

# Regulatory Procedures Manual

## CHAPTER 10 – OTHER PROCEDURES

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## **10-1 COMMUNICATIONS – OFFICE OF REGULATORY AFFAIRS AND CENTER RESPONSIBILITIES**

### **10-1-1 Regulatory Actions that Require Center Concurrence**

When a decision is made by the Program Division that initiation of a regulatory action is appropriate, the Division should notify the appropriate Center compliance unit regarding its intent to submit a recommendation. Division Compliance staff should also remember to enter the “In Review” profile status as “pending” on the Maintain Profiles screen in eNSpect for each profile class covered when the recommendation is a result of a Current Good Manufacturing Practice (CGMP) or Quality System (QS) inspection of a domestic drug, biologics, or medical device facility. Compliance staff should also notate the Remarks field to explain the action being recommended. When the action recommendation is forwarded to a Center for review, the Remarks field should be updated to reflect that and include the date forwarded. With regard to foreign inspections, Center Compliance staff are responsible for the review and evaluation, and should enter the In Review “pending” status and notate the corresponding Remarks field as appropriate. See “Firm Profile Updates in eNSpect” in Chapter 4 for more information.

The Center will notify Program Division as soon as a case (compliance) officer has been assigned. This early communication will create opportunities to discuss the case, including the overall strategy, as well as the history, violations, rationale, charging scheme, regulatory and policy considerations, local knowledge, and national/program issues.

If, after its initial review of a Program Division's recommendation, the Center compliance unit is inclined not to concur with the Division's recommendation, the Center will promptly notify and provide the Division with an oral explanation for its preliminary decision not to concur with the recommendation. If the Division does not agree with the basis for the potential disapproval, it should provide the Center with additional justification for proceeding with the recommended action within three business days. The additional justification should be limited to information currently available to the Division, not a commitment to gather additional information to support the recommendation. The Center will consider this additional justification before making a final disposition on the Division's recommendation, apprise the Division of its decision, and prepare the final memo. The Center's final disposition on the recommendation (approved or disapproved) will normally not be delayed if it is determined that an inspection will be necessary to collect additional supporting evidence. The involved compliance officer and the appropriate division should participate in discussions with the Center that occur during the process described in this paragraph. If the official action proposed was not the subject of a formal recommendation from the Division (e.g. BIMO, foreign inspection), the same communication principles should apply between involved Center and Division staff.

### **10-1-2 Regulatory Actions prepared by a Center for Program Issuance and/or Follow-up**

When a decision is made by a Center that a Program Division issuance, involvement and/or follow-up is an appropriate course of action, the Center should notify the appropriate Division compliance unit(s) regarding its intent to prepare a regulatory action, and provide the Division(s) with an opportunity to collaborate on the compliance strategy and the substance of the action.

### **10-1-3 Debarment - Notification Responsibilities of FDA Employees**

#### **1. Background**

- a. Purpose and Authority for Debarment - Debarment is a remedial measure taken under section 306 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to prohibit a person (e.g., an individual, corporation, partnership, or association) from participating in FDA-regulated activities, as described below:
  - i. A person other than an individual may be prohibited from submitting, or assisting in the submission of, any abbreviated drug application. Sections 306(a)(1) and 306(b)(1)(A).
  - ii. An individual may be prohibited from providing services in any capacity to the sponsor of an approved or pending drug product application. Sections 306(a)(2) and 306(b)(1)(B).
  - iii. A person may be prohibited from importing an article of food, or offering an article of food for import, into the United States. Section 306(b)(1)(C).
  - iv. A person may be prohibited from importing or offering for import into the United States any drug. 306(b)(1)(D)
  - v. A person may be prohibited from being accredited to inspect eligible device manufacturers and from carrying out activities under agreements with foreign countries to facilitate commerce in devices. Section 306(m)(1).

Debarment may be based on a criminal conviction or on conduct, as identified in section 306 of the Act. See *Persons Subject to Debarment* in paragraph 3 in this subsection.

- b. “Drug Product” - For purposes of section 306, the term “drug product” means a drug subject to regulation under section 505 (new drugs), section 512 (new animal drugs), or section 802 (exports of certain

unapproved products) of the Act, or under section 351 (regulation of biological products) of the Public Health Service Act. Section 201(dd).

- c. Other Possible Actions - Civil Penalties
- d. Under section 307(a)(6) of the Act, any person with an approved or pending drug product application who knowingly engages the services of a debarred person is liable for civil penalties.
- e. Under 307(a)(7), debarred individuals are subject to civil penalties for providing services to a person with an approved or pending drug product application.

## 2. Notification Responsibilities

- a. Authority - Staff Manual Guide (SMG) [7712 - Debarment Proceedings](#) provides general procedures for FDA staff to follow for debarment actions and defines the responsibilities of FDA employees. ORA's Division of Enforcement (DE) has responsibility for initiating and pursuing debarment actions. All FDA employees have a responsibility to notify DE of any persons that may be subject to debarment and to forward relevant materials to DE within specified timeframes, as detailed below.
- b. Required Notification - In accordance with [SMG 7712](#), all FDA employees have the following responsibilities:
  - i. Ensuring that ORA's Division of Enforcement (DE) is notified when the employee observes conduct or has notice (from an oral or written communication) that a person may be subject to debarment.
  - ii. Ensuring that DE is provided with copies of all relevant materials (e.g., any written notice or petition for debarment and information supporting debarment) in the employee's possession.

Send the notification and materials to the attention of the Debarment Specialist, DE via electronic transmission, interoffice or regular mail, or FAX. Include your name, office, and phone number. The debarment specialist can be reached at [debarments@fda.hhs.gov](mailto:debarments@fda.hhs.gov) or 240-402-8743. Contact the debarment specialist if you have any questions about notification or debarment, or if you need further information.

- c. Timeframes for Notification - If the person who may be subject to debarment:
  - i. has an approved or pending drug application;
  - ii. is an employee of such a person;
  - iii. is a clinical investigator;
  - iv. is currently engaged in importing food or offering it for import; or
  - v. is currently engaged in importing a drug or offering it for import;  
or
  - vi. has been convicted of a felony under section 301(gg) of the Act,

FDA employees will notify DE as soon as is practicable. Otherwise, employees will notify DE within ninety (90) days of receiving the oral or written notice.
- d. Requirements Applicable to OCI - The Office of Criminal Investigations (OCI) is responsible for providing quarterly reports to the DE that set forth all convictions that have occurred within the preceding three (3) months that may trigger debarment.

### 3. Persons Subject to Debarment

The triggering event for debarment is ordinarily a felony or misdemeanor conviction under Federal law or a felony conviction under State law. However, certain conduct may subject a food or drug importer, and, for drugs and biologics, a high managerial agent (and other individuals) to debarment. The types of convictions and conduct that may subject persons to debarment are detailed in section 306 of the Act and summarized below, by product type.

- a. Foods: A person (an individual, corporation, partnership, or association) is subject to debarment if the person has been convicted of a felony for conduct relating to the importation into the U.S. of any food, or has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals. Section 306(b)(3).
- b. Drug Imports: A person (an individual, corporation, partnership, or association) is subject to debarment if the person has been convicted of a felony for conduct relating to the importation into the U.S. of any drug or controlled substance (as defined in section 102 of the

Controlled Substances Act [21 USCS § 802]), or has engaged in a pattern of importing or offering for import, (i) controlled substances that are prohibited from importation under section 401 (m) of the Tariff Act of 1930 (19 U.S.C. 1201(m)) or, (ii) adulterated or misbranded drugs that are (I) not designated in an authorized electronic data interchange system as a product that is regulated by the Secretary or (II) knowingly or intentionally falsely designated in an authorized electronic data interchange system as a product that is regulated by the Secretary. Section 306(b)(3).

- c. Drugs (Drugs Applications) – Corporations, Partnerships, and Associations: A person other than an individual is subject to debarment if that person has been:
  - i. Convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application. Section 306(a)(1).
  - ii. Convicted for conduct that relates to the development or approval, including the process for development or approval, of any abbreviated drug application, and is a misdemeanor under Federal law or a felony under State law. Section 306(b)(2)(A)(i).
  - iii. Convicted of a conspiracy to commit, or aiding or abetting, a criminal offense described in i. or ii. above. Section 306(b)(2)(A)(ii).
- d. Drugs/Biologics (Drug Applications) – Individuals: An individual is subject to debarment if s/he has been:
  - i. Convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product, or otherwise relating to the regulation of any drug product under the Act. Section 306(a)(2).
  - ii. Convicted of a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product, or otherwise relating to the regulation of drug products under the Act, or has been convicted of a conspiracy to commit, or aiding or abetting, a criminal offense described in this paragraph or the preceding paragraph. Section 306(b)(2)(B)(i).



- iii. Convicted of a felony under Federal law or a felony under State law which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or a conspiracy to commit, or aiding or abetting, such felony. Section 306(b)(2)(B)(ii).
- e. Drugs/Biologics (Drug Applications) – Debarment based on Conduct:  
An individual is also subject to debarment:
- i. If s/he materially participated in acts that were the basis for a conviction for an offense subject to debarment. Section 306(b)(2)(B)(iii).
  - ii. If s/he is a high managerial agent who:
    - worked for, or worked as a consultant for, the same person as another individual during the period in which such other individual took actions for which a felony conviction was obtained and which resulted in the debarment of such individual;
    - had actual knowledge of the actions described above of such other individual, or took action to avoid such actual knowledge, or failed to take action for the purpose of avoiding such actual knowledge;
    - knew that the actions were violative of law; and
    - did not report such actions, or did not cause such actions to be reported, to an officer, employee, or agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable time after such agent first knew of such actions. Sections 201(bb) and (cc), and 306(b)(2)(B)(iv).
  - f. Devices: A person (an individual, corporation, partnership, or association) accredited to inspect eligible device manufacturers is subject to debarment if the person has been convicted of a felony for one or more prohibited acts under section 301(gg) of the Act. Section 306(m).

Section 301(gg) prohibits the knowing failure to notify the Secretary of a condition the accredited person discovered during an inspection that could cause or contribute to an unreasonable risk to the public health as

required by section 704(g)(7)(E), or an accredited person's knowing inclusion of false information in an inspection report prepared under section 704(g)(7)(A), or the knowing failure to include material facts in such a report.

## 10-2 PRIOR NOTICE

### 10-2-1 Purpose

This section defines "prior notice" and establishes uniform criteria to determine if adequate prior notice has been provided.

### 10-2-2 Background

Except in a few specifically defined areas, the Food and Drug Administration (FDA) has no legal obligation to warn firms or individuals that they, their practices, or their products are in violation of the law prior to taking formal enforcement action. However, a basic principle of FDA's enforcement policy is the belief that the majority of persons will voluntarily comply with the law when given information as to what is required, what violations appear to exist, and, in the case of violations of regulatory significance, that failure to comply may result in the initiation of enforcement action.

### 10-2-3 Prior Notice

When it is consistent with the public protection responsibilities of the agency and if a violative situation does not present a danger to health or does not constitute intentional, gross or flagrant violations, it is FDA's practice to afford individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action. If voluntary correction is not achieved, documentation that adequate prior notice was provided strengthens the agency's position in enforcement actions by establishing that responsible individuals continued violating the law despite having been warned by the agency.

The following factors should be considered in evaluating the adequacy of prior notice (prior warning):

1. The conduct, condition, practice, or product violates the laws enforced by FDA.
2. The notice (warning) adequately identified the violative conduct, condition, practice or product.

**Note:** Similar violations do not need separate prior notices, for example, separate prior notices are not necessary for each unapproved new drug shipped.

3. Notice (warning) was provided to the firm and the most responsible individuals.

4. The firm was afforded a reasonable amount of time to implement corrections. Corrections may include halting shipments, recalling product in violation, or changing procedures and controls.
5. Consider if situations have occurred that may affect the adequacy of prior notice, such as a change in ownership or responsible management. For example, consider what is known by the new management, and if the "firm" received notice.

**Note:** Prior Notice may be provided orally or in writing. Where there is no dispute as to what is required to comply with the law, adequate notice may well be the Investigator's discussion of objectionable conditions with responsible management at the conclusion of the inspection. If, however, the violative conduct involves a controversial area, an area in which policy is still emerging, or one that has not been pervasively regulated in the past, written notice (usually in the form of a Warning Letter) may be required prior to the initiation of enforcement action.

Consideration of these factors will facilitate meeting the prior notice requirements for civil and certain criminal actions.

#### **10-2-4 Procedures**

Warning Letters are the principal means by which the agency provides prior notice of violations and of achieving voluntary compliance. See RPM Chapter 4, Advisory Actions. However, Prior Notice may be provided by means of a civil suit, administrative action, or other less formal ways, including the following:

1. Enforcement action or notification by State, municipal or other Federal agencies involving the same or similar violations.
2. Issuance of the FDA-483, List of Observations, at the conclusion of an inspection. Issuance of a copy of the FDA-483 to a firm's most responsible person(s) must follow guidance in [IOM Chapter 5 – Establishment Inspections](#).
3. Discussion with management by an FDA investigator, documented in the EIR.
4. Recall Classification Notification Letters.
5. Properly documented meetings or telephone conversations between agency officials and a firm's top management (see section [10-3, Regulatory Meetings](#)).
6. Properly documented advisory communications by FDA Center personnel concerning critical scientific issues.

**Note:** For further information related to "properly documented" telephone conversations and meetings, see [SMG 2126.2, Memoranda of Telephone Conversations and Meetings with Non-FDA Persons](#).

### 10-3 REGULATORY MEETINGS

A Regulatory Meeting is a meeting requested by FDA management at its discretion, to inform responsible individuals or firms about how one or more products, practices, processes, or other activities are considered to be in violation of the law. FDA is not required to hold a Regulatory Meeting and, except for a few specifically defined areas (see [RPM Chapter 4, Advisory Actions](#) > Warning Letter Procedures), is not required to provide any other form of prior notice prior to taking an enforcement action.

Regulatory Meetings can be an effective enforcement tool to obtain prompt voluntary compliance, and have been used successfully in a variety of different situations, including:

1. As a follow-up to a Warning Letter when firms have corrected the majority of violative conditions noted in the Warning Letter, to provide additional encouragement, direction, and assistance in achieving compliance. As a follow-up to a Warning Letter, FDA officials may remind a firm or individual in a Regulatory Meeting that failure to make appropriate corrections in a timely manner may result in enforcement action.
2. To communicate documented violations that do not warrant the issuance of a Warning Letter. Under these circumstances, a Regulatory Meeting provides the added benefit of real time, two-way discussion of the violations and the appropriate corrective actions.

A Regulatory Meeting should not be used as a substitute for an Untitled Letter when a particular compliance program calls for the issuance of an Untitled Letter. Also, in most cases, a Regulatory Meeting should not be used to initially communicate violations of regulatory significance. Such violations are generally best communicated in the form of a Warning Letter. However, there are some situations when a regulatory meeting may be used to initially communicate violations of regulatory significance. Examples include:

1. When a Regulatory Meeting is held to communicate a health hazard and the necessity for immediate corrective action to address violative product that is on the market.
2. When a Regulatory Meeting is held in conjunction with the issuance of a Warning Letter to emphasize the significance of the violations.

A successful outcome of a Regulatory Meeting would include a commitment by the responsible individuals to correct the conditions or practices at their facility that are in violation of the law. The divisions, at their discretion, would typically verify these

commitments through evaluation of subsequent communication and documentation and/or a follow-up inspection. The inspection classification should reflect the significance of the violations and can be appropriately modified based on the adequacy of the corrective action. In those instances where the corrective actions are not satisfactorily carried out, definitive plans should be made for follow up action by the Division. Consult with the involved Center and DE is advisable.

Any FDA organization with regulatory oversight of a firm or individual has the discretion to decide whether or not to hold a Regulatory Meeting. If a Center decides to hold a Regulatory Meeting concerning observations made by one or more Divisions, the Center should invite any -ORA DE staff involved and consider any objections that such division(s) may have to such meeting. Centers are also encouraged to invite division participation in Regulatory Meetings concerning observations or matters originating in the Center (e.g., unapproved new drug or device issues). Any disagreement between a Center and a Division about whether to conduct a Regulatory Meeting should be resolved by collaborative discussion with the Center, Division, and DE.

For situations that involve corporate-wide violations or multiple divisions, the meeting should include the affected Centers, DE, and the involved Divisions. The location of the meeting should be negotiated by the involved parties.

Summary minutes must be prepared for all regulatory meetings.

## **10-4 INSPECTION OF FOOD RECORDS – SECTIONS 414(a) and 704(a)**

### **10-4-1 Purpose**

This section describes the authority, criteria, and procedure for inspecting records under sections 414(a) and 704(a) of the FD&C Act.

### **10-4-2 Authority**

1. The FD&C Act:
  - a. Section 414(a) Records Inspection – Criteria for records access, see subsection [10-4-3](#) below.
  - b. Section 414(b)- Authority to issue regulations to establish requirements for the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food. See 21 CFR 1.326 to 1.368.
  - c. Section 414(c)- Protection of sensitive information. FDA shall take appropriate measures to ensure that effective procedures are in place to prevent the unauthorized disclosure of any trade secret or

confidential information that is obtained by FDA pursuant to section 414.

- d. Section 414(d) Limitations- This section shall not be construed -- (1) to limit the authority of FDA to inspect records or require establishment and maintenance of records under any other provision of this Act; (2) to authorize FDA to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq); (3) to have any legal effect on section 552 of title 5, United States Code, or section 1905 of title 18, United States Code; or (4) to extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).
- e. Section 704(a)(1)(B)- Requirement that, during an inspection, any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods provide access to all records and other information described in section 414, when the criteria for records inspection in section 414(a)(1) or (a)(2) are satisfied, subject to the limitations in section 414(d).
- f. Section 301(e)- Authority to treat the refusal to permit access to or copying of any record required by section 414 or 704(a) or the failure to establish or maintain any record required by section 414(b) as prohibited acts.

## **2. 21 CFR 1.361: What are the Record Availability Requirements?**

When FDA has a reasonable belief that an article of food, and any other article that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (SAHCODHA), or when FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the FDA reasonably believes is likely to be affected in a similar manner, will cause SAHCODHA, any records and other information accessible to FDA under section 414 or 704(a) of the FD&C Act must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the request.

### **10-4-3 Statutory requirements for invoking records inspection authority**

FDA can invoke its authority to access and copy records when the statutory requirements in section 414(a)(1), 414(a)(2), or section 704 of the FD&C Act are satisfied, whether or not intentional adulteration is known or suspected.

#### **1. Section 414(a)(1) Adulterated Food**

If FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA has authority to access and copy all records relating to such articles that are needed to assist FDA in making this determination.

#### **2. Section 414(a)(2) Use of or Exposure to Food of Concern**

If FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, FDA has authority to access and copy all records relating to such article, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, that are needed to assist FDA in making this determination.

Sections 414(a)(1) and 414(a)(2) apply to any person - *excluding farms and restaurants* - who manufactures, processes, packs, distributes, receives, holds, or imports such article of food. Appropriate credentials and a written notice must be presented and the request for records must be conducted at reasonable times, within reasonable limits, and in a reasonable manner. See 10-4-7.

For foreign firms, section 414 applies to any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports such article intended for U.S. commerce.

### **10-4-4 Records that may be accessed and copied under this authority**

FDA may access and copy all records, as authorized under section 414 and 704 relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of the article of food that are maintained by or on behalf of an entity in any format (including paper and electronic formats) and at any location, which are needed to meet the criteria in section 414(a)(1) or (a)(2). See 21 CFR 1.326.

The Investigator should initially request and review the records most likely needed to establish adulteration and serious adverse health consequences or death to humans or

animals. See sections 414(a)(1) and (a)(2). The Investigator, as appropriate, should extend the review to other necessary records.

#### **10-4-5 Records that may *not* be accessed and copied under this authority**

FDA's authority under sections 414 and 704(a) of the FD&C Act does not apply to: recipes for food, financial data, pricing data, personnel data, research data (except test marketing a food), or sales data (other than shipment data regarding sales), all of which are excluded under section 414(d). In addition, FDA may not access records from farms and restaurants. See 21 CFR 1.362.

In 21 CFR 1.328, "recipe" is defined as "the formula, including ingredients, quantities, and instructions necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe." Accordingly, FDA has authority to access such a list of ingredients in a records request.

#### **10-4-6 Procedure for Invoking Records Inspection Authority**

The Program Division must obtain ORA/Division of Enforcement (DE) concurrence in accordance with the procedures below before making a request to any person for access to records under sections 414(a) and 704(a). The procedure should be expedited and be initiated upon receiving the firm's refusal. The final determination to invoke this authority should occur within 24 hours of initiating this procedure.

1. FDA's Office of Emergency Operations (OEO) will coordinate activities to obtain ORA/DE concurrence on a records request and should be initially contacted as follows:
  - a. During a domestic inspection, Program Division or other FDA personnel notifies FDA's OEO at 866-300-4374 or 301-796-8240; or via email at [Emergency.Operations@fda.hhs.gov](mailto:Emergency.Operations@fda.hhs.gov) – 24 hours/day. OEO may be contacted in advance of an inspection if the refusal of records is likely.
  - b. During a foreign inspection, the FDA investigator conducting the inspection notifies the Division of Foreign Human and Animal Food Operations (DFHAFO) for guidance. DFHAFO then notifies OEO.
2. OEO notifies the appropriate Center (CFSAN and/or CVM) and ORA/DE either verbally or in writing.
3. OEO schedules a conference call with the Program Division, appropriate Center compliance unit, ORA/DE, and the Office of Chief Counsel (OCC). Prior to the conference call, the Program Division should prepare a draft recommendation



memorandum (Exhibit 10-1) and a draft Form FDA 482c for OEO to distribute to call participants on the call. During the conference call:

- a. The Program Division must be prepared to address the following:
    - Rationale for why there is a reasonable belief regarding an article of food as required by section 414(a)(1) and/or a reasonable probability regarding an article of food as required by section 414(a)(2) of the FD&C Act;
    - Details surrounding record refusal, including the reason for refusal and FDA's attempts at obtaining necessary records;
    - Date/s of the inspection;
    - List of records to be requested and rationale for why the records meet the statutory requirements of section 414 of the FD&C Act; and
    - Approximate timeframe for when the Form FDA 482c could be issued, if approved, and any concerns surrounding issuance.
  - b. The appropriate Center, with the concurrence of ORA/DE, determines that there is a reasonable belief that the food is adulterated and presents a threat of SAHCODHA, or that there is a reasonable probability that the use of or exposure to the food will cause SAHCODHA.
  - c. ORA/DE concurs with any requests for access to records, and works with the appropriate Center to determine the scope of the request and ensures the requested records are necessary to assess whether the food, and any other food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of SAHCODHA or whether there is a reasonable probability that the use of or exposure to the food, and any other food that FDA reasonably believes is likely to be affected in a similar manner, will cause SAHCODHA.
  - d. The appropriate Center consults with OCC on the determination of whether there is a reasonable belief that the food is adulterated. ORA/DE will consult with the appropriate Center and OCC in determining the appropriate scope of the records request.
4. After concurrence has been reached on the call from ORA/DE, the Center, and OCC, the Program Division finalizes the recommendation memorandum (Exhibit 10-1) and forwards it to the Center for final concurrence. OEO prepares a record of the call and distributes the record to the participants on the call.

5. The delegated official from the Center signs the final determination (Exhibit 10-1). See [SMG 1410.306, Determinations Related to Records Access for Human and Animal Foods under Section 414 of the Federal Food, Drug, and Cosmetic Act](#), for delegations of authority.
6. Once the final determination is signed by the Center, the Center provides the signed memorandum to ORA/DE. ORA/DE conveys the information to the Program Division Director for the facility being inspected (domestic inspection) or DFHAFO (foreign inspection). If it is a foreign inspection, DFHAFO conveys the information to the appropriate foreign inspection investigator.
7. The Program Division maintains the case documentation in CMS, including a record of concurrence by each office. For foreign inspections, the Center is responsible for managing the case in CMS. Once the 482c is issued, the case may be closed. The case may be withdrawn if the decision is made to not pursue the records request.

#### **10-4-7 Issuing Form FDA 482c**

After the necessary determination has been made in accordance with the procedures in section [10-4-6](#) above, an investigator or other authorized FDA personnel upon presentation of credentials will issue a written notice, Form FDA 482c, to the owner, operator, or agent in charge, informing that person of the records requested and FDA's legal authority to obtain such records. The Form FDA 482c and the related procedures are described in the Investigations Operations Manual (IOM) [Chapter 5 - Establishment Inspections Subchapter 5.4 - Food](#). FDA may request additional records related to the implicated food at a later time under the same authority. For foreign inspections, consult with OCC.

#### **10-4-8 Timeframes for compliance**

For all persons except foreign firms, records and other information requested under this authority must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the request. 21 CFR 1.361. The Division should document in CMS the outcome and the firm's compliance with request.

#### **10-4-9 Failure to provide records**

The refusal to permit access to or copying of any record required by section 414 or 704(a) and the failure to establish or maintain any record required by section 414(b) are prohibited acts under section 301(e) of the Act. See 21 CFR 1.363.

## **10-5 ESTABLISHMENT INSPECTION REPORT (EIR) CONCLUSIONS AND DECISIONS**

For further information, see Field Management Directive (FMD) [No. 86 Establishment Inspection Report Conclusions and Decisions](#), or refer to the FDA's [FMD web site](#).

Please remember to update the firm's profile information at each stage in the review process to its conclusion, as appropriate, for any Current Good Manufacturing Practice (CGMP) or Quality System (QS) inspection of a domestic or foreign drug, biologics, or medical device facility that involves compliance activity or status. See "Firm Profile Updates in eNSpect" in RPM Chapter 4 for further information.

### **10-5-1 Release of the Establishment Inspection Report**

For further information on the criteria and instructions for releasing one copy of an Establishment Inspection Report, to the firm's top management or designee at the inspected firm, see Field Management Directive [No.145 Release of the Establishment Report](#).

### **10-5-2 No Action Indicated (NAI) and Voluntary Action Indicated (VAI) 90 day Decisional Letters for Drug Inspections**

For further information on the criteria and instructions for the new NAI and VAI 90 Day Decisional Letters, see Field Bulletin [No.63 - FMD-145 NAI/VAI 90 Day Decisional Letters for Drug Inspections](#)

## **10-6 INTERSTATE TRAVEL PROGRAM (ITP) CLASSIFICATIONS AND ADMINISTRATIVE ACTIONS**

For further information related to ITP see [Compliance Program 7318.029, Interstate Travel Program-- Conveyances and Support Facilities](#).

## **10-7 REPORTING AND MONITORING**

The Field Accomplishments and Compliance Tracking System (FACTS) replaces this section. Please see your FACTS Lead User for further guidance.

## 10-8 AD HOC COMMITