 Parklawn Drive,  
Rockville, MD 20857.

## **3-7 CONSIDERATIONS AFTER COMMISSIONING**

### **3-7-1 Duration**

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

### **3-7-2 Background Investigation**

#### **1. State or local officials**

In addition to background investigations conducted prior to commissioning (see [subsection 3-3-3](#)), in its discretion, FDA may conduct a background investigation on a state or local government official after FDA commissions that official (e.g., when a commission is renewed) and should inform the official of FDA's authority to do so.

#### **2. Federal officials**

For Federal officials, the MOU may contain provisions about a background investigation.

### 3-7-3 Legal restrictions

#### 1. *General*

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.

#### 2. *State or local officials*

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.

#### 3. *Federal officials*

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 the Office of Partnerships.

### 3-7-4 Renewal of Commission

#### 1. *State or local officials*

Commissions of state or local officials are valid for five years. The division will review the commissioned official's record approximately three (3) months prior to expiration of the commission. This review considers all pertinent aspects of 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 completed application package ([Exhibit 3-3](#)) should be sent to the District, from the state or local official, signaling the intent to request a renewal.

If the DD agrees to a renewal, the application package should be sent to the Office of Partnerships for processing. The FDA has the option to conduct a background investigation at any time during the renewal process, if deemed necessary. The expired pocket credential must be returned to Office of Partnerships. See [Exhibit 3-3](#).



## **2. Federal officials**

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**

#### **1. General**

FDA will not renew a commission if the holder has changed positions outside of the organization/agency, resigned, or retired. 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."

#### **2. State or local officials**

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 pocket credentials, the division commissioning contact collects the pocket credentials as soon as a decision is made that a commission will not be renewed. The division commissioning contact will destroy the expired pocket credential in accordance with their division procedures and will inform OP when the destruction has been completed. Non-renewal of a commission is without prejudice; that is, FDA may commission that official later should conditions change.

#### **3. Federal officials**

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

### **3-7-6 Suspension of Commission**

#### **1. General**

ORA may use discretion at any time to revoke or suspend the commission of such authorized officials who is in violation of the following:

- a. Charges of a felony.
- b. Charges of a misdemeanor, excluding minor traffic offenses where the fine is less than \$500.
- c. Pending trial for a felony or misdemeanor charge, excluding minor traffic offenses where the fine is less than \$500.
- d. Pending investigation related to a felony or misdemeanor charge, excluding minor traffic offenses where the fine is less than \$500.

The decision to revoke or suspend an FDA commission will be communicated within 30 calendar days to both the individual and his/her supervisor.

## **2. State or local officials**

For commissioned state or local officials, within ten (10) calendar days after receiving a felony or misdemeanor charge (or pending trial or investigation), the details of the applicable charge must be communicated to their employer, and to the DD, deputy director, executive official, director of state programs, or other official specifically charged with oversight of the commissioning program. Within five (5) calendar days after receiving details of the charge, the DD must inform OP's National Commissioning Coordinator at [StateCommissioning@fda.hhs.gov](mailto:StateCommissioning@fda.hhs.gov). OP's National Commissioning Coordinator will work with Office of Security Operations and OP Senior Management to decide if suspension of the commission is required. After a decision has been reached, the OP National Commissioning Coordinator will recommend the appropriate action, to the DD specifically charged with oversight of the commissioning official..

If suspension of commission is not required and the DD concurs, a letter signed by the DD should be sent to the agency head stating that no further action will be taken.

If suspension of commission is required and division concurs, a letter signed by the DD should be sent to the agency head stating the details of the suspension and requesting that the certificate of commission, pocket credentials (if any), and any documents belonging to FDA be collected and returned to OP. The documents and all additional documentation from the division must then be sent via e-mail to [StateCommissioning@fda.hhs.gov](mailto:StateCommissioning@fda.hhs.gov).

Once a commission has been suspended, the FDA will wait for the final verdict of the charge to make its decision on revoking or reinstating the commission. If the state or local official is not charged with the felony or misdemeanor, FDA will use discretion to reinstate their commission. A follow up letter signed by the DD including the official's certificate of commission and pocket credential (if any), should be sent to the agency head stating the decision to reinstate. If the state or local official is charged with the felony or misdemeanor, their commission will be revoked immediately. A follow up letter signed by the DD should be sent to the agency head stating the decision of revocation. Once a commission has been revoked, that individual is no longer eligible for an FDA commission.

