

Regulatory Procedures Manual

Chapter 3: COMMISSIONING AND INFORMATION SHARING

COMMISSIONING FEDERAL, STATE, AND LOCAL OFFICIALS AND SHARING NON-PUBLIC INFORMATION

This chapter contains sections on commissioning, information sharing agreements, and information disclosure.

Section	Topic	Page
3-1	INTRODUCTION	2
3-2	COMMISSIONING DEFINITION	2
3-3	COMMISSIONING AUTHORITIES.....	3
3-4	OTHER INFORMATION SHARING AUTHORITIES.....	4
3-5	COMMISSIONING AND OTHER INFORMATION SHARING AGREEMENT TYPES.....	5
3-5-1	Commissioning Types.....	5
3-5-2	Other Information Sharing Agreement Types.....	6
	20.88 ISA	6
	20.85 ISA	6
3-6	COMMISSIONING CONFLICT OF INTEREST.....	6
3-6-1	Written Assurances	6
3-7	INFORMATION SHARING AND PROTECTION OF NON-PUBLIC INFORMATION	8
3-7-1	Written Assurance.....	8
3-7-2	Protection of Non-Public Information.....	9
3-7-3	Sharing Non-public Information Under Commission	10
3-7-4	Sharing Non-public Information Under 21 CFR § 20.88 (State or Local)	11
3-7-5	Sharing Non-public Information Under 21 CFR § 20.85 (Federal)	12
3-7-6	Information Sharing Training.....	12
3-7-7	Privacy Act	13

3-8	COMMISSIONING ADMINISTRATIVE CONSIDERATIONS.....	13
3-8-1	Duration	13
3-8-2	Commissioning Request	13
3-8-3	Authorities Granted	14
3-8-4	Suitability for a Commission.....	15
3-8-5	Accountability.....	16
3-8-6	Renewal of Commission	17
3-8-7	Non-renewal of Commission	18
3-8-8	Administrative Hold of Commission.....	18
3-8-9	Suspension of Commission.....	20
3-8-10	Revocation of Commission	21
3-8-11	Returning of Pocket Credentials	22
3-8-12	Relationship with Commissioned Officials.....	22
3-9	FDA EMPLOYEE ACCEPTING A STATE’S COMMISSION	23
3-10	EXHIBITS	24
	Exhibit 3-1: SAMPLE STATE POCKET CREDENTIAL CARD.....	24
	Exhibit 3-2: SAMPLE FORM FDA 3716: CERTIFICATE OF COMMISSION.....	25

3-1 INTRODUCTION

This chapter describes the Food and Drug Administration’s (FDA) procedures and responsibilities for commissioning and entering into other information sharing agreements (ISA) with other government employees and officials and an overview of information sharing with these employees and officials.

3-2 COMMISSIONING DEFINITION

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 cooperative 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).

A state and local official may be either be commissioned with a certificate of commission or pocket credentials. A certificate of commission grants federal authority to receive and review non-public information “for use only in their work with the FDA”.¹ Pocket credentials grant federal authority to conduct contract inspections on behalf of FDA when the state doesn’t have similar authorities and also grants federal authority to receive and review non-public information for use in their work with the FDA.

An EXECUTIVE (EXEC) Certificate of Commission is a specialized subset of the certificate of commission. This grant of authority for top state agency officials allows for the receipt and review of all FDA program/commodity areas under the official’s purview. This certificate is exclusively restricted to top state agency officials that meet the following criteria: a) US Citizen or National that is the Head of Agency, or Principle Deputy/Delegate and b) Directly responsible for more than four program/commodity areas. While this grant authority allows access to more commodity specific information than other types of commissioning, the holder of an Executive Certificate is still required to follow all of the requirements related to the protection of non-public information listed within the Commissioning Guide and the Acceptance of Commission Agreement.

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). It also discusses other types of information sharing agreements used to share non-public information with federal, state, and local officials.

3-3 COMMISSIONING AUTHORITIES

Section 702(a)(1)(A) of the Act authorizes FDA “to conduct examinations and

¹ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=20.84>

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.

FDA’s Office of Regulatory Affairs (ORA), Office of Partnerships (OP) has primary responsibility for overseeing the implementation of FDA’s Commissioning Program and its maintenance on a national scale. The Program Division Directors (PDDs) have primary responsibility for administering and executing the program for commissioning state and local officials. Commissioning for tobacco retail contract inspections is executed jointly between Center for Tobacco Products (CTP) and OP. 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.

Individuals seeking commissions should be referred to their relevant FDA District Office or State Liaison. The exception is those seeking commissions for tobacco retail compliance should contact FDA’s Center for Tobacco Products at CTPTrainer@fda.hhs.gov.

3-4 OTHER INFORMATION SHARING AUTHORITIES

Section 21 CFR § 20.88 authorizes FDA to share certain non-public information with counterpart state, local and U.S. territory government agencies provided that agency

has entered into a written agreement to protect FDA's information from further disclosure. Information shared with these agencies under this section allows FDA's discretionary sharing of authorized non-public information, under certain circumstances (see section 3-7 below).

Section 21 CFR § 20.85 authorizes FDA to share certain non-public information with non-HHS federal government agencies provided the agency has entered into a written agreement to protect FDA's information from further disclosure.

ORA's Division of Information Disclosure Policy (DIDP) is responsible for developing and maintaining 20.88 and 20.85 agreements. Any state or federal agency should first contact DIDP to properly determine if the state and federal agency can enter into such an agreement with FDA. Division representatives must also contact DIDP first before further sharing any non-public information with any outside agency to ensure proper agreements are in place before sharing. DIDP is responsible for oversight in developing ORA's information sharing policies as well as helping administer the sharing of ORA's information with outside parties, including Freedom of Information (FOI) requests. To contact DIDP, e-mail ORAInfoShare@fda.hhs.gov.

3-5 COMMISSIONING AND OTHER INFORMATION SHARING AGREEMENT TYPES

3-5-1 Commissioning Types

Federal authority can be granted via pocket credentials to state and local officials who will actively engage in investigational and inspectional activities on behalf of the FDA. FDA may issue pocket credentials to other federal officials pursuant to a memorandum of understanding between the Secretary and the head of the other federal department or agency ([see Exhibit 3-1 for a sample credential](#)). 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. Adequate justification that pocket credentials are needed for inspection or investigation activities under federal authority must be provided for all state and local officials requesting pocket credentials. Pocket credentials are for official business only for inspections and investigations. They shall not be used as a means of personal identification or for other personal purposes.

Federal authority can be granted via a certificate of commission to state and local officials allowing them to receive and review non-public information. ([See Exhibit 3-2 for a sample certificate of commission](#)).

Adequate justification that a certificate of commission is required must be provided for all state and local officials requesting a certificate of commission. Refer to section 3-7 below for information about sharing information under commission and section 3-8 below for additional information regarding issues to consider prior to commissioning including needs and process for justification.

3-5-2 Other Information Sharing Agreement Types

20.88 ISA

States and local governments can enter into 20.88 information sharing agreements with FDA to allow for sharing of FDA information, with limitations (see also section 3-7). There are two types of information sharing agreements states and local governments can enter into: single-signature long-term and case-specific agreements. Entering into either type of agreement doesn't prevent entering into the other. Long-term agreements are commodity specific (food (including animal food) and cosmetics; pharmacy compounding and drug security; imports; and drugs and biologics) and last a duration of up to 5 years (all 20.88 agreements expire at the same time, regardless of when entered into with FDA). Information can be further shared within the agency with anyone under the signatory's chain of command.

State and local governments may also enter into case-specific agreements, especially if entering into long-term agreements aren't possible. Case-specific agreements are written for specific events or situations, allowing ORA to share only within what is detailed in the agreement. Information can only be shared with those that have signed the confidentiality form.

20.85 ISA

Similarly, non-HHS federal agencies can enter into 20.85 case-specific agreements that allow sharing with the agency/office/division that have signed the agreement.

3-6 COMMISSIONING CONFLICT OF INTEREST

3-6-1 Written Assurances

1. State or local officials

State or local officials seeking commissioning and Commissioned Officials considered for renewal are required to attest in writing, e.g., through the

Acceptance of the Commission form, 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.

A state or local government employee recommended for a commission should discuss questions about the conflict of interest with his/her sponsoring FDA district official, or CTP Contract Officer Representative (COR). If the candidate/official becomes aware of a potential financial interest that would affect participation under the FDA Commissioning Program, the sponsoring FDA district official or CTP COR will summarize the issues and submit them along with other documentation to the FDA Division, OP, and/or CTP for resolution. OP will discuss the matter with the PDD/DD, or CTP, and appropriate FDA Ethics Officials; a decision will be reached as to whether the individual can be commissioned. OP may contact the FDA's Ethics and Integrity Staff (HFA-320). This discussion should ideally be conducted in person by the PDD/DD in the case of a state agency head. If circumstances make this impractical, a PDD/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 PDD/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.

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

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.

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 the 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.

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.

3-7 INFORMATION SHARING AND PROTECTION OF NON-PUBLIC INFORMATION

3-7-1 Written Assurance

Outside agencies, whether entering into either a commission or an information sharing agreement with FDA, must be able to maintain the confidentiality of any and all information FDA shares, unless ORA has reviewed and approved the information for further disclosure. For example, state or local officials seeking a commission or commission renewal are required to attest in writing, e.g., through the Acceptance of Commission form for commissioning or the Tobacco Acceptance of Commission form for tobacco commissioning, that they understand that any non-public information FDA provides for review is entitled to significant protection under federal law. The state or local official further understands that if they make any unauthorized disclosures of non-public information, they may be committing a possible violation under federal Law (21 U.S.C. § 331(j), 5 U.S.C. § 552a(i)(1), and 18 U.S.C. § 1905) which could result in civil or criminal penalties including fines and/or imprisonment. In long-term 20.88 and 20.85 agreements, agency or department signatories attest to a confidentiality commitment for their organization contained within the agreement establishing that the state or federal government agency has the authority to protect the non-public information from disclosure and the government agency will not further disclose any such information provided to it. Furthermore, a single-signature non-disclosure agreement, is signed by state agencies awarded contracts. These commitments apply to anyone under the signatory's chain of command. In case-specific 20.88 and 20.85 agreements, individuals receiving non-public information must sign the agreement's confidentiality form.

3-7-2 Protection of Non-Public Information

FDA may share “non-public information” outside of FDA for various reasons (for example, during an outbreak investigation). Non-public information generally includes confidential commercial information, trade secrets information), deliberative process, open investigatory records, and personal privacy information). This may include, but not limited to: written reports, manufacturing and production techniques, equipment used, official FDA documents, etc. The only individuals eligible to see or hear FDA-provided non-public information are:

- a) Commissioned officer(s) who collected or received the information that have a valid FDA use for the information,
- b) An employee at the same state/territorial agency who **also holds** an FDA commission within the same commodity area,
- c) Officers or employees of the Food and Drug Administration or the Department of Health and Human Services,
- d) Any state official covered by an appropriate 20.88 information sharing agreement (with the exception of trade secret information),
- e) Any non-HHS federal official covered by an appropriate 20.85 information sharing agreement (with the exception of trade secret information).
- f) A state official covered by a state contract’s single signature non-disclosure agreement.

Information obtained during a contract inspection, through FDA systems, or any other information obtained pursuant to a commission by a commissioned official is an official FDA record. Information obtained pursuant to a commission is for that official’s use exclusive in their work with the FDA unless further disclosure is authorized by FDA. Information shared by FDA under commission cannot be copied into state memoranda, emails, or other documents, or discussed with individuals not covered above, without first consulting FDA. If in doubt, consult with FDA. Any requests to further share FDA’s information received beyond that which is authorized in the above paragraph should be referred to ORA’s Division of Information Disclosure Policy (DIDP) at ORAInfoShare@fda.hhs.gov.

Pursuant to 21 U.S.C. § 372(a), commissioned state and local government officials are “officers” of the U.S. Department of Health and Human Services, making them subject to the same disclosure restrictions and penalties as any other employee of FDA. Any public requests for information shared by FDA under a commission, including FDA contract inspections performed by an agency using FDA authority, are to be directed to file a Freedom of Information Act request directly with the FDA FOIA office to obtain copies of those records. Information obtained during an inspection by a commissioned official is an official FDA record

and may not be disclosed by an agency in response to such a request. If presented with a formal request or subpoena for information obtained in the course of using the FDA commission, the commissioned official or state agency should immediately contact ORA's DIDP at ORAInfoShare@fda.hhs.gov.

Information shared under 20.88 or 20.85 information sharing agreements must be first reviewed and redacted for trade secret information. Per 21 CFR § 20.61 and 21 U.S.C. § 331(j), trade secret information cannot be shared under any of these agreements. Information shared under either of these types of agreements can be used by states to inform decisions made by the agency (i.e., state-level compliance actions, the need for non-contract inspections, etc.).

Further, while FDA's sharing of personal privacy information is discretionary, FDA's practice is not to share any personal privacy information with any non-FDA federal (including other HHS agencies), state, or local agencies, including any whistleblower information. This includes any information that could potentially aid anyone to determine a whistleblower or complaint's identity. FDA may decide to share certain personal privacy information only if a substantive rationale is provided in order to complete follow up work as needed. In addition, some information containing personal privacy information is subject to the Privacy Act and may not be shared under these agreements unless authorized under the Privacy Act (e.g., written consent or a routine use). Prior to releasing any personal privacy information, DIDP should be contacted before any information disclosure occurs. Redactions in any of these situations, or questions regarding the need to redact, are to be directed to DIDP at ORAInfoShare@fda.hhs.gov.

3-7-3 Sharing Non-public Information Under Commission

FDA may provide a state or local official commissioned in a commodity area to "receive and review FDA information", with information for use only for their work with the FDA (including for situational awareness). The information shared may only pertain to their authorized commodity area if it is protected from disclosure to the public by the Freedom of Information Act (see 21 CFR § 20.84). Per this regulation, this information may not be used to inform state action and is for use only in their work with the Food and Drug Administration.

Trade secret information can be shared under a commission (either credential or certificate) for a valid FDA use. Personal privacy information is not be shared outside of FDA unless the non-FDA user can demonstrate a sustainable need for that information (see above section on sharing of non-public information).

To verify an individual's commission and their approved commodity area prior to transmitting information, please contact StateCommissioning@fda.hhs.gov for

access to the Commissioning Officials database and for any other questions you might have regarding commissioning.

Commissioned officials may only further share FDA information with members of their staff who hold FDA commissions within the same commodity program area, or an official with an Executive Certificate of Commission specifying that they can receive and review official FDA documents. The information may not be copied into state memoranda, emails, or other documents, or discussed with noncommissioned officials. Any requests to further share FDA information received pursuant to a commission beyond that which is authorized should be referred to ORA's Division of Information Disclosure Policy at ORAInfoShare@fda.hhs.gov.

Whenever FDA provides non-public information to commissioned officials, in accordance with the Act and FDA regulations, FDA should indicate the information is non-public by affixing a [transmittal letter](#) which cautions the recipient against further disclosure, marking the documents with a [non-public information coversheet](#), password encrypting electronic files where possible, and adding [E-mail and oral disclaimers](#), as appropriate. When sending documents via non-electronic means, the document's envelope should be identified "To Be Opened By Addressee Only."

3-7-4 Sharing Non-public Information Under 21 CFR § 20.88 (State or Local)

FDA may share certain non-public information pursuant to 21 CFR § 20.88(c) and (d) with state and local officials, as part of cooperative law enforcement or regulatory efforts. This information may be used to inform a state action (i.e., state-level compliance actions, the need for non-contract inspections, etc.). For FDA to share non-public information, there must be a written statement from the state agency establishing that the State government agency has the authority to protect the non-public 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 case-specific 20.88 agreement.

Any documents shared under 21 CFR § 20.88 must have an information disclosure review performed to redact all trade secret information and should not include personal privacy-related information unless there is a demonstrated need by the state agency for the information. When transmitting the records FDA indicates that the information is non-public, e.g., by affixing a [transmittal letter](#) or [disclaimer language in an email](#) which cautions the recipient against further disclosure, marking the documents with a [non-public information coversheet](#), password encrypting electronic files where possible, etc.

To verify an agency is currently covered under a long-term sharing agreement, check the [20.88 Long Term Information Sharing Agreement Database](#) or check with DIDP at ORAInfoShare@fda.hhs.gov. Any records request not covered under a long-term agreement should be forwarded to DIDP for authorization, with a copy to the relevant State Liaison.

For any questions you might have regarding the sharing of non-public information with a state or local entity, please contact DIDP at ORAInfoShare@fda.hhs.gov.

3-7-5 Sharing Non-public Information Under 21 CFR § 20.85 (Federal)

FDA may share certain non-public information with another federal agency under 21 CFR. §20.85 (Disclosure to other federal government departments and agencies). ORA's Division of Information Disclosure Policy (DIDP), Office of Strategic Planning and Operational Policy (OSPOP) manages all 20.85 agreements for the FDA. Any requests for records from a federal agency should be forwarded to the DIDP at ORAInfoShare@fda.hhs.gov with a copy to the relevant State Liaison.

For FDA to share confidential commercial information, pre-decisional information, open investigatory records, and personal privacy information, there must be a written statement from the federal agency establishing that the federal agency has the authority to protect the non-public information from disclosure and a written commitment that the federal agency will not further disclose any such information provided to it. Trade secret information may not be shared under 20.85 agreements. Personal privacy information pertinent or in furtherance of the agency's investigation may be released under a 20.85 authorization.

Any documents shared under a valid 20.85 agreement must have an information disclosure review performed to redact all trade secret information and should not include personal privacy-related information unless there is a demonstrated need by the state agency for the information. When transmitting the records FDA indicates that the information is non-public, e.g., by affixing a [transmittal letter](#) (or use transmittal letter language in an email) which cautions the recipient against further disclosure, marking the documents with a [non-public information coversheet](#), password encrypting electronic files where possible, etc.

For any questions you might have regarding the sharing of non-public information with a federal entity contact DIDP at ORAInfoShare@fda.hhs.gov.

3-7-6 Information Sharing Training

It is imperative that non-public information remains secure and confidential after changing hands. The FDA Information Sharing Training module is designed to

clarify the roles and responsibilities of recipients of various types of non-public information, and it is highly recommended for all of FDA's state and local partners and those FDA employees involved with those partners.

See the [FDA Information Sharing webpage](#)

3-7-7 Privacy Act

The FDA District Office, CTP, Office of Security Operations, and the Office of Partnerships maintain records on individuals who have applied to be commissioned (i.e., photograph, commissioning application package).

Any person may review his or her own file by requesting a copy of it from the Division of Freedom of Information under the Privacy Act. All other questions about Privacy Act records should be addressed to:

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857
301-796-3900 (main)
301-827-9267 (fax)
FDAPrivacyOffice@fda.hhs.gov

3-8 COMMISSIONING ADMINISTRATIVE CONSIDERATIONS

3-8-1 Duration

Generally, each state or local commission is issued for a period of five years. At the end of each five-year term, FDA will review the commission and determine whether it should be renewed. For federal commissioned officials, the MOU should include the duration of commission, which might be a term other than five years.

3-8-2 Commissioning Request

A formal request for a commission is considered when a completed application is received by the district for traditional commissioning and CTP for Tobacco.

A Certificate of Commissioning [application packet](#) or [tobacco application packet](#) includes, a completed and signed Basic Information From a Candidate for an FDA Commission and Acceptance of Commission forms. Additional reference materials are distributed with the application packet, i.e., Instructions to

Candidates for an FDA Traditional Commission and The FDA Commission:
Granting Federal Authority to State and Local Officials.

3-8-3 Authorities Granted

An individual commissioned by FDA must understand the nature of the federal authority that is granted. It may be used only for the stated purposes when acting on behalf of FDA and does not delegate any federal authority beyond that specified. The authorities granted by an FDA commission are valid **only** for the specific program area(s) for which the candidate applies, up to a maximum of four (4) programs, excluding the Executive Certificate of Commission. The program areas include:

Bioterrorism, Animal Feeds, Biologics, BSE Activity, Cosmetics, Dairy, Drugs, Eggs, Foods, Medical Devices, Produce, Pesticide Residue, Radiological Health, Shellfish, and Tobacco.

An FDA commission confers upon the recipient the authority to perform activities in designated program areas as a federal official within their own state or local jurisdiction. A commission with pocket credentials permits the holder to perform the following activities:

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

Commissioned officials who will be performing activities 1 and 2 above may be requested to show when entering a firm for an inspection. The firm is only required to admit inspectors with up-to-date credentials in an appropriate program area.

A Certificate of Commission and the Executive Certificate of Commission allows the commissioned official to perform activities 3 and 4, listed above. Any records received under activities 1- 4 above should be identified and stored as FDA records.

Additionally, information directly related to an FDA contract can be shared with anyone working on that contract without the need for a commission. Employees receiving non-public information under an FDA contract must be covered under the Single Signature Non-Disclosure Agreement.

3-8-4 Suitability for a Commission

To be considered for an FDA commission, the applicant must be a citizen of the United States or a United States National. Nationals are persons born in an outlying possession of the United States (American Samoa or Swains Island) or born of a parent or parents who are non-citizen nationals who meet certain physical presence or residence requirements. Permanent residents and green card holders are not US nationals and are not eligible for commissioning.

PDDs/DDs are approving authorities for commission requests. Requests must be accompanied by a justification as to why a commission is required in performing work for the FDA. PDDs/DDs are required to provide a justification for all Certificate of Commission approved requests as to why a 20.88 agreement will not suffice for information sharing purposes. The justification must also make clear that the use of the information shared with the commissioned individual won't be used for further work outside of that with FDA.

Prior to issuing a commission, FDA will determine that the candidate is qualified to carry out the duties of a commissioned official. In most cases, the sufficiency of the individual's qualifications will be stipulated by their agency; however, FDA reserves the right to inquire further into the candidate's qualifications. In addition, FDA will conduct a Minimum Background Investigation (MBI) - Level 5 Moderate Risk Public Trust investigation via the Electronic Questionnaires for Investigations Processing (e-QIP) system for all pocket credential requests and, in some cases, certificate of commission requests, if deemed appropriate by the PDD/DD.

Candidates will be required to complete the e-QIP Initiation Form to be given access to the e-QIP system. Candidates will electronically enter data for review and submission to the Office of Personnel Management (OPM). The e-QIP system is part of E-GOV, which is an integral part of the President's Management Agenda (PMA). The MBI will consist of searches of records covering specific areas of an individual's background during the past ten years. Inquiries are sent to current and past employers, schools attended, references and local law enforcement authorities. A credit check and face to face interview with an investigator will also be conducted.

The Office of Personnel Management's (OPM) Federal Investigative Services (FIS) conducts background investigations on federal applicants, employees, contractor personnel, and commissioning candidates for suitability and security determination purposes. A credit search is a routine part of many of these investigations. The subjects of background investigations are requested to sign a release form allowing a check of his or her credit history. Searches are conducted for each name variation a person has used; therefore, there may be more than

one search by OPM showing on a person's credit report. Credit inquiries from OPM investigations are included in the Regular Inquiries portion of a credit record, but these inquiries are "soft" hits and do not have an impact on a person's credit score. Failure to provide FDA with required information within the allotted timeframe will result in a denial for the commission request.

If an individual already possesses a background investigation, the investigation will be reviewed by FDA. If the investigation is compliant with FDA standards, the individual will not need to undergo an additional investigation.

FDA Form 2115s State Credentialing Record is required for all candidates requesting to be commissioned with pocket credentials. A copy of this form is provided to the candidate in the [application packet](#) or [tobacco application packet](#).

3-8-5 Accountability

The commissioning candidate is responsible for contacting FDA when:

- A conflict of interest arises
- An ethical dilemma arises in which a conflict of interest could arise
- Any potential unauthorized or inadvertent release of non-public information
- Any civil, criminal, or illegal activity which could jeopardize the Level 5 MBI obtained by the individual
- When a credential is lost or stolen.
- When a subpoena is received for information that was obtained under a commissioning agreement

FDA reserves the right to deny, administratively hold, suspend, or revoke a commission at any time. In some instances, FDA may pursue civil or criminal charges if the commissioned official is not upholding his or her duties as a commissioned official. Grounds for action may include 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.
- e. The abuse or misuse of the commission.
- f. 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.

- g. A conflict of interest.
- h. Change in criminal or credit history.
- i. Conviction of a crime.
- j. Substance abuse.
- k. Behavior that may discredit the agency.
- l. Inappropriate disclosure of non-public information.
- m. Contract discrepancies.
- n. FDA policy violations.
- o. Programmatic hurdles.

Credentials are considered federal government property. Therefore, the credential must be returned to FDA if the commissioned official leaves the state or local agency or otherwise no longer has a need for the credential. The certificate of commission does not need to be returned to FDA upon its expiration.

3-8-6 Renewal of Commission

1. *State or local officials*

Commissions of state or local officials are valid for five years. The district will review the commissioned official's record approximately three (3) months prior to expiration of the commission and notify the applicant's supervisor of the impending expiration. 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 for traditional commissioning should be sent to the District, from the state or local official, signaling the intent to request a renewal.

Office of Partnerships will work with CTP and State Program Coordinators to renew tobacco retail compliance commissions.

Application packets for tobacco and non-tobacco are specific to those programs.

All renewal applications from the state agency should be entered into the National Commissioning Inventory (NCI) to be routed for approval and processing. ORA has the option to conduct a background investigation at any time during the renewal process, if deemed necessary.

2. *Federal officials*

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

3-8-7 Non-renewal of Commission

1. State or local officials

ORA reserves the right to deny renewal commissioning requests. The PDD/DD will consider the state agency needs, justification, and make a decision based on all pertinent aspects of the commission including inspections, collection of samples, consultation extended, cooperation in routine and emergency situation, non-public document review, and any breaches of confidentiality. FDA will not renew a commission if the holder has changed positions outside of the organization/agency, resigned, or retired. All renewal applications in progress will be withdrawn if the official changes positions outside the organization/agency, resigns, or retires. If the commissioning request is not renewed, the district aided by the NCI with OP's Commissioning Team's signature block or in cases of tobacco, CTP, will send a notification to the applicant and their supervisor advising of the decision.

2. Federal officials

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

3-8-8 Administrative Hold of Commission

1. General

ORA may use discretion at any time to administratively hold the commission of such authorized officials on the grounds of violations.

The decision to administratively hold 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), or after violation for an administrative hold has occurred, details of the applicable charge or violation must be communicated to their employer, and to the PDD/ 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 or violation, the PDD/DD must inform OP's National Commissioning Coordinator at StateCommissioning@fda.hhs.gov. OP's National Commissioning Coordinator will work with Office of Security Operations and OP Senior Management to decide if an administrative hold of the commission is required. After a decision has been reached, the OP National Commissioning Coordinator will recommend the appropriate action, to the PDD/DD specifically charged with oversight of the commissioning official.

If an administrative hold of commission is not required and the PDD/DD concurs, a letter signed by OP's Commissioning Team should be sent to the district to notify the agency head stating that no further action will be taken.

If an administrative hold of commission is required and division concurs, a letter signed by OP's Commissioning Team should be sent to the district for dissemination to the agency head stating the details of the administrative hold and requesting that all commissioning instruments 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.

Once a commission has been administratively held, the FDA will wait for the final verdict of the charge or violation to make its decision on revoking/suspending or reinstating the commission. If the state or local official is not charged with the felony or misdemeanor, or in violation of any of the mentioned scenarios, FDA will use discretion to reinstate their commission. A follow up letter signed by OP's Commissioning Team including the commissioning instruments, should be sent to the district for distribution to the agency head stating the decision to reinstate.

If the state or local official is charged with the felony or misdemeanor, or in violation of any of the mentioned scenarios, their commission will be revoked/suspended immediately. A follow up letter signed by OP's Commissioning Team should be sent to district to notify the agency head stating the decision of revocation/suspensions. Once a commission has been revoked/suspended, that individual is no longer eligible for an FDA commission.

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

decision.

3-8-9 Suspension of Commission

1. General

ORA may use discretion at any time to suspend the commission of such authorized officials on the grounds of violations.

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 PDD/ 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 PDD/DD must inform OP's National Commissioning Coordinator at 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 PDD/DD specifically charged with oversight of the commissioning official.

If suspension of commission is not required and the PDD/DD concurs, a letter signed by OP's Commissioning Team should be sent to the district to notify the agency head stating that no further action will be taken.

If suspension of commission is required and division concurs, a letter signed by OP's Commissioning Team should be sent to the district for dissemination to the agency head stating the details of the suspension and requesting that all commissioning instruments 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.

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 OP's Commissioning Team including the commissioning instruments, should be sent to the district for distribution 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 OP's Commissioning Team should be sent to district to notify 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 PDD/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.

3-8-10 Revocation of Commission

1. General

ORA may use discretion at any time to revoke the commission of such authorized officials on the grounds of violations.

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 PDD/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 PDD/DD specifically charged with oversight of the commissioning official.

If the PDD/DD concurs, a letter signed by OP's Commissioning Team

should be sent to district to notify the agency head stating the details of the revocation and requesting that the commissioning instruments, 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.

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 PDD/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.

3-8-11 Returning of Pocket Credentials

It is the responsibility of the state agency to return all FDA issued pocket credentials when no longer needed. Examples include expired credentials, individuals that have retired or changed agencies, or when no longer needed to conduct inspections under FDA authority. The expired pocket credentials must be returned to the State Liaison in their respective district office for processing and then forwarded to Office of Partnerships. Tobacco retail compliance credentials should be returned directly to the OP Tobacco Commissioning Coordinator.

3-8-12 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.

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 PDD/DD should consider the following:

- **Literature and publications**

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

1. [FDA Inspection References](#)

- a. Investigations Operation Manual
 - b. FDA Compliance Policy Guides Manual
 - c. FDA Regulatory Procedures Manual
2. [Catalog of Courses and Training Materials](#)
 3. [Laboratory Information Bulletin](#)
 4. [Orange Book: Approved Drug Products With Beneficial Equivalence Evaluations](#)
 5. [FDA Information Sharing Course](#)
 6. [Section 702\(a\)](#) of the Federal Food, Drug and Cosmetic Act (21 USC 372)
 7. [21 CFR §20.88](#) Communications with State and local government officials
 8. [SMG 2280.3](#) – FDA Official Credentials and Badges
 9. [SMG 3297.4](#) – Implementation of the Privacy Act and the FDA Privacy Program: Overview

3-9 FDA EMPLOYEE ACCEPTING A STATE'S COMMISSION

Rarely, 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:

The commission is offered by a state agency whose agency head holds an FDA Commission.

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

Exhibit 3-1: SAMPLE STATE POCKET CREDENTIAL CARD

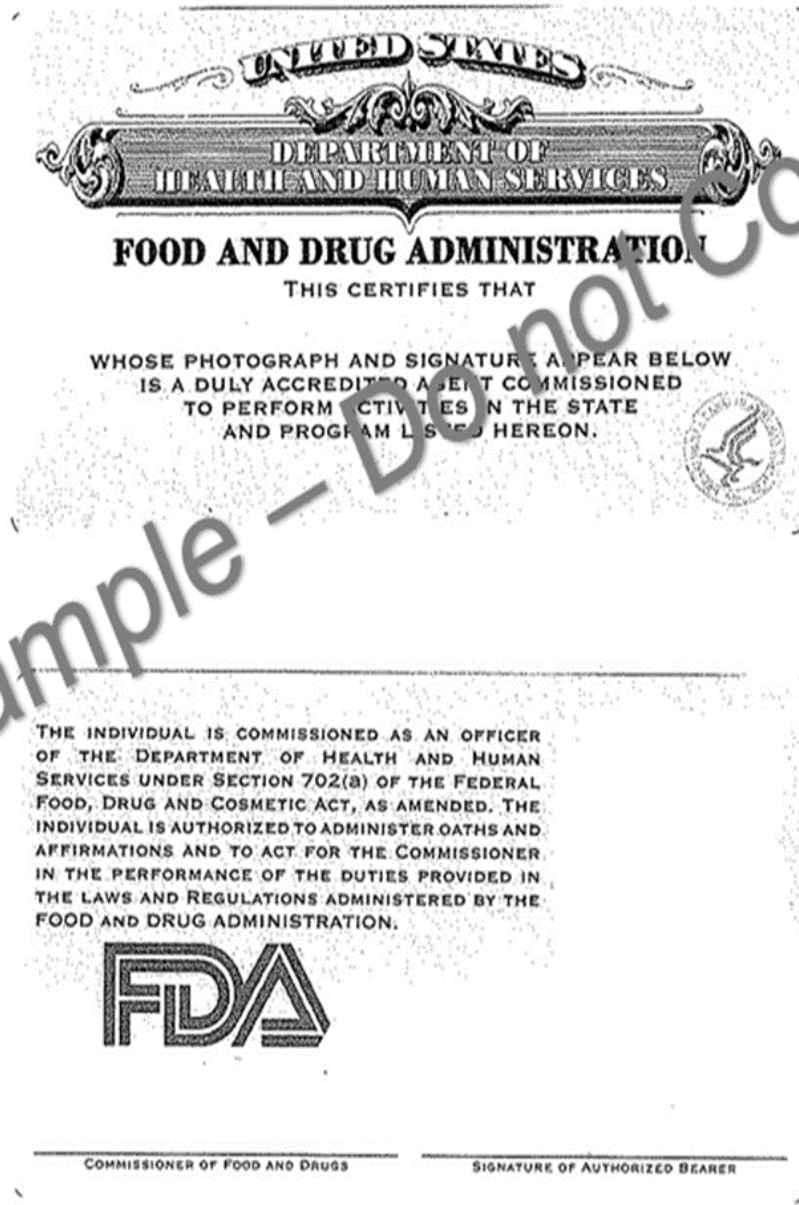


Exhibit 3-2: SAMPLE FORM FDA 3716: CERTIFICATE OF COMMISSION

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 STATE OF _____ FOR THE PURPOSE OF THE A T. THIS COMMISSION EXPIRES _____.

COMMISSIONER OF FOOD AND DRUGS

FORM FDA 3716 (5/11)