If there is a dissenting opinion between the DD and another FDA official regarding the suspension of an individual's commission, the ACRA, or appropriate senior ORA official, will be consulted for a final decision.

### 3-7-7 Revocation of Commission

#### 1. *General*

The issuance of a commission is discretionary and ORA may revoke a commission at any time. Reasons for revocation could include:

- a. The abuse or misuse of the commission.
- b. The transmittal of confidential information from a commissioned state or local official to individuals who are not employees or commissioned officials of the Department of Health and Human Services.
- c. A conflict of interest.
- d. Change in criminal or credit history.
- e. Conviction of a crime.
- f. Substance abuse.
- g. Behavior that may discredit the agency.

The decision to revoke an FDA commission will be communicated in 30 calendar days to both the individual and his/her supervisor.

#### 2. *State or local officials*

For state or local officials, within ten(10) calendar days after violation for revocation has occurred, details of the violation must be communicated to their place of employment who must then communicate the details to the FDA DD, deputy director, executive official, director of state programs, or other official specifically charged with oversight of the commissioning program. Within five (5) calendar days after receiving details of the charge, the Division must inform the Office of Partnership's National Commissioning Coordinator. The Office of Partnership's National Commissioning Coordinator will work with Office of Security and the Office of Partnership's senior management to decide if revocation of commissions is required. After a decision has been reached, the Office of Partnership's National Commissioning Coordinator will recommend the appropriate action to the DD specifically charged with oversight of the commissioning official.

If the DD concurs, a letter signed by the DD should be sent to the agency head stating the details of the revocation and requesting that the certificate of commission, pocket credentials (if any), and any documents belonging to FDA be collected and returned to OP. The documents and all additional documentation from the Division office must then be sent via e-mail [StateCommissioning@fda.hhs.gov](mailto:StateCommissioning@fda.hhs.gov). Original certificates and credentials should be returned by mail. Once a commission has been revoked, that individual is no longer eligible for an FDA commission. If there is a dissenting opinion between the DD and another FDA official regarding the revocation of an individual's commission, the ACRA will be consulted for a final decision.

### **3. *Federal officials***

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

#### **3-7-8 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. State and local officials who hold FDA commissions help FDA enforce its laws and regulations. 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 DD should consider the following options:

##### **1. *Periodic 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 an in-person meeting. Remote meetings may also be considered.

##### **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 OP 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 paper or electronic binder(s) appropriate for the material FDA provides them.

### **5. Literature and publications**

The manuals listed below are available on the FDA internet and can be accessed at: [www.fda.gov](http://www.fda.gov). For further assistance please contact OP at [StateCommissioning@fda.hhs.gov](mailto:StateCommissioning@fda.hhs.gov).

- a. FDA [Inspection References](#)
  - i. Investigations Operation Manual
  - ii. FDA Compliance Policy Guides Manual
  - iii. FDA Regulatory Procedures Manual
- b. [Catalog of Courses and Training Materials](#):
- c. Annual Directory of State & Local Officials:  
<http://dslo.afdo.org/>
- d. [Laboratory Information Bulletin](#):
- e. [Approved Drug Products With Therapeutic Equivalence Evaluations \(and cumulative supplements\):http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM07146.pdf.pdf](#)
- f. Special reports in the area in which the commission is held.

### **6. Training**

Provide training course announcements to state officials and when possible, give priority to commissioned officials to attend courses.

### **7. 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. Officials compiling material for the FDA Consumer Updates page should include stories concerning the activities of commissioned officials.

### **8. District meetings**

Invite commissioned officials to all or part of annual district meetings.

### **9. 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**

Information for the public on administration considerations related to commissioning Federal, state, and local regulatory officials; and accepting a

state's commission now can be found on the following Office of Partnership's page, [For Federal, State, Local, Tribal, and Territorial Officials](#), including [Office of Partnerships Contacts](#) and [Communications & Outreach](#).

Procedures for FDA staff can be found on the Office of Partnerships and Operational Policy/Office of Partnership's Intranet page.

### **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:

1. The commission is offered by a state agency whose agency head holds an FDA Commission.
2. 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 EXHIBITS**

- 3-1 SAMPLE QUESTIONS LISTED ON A CURRICULUM VITAE
- 3-2 FORM: ACCEPTANCE OF COMMISSION
- 3-3 FORM FDA 2115s: STATE CREDENTIAL RECORD
- 3-4 MODEL STATE CREDENTIAL CARD
- 3-5 FORM FDA 3716: 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: E-QIP INITIATION FORM
- 3-10 INSTRUCTIONS TO CANDIDATE
- 3-11 MODEL LETTER TRANSMITTING NON-PUBLIC INFORMATION
- 3-12 FORM FDA 2081: COMMISSIONED OFFICER'S RECORD
- 3-13 FORM: ANNUAL VALIDATION OF FDA CREDENTIALS
- 3-14 MODEL ANNUAL VALIDATION LETTER

**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****SAMPLE FORM: ACCEPTANCE OF COMMISSION**

(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.

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Signature

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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.

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Signature of Agency Head



## Exhibit 3-3

## FORM FDA 2115s: STATE CREDENTIAL RECORD

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

## STATE CREDENTIAL RECORD

- Sign in the center of the box below - **DO NOT EXTEND OVER THE LINE**
- Use **BLACK** ink only

1. Name of Applicant <i>(Last, First, MI)</i>	2. Title of Applicant
3. Office Address	4. Telephone No. <i>(Include Area Code)</i>
	5. Issuance Status of Credentials <i>(Check ONE)</i> <input type="checkbox"/> New Issuance <input type="checkbox"/> Reissue
6. Justification	

7. Program Area(s)		8. State	
9. Title of State Supervisor <i>(Please print)</i>	Signature	Date <i>(mm/dd/yyyy)</i>	
10. Title of Authorizing ORA Official <i>(Please print)</i>	Signature	Date <i>(mm/dd/yyyy)</i>	
<i>I certify that the information above is true and correct to the best of my knowledge. I also certify that I have read the Acceptance of Commission and Privacy Act Notice concerning the use of this information and have been advised of use, retention, and turn-in provisions.</i>			
11. Signature of Applicant			Date <i>(mm/dd/yyyy)</i>

## FOR ISSUING OFFICE ONLY

12.a. Credential No.		b. Date Issued <i>(mm/dd/yyyy)</i>		c. Expiration Date <i>(mm/dd/yyyy)</i>	
13. Issued By	a. Name			b. Office	
14. Subsequent Actions	a. Type of Action	b. Date Returned <i>(mm/dd/yyyy)</i>	c. Date Destroyed <i>(mm/dd/yyyy)</i>	d. Destroyed By <i>(Initials)</i>	

### **Privacy Act Notice**

#### **Authority**

This information is provided pursuant to Public Law 93-579 (Privacy Act of 1974), December 31, 1974, for the individuals applying for official FDA commissioned officials' credentials. Sections 702 to 704, the Federal Food, Drug and Cosmetic Act (21 U.S.C 372 to 374) authorizes the maintenance of a system for providing assurance to regulated enterprises that an individual is a duly designated enforcement officer and, in the case of State employees, an officer commissioned as an officer of the Department.

#### **Purpose and Uses**


The principal purpose of the Credential Record, Form FDA 2115s, is to maintain a record of all holders of FDA credentials for renewal and recovery purposes. Information may be disclosed to: regulated enterprises to provide assurance that an individual is a designated enforcement officer; a congressional office; and the Department of Justice, a court, or other tribunal for possible legal action.

#### **Effects of Nondisclosure**


Failure to complete any item on Form FDA 2115s will result in refusal by the issuing officer to issue FDA credentials to applicants.

## Exhibit 3-4


## MODEL STATE CREDENTIAL CARD

  
**FOOD AND DRUG ADMINISTRATION**  
THIS CERTIFIES THAT

WHOSE PHOTOGRAPH AND SIGNATURE APPEAR BELOW  
IS A DULY ACCREDITED AGENT COMMISSIONED  
TO PERFORM ACTIVITIES IN THE STATE  
AND PROGRAM LISTED HEREON.



THE INDIVIDUAL 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. THE  
INDIVIDUAL IS AUTHORIZED TO ADMINISTER OATHS AND  
AFFIRMATIONS AND TO ACT FOR THE COMMISSIONER  
IN THE PERFORMANCE OF THE DUTIES PROVIDED IN  
THE LAWS AND REGULATIONS ADMINISTERED BY THE  
FOOD AND DRUG ADMINISTRATION.



\_\_\_\_\_  
COMMISSIONER OF FOOD AND DRUGS

\_\_\_\_\_  
SIGNATURE OF AUTHORIZED BEARER

## Exhibit 3-5

## SAMPLE FORM FDA 3716: CERTIFICATE OF COMMISSION

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

**Certificate of Commission**

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 FIELD OF \_\_\_\_\_ FOR THE PURPOSE OF  
THE ACT. THIS COMMISSION EXPIRES \_\_\_\_\_.

COMMISSIONER OF FOOD AND DRUGS

FORM FDA 3716 (5/11)

**Exhibit 3-6**

**MODEL LETTER OFFERING A COMMISSION TO AN AGENCY HEAD**

(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 or territory). Your acceptance of this commission is a continuation of this important cooperation and coordination.

Sincerely,

Enclosure(s)  
[Title] Food and Drug Director

**Exhibit 3-7**

**MODEL LETTER OFFERING COMMISSION TO NON-AGENCY HEADS**

(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,

[Title] Food and Drug Director

Enclosure(s)

**Exhibit 3-8****SAMPLE FORM: BASIC INFORMATION FROM CANDIDATE**

(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 Division 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: \_\_\_\_\_

**Home Address:** \_\_\_\_\_

City, State, and Zip: \_\_\_\_\_

Job Title: \_\_\_\_\_

Agency: \_\_\_\_\_

Division or Department: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, and Zip: \_\_\_\_\_

Email Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

I affirm that I am a United States citizen or United States National (describe below).

\_\_\_\_\_  
(date)\_\_\_\_\_  
(signature)\_\_\_\_\_  
(Describe qualifications as United States national)

## Exhibit 3-9

E-QIP Initiation Form

In line with new regulations mandated by the U.S. Office of Personnel Management Investigative Services and the Department of Health and Human Services, the FDA Personnel Security Branch is implementing the Electronic Questionnaires for Investigations Processing (E-QIP) System. As a result, electronic submission of the standard form 85, for suitability background investigations (NACI) or the Standard Form 85P, for Public Trust, is now required. The FDA requires all applicants to be processed for a suitability background investigation, in accordance with Executive Order 10450 and the Homeland Security Presidential Directive (HSPD-12), in order to obtain employment, gain access to FDA property and/or receive an FDA badge.

The following information is required in order to initiate the applicant into the Electronic Questionnaires for Investigations Processing (E-QIP) system. After the applicant is initiated into E-QIP, they will receive an email containing the website including instructions and additional forms needed for the suitability background investigation.

**The below contact information is pertaining to the applicant only.**

First Name →		Middle Name given at Birth (if none, write NMN) →		Last Name	
<input type="text"/>					
Position Title or Name of Contractor →				FDA Center	
<input type="text"/>				<input type="text"/>	
Social Security Number →				Date of Birth (mm/dd/yyyy)	
<input type="text"/>				<input type="text"/>	
Place of Birth: City →				State or Foreign Country	
<input type="text"/>		<input type="text"/>		<input type="text"/>	
Phone Number →				Email address	
<input type="text"/>		<input type="text"/>		<input type="text"/>	
Have you ever been investigation by another FEDERAL AGENCY? If yes, complete name of agency and approx date.					
<input type="text"/>					

=====

OSO/PERSONNEL SECURITY OFFICE USE ONLY

e-QIP Initiation Date: \_\_\_\_\_ ID#: \_\_\_\_\_

FP Date: \_\_\_\_\_ Date FP Results Recd: \_\_\_\_\_

Release to OPM/HHS Date: \_\_\_\_\_



**Exhibit 3-10****SAMPLE INSTRUCTIONS TO CANDIDATE**

(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.
- **State Credential Record**. If you are to be issued credentials, we need your signature on the state credential record form. Please sign in black ink. Please fill out the top section of this form, except for item 10. Return this completed form along with your other paperwork.
- **Photographs**. If you are to be issued credentials, we need a color picture of your face, including a portion of your upper shoulders. The photo needs to be at a high resolution. The background of the picture must be white. The picture needs to be in JPG format and can be emailed as an attachment.

If you have any questions about this material, please contact \_\_\_\_\_,  
Commissioning Coordinator, FDA \_\_\_\_\_ [Program/Division] at xxx -xxx-xxxx or  
by email at \_\_\_\_\_.

**Exhibit 3-11****MODEL LETTER TRANSMITTING NON-PUBLIC INFORMATION TO COMMISSIONED  
FEDERAL, STATE, OR LOCAL OFFICIAL**

(Letterhead)

*Remove the italicized information in brackets prior to sending the letter.)***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 State 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 Office of Partnerships at [StateCommissioning@fda.hhs.gov](mailto:StateCommissioning@fda.hhs.gov) for the appropriate procedures.

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

---

Sincerely,

[Program/Division]  
Food and Drug Director

Enclosure(s)

## Exhibit 3-12

## FORM FDA 2081: COMMISSIONED OFFICER'S RECORD

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration <b>COMMISSIONED OFFICER'S RECORD</b>										Date (mm/dd/yyyy)	
Name						Position or Title					
State		Agency				Head of Agency/Office					
<b>Type of Authority</b> (Select one)											
<input type="checkbox"/> <b>FDA Credential (code: A)</b> <ul style="list-style-type: none"> <li>Conduct inspections</li> <li>Collect samples</li> <li>Receive, review, and copy FDA documents</li> </ul> <input type="checkbox"/> <b>Certificate Only (code: B)</b> <ul style="list-style-type: none"> <li>Receive, review, and copy FDA documents</li> </ul>											
<b>Programs</b> (Select applicable)											
<b>Foods</b>	<b>Eggs</b>	<b>Animal Feeds</b>	<b>Medical Devices</b>	<b>Drugs</b>	<b>Tissue Residue</b>	<b>Shellfish</b>	<b>Grain/ Bean Storage</b>	<b>Tobacco</b>	<b>All Articles</b>	<b>Other</b>	<b>Indicate specific Program(s) if "Other" selected</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Basic Personnel Data</b>											
<b>Item</b> (Select applicable)				<b>Date</b> (mm/dd/yyyy)		<b>Item</b> (Select applicable)				<b>Date</b> (mm/dd/yyyy)	
District Recommendation Received <input type="checkbox"/>						Credentials (Laminated) & Certificate Mailed <input type="checkbox"/>					
Commissioning Candidate Package Mailed <input type="checkbox"/>						Certificate Only Mailed <input type="checkbox"/>					
<ul style="list-style-type: none"> <li>Offer Letter of Commission</li> <li>Acceptance of Commission</li> <li>Basic Information Form</li> <li>E-QIP Initiation Form</li> <li>Form 2115s - Credential Record</li> <li>Instructions to Candidate</li> <li>Request for FDA Materials</li> <li>Form 2081 - Commissioned Officer's Record</li> </ul>						<b>Renewal Request</b>					
						Letter Mailed <input type="checkbox"/>					
						Expired Credentials Received <input type="checkbox"/>					
<b>FOR OFFICE USE ONLY</b>											
<b>Record of Commission</b>											
ID Number or (only if no ID Number) CERT						Status (Cancelled, Retired, etc.)					
Issued Date (mm/dd/yyyy)				Renewal Date (mm/dd/yyyy)				Expiration Date (mm/dd/yyyy)			

FORM FDA 2081 (4/10)

PSC Graphics (301) 443-1090 EF

**Exhibit 3-13**

**SAMPLE FORM: ANNUAL VALIDATION OF FDA CREDENTIALS**

(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**

(Letterhead)

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

Date

Dear Commissioner:

As you are aware, the FDA pocket 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 pocket 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 pocket credentials and the identification numbers assigned to these pocket credentials. We ask that you, or an official designated by you, make a personal examination of each pocket credential, confirm that its number matches the number on our form, and then certify to FDA that the pocket 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 pocket credentials, please indicate this on the form by crossing off his or her name. I'd also appreciate it if the pocket credentials could be collected from the individual(s) and returned to me via registered letter.

If any pocket credentials cannot be located, please advise me immediately.  
Thank you for your assistance.

Sincerely yours,

[Title] Food and Drug Director

Enclosure(s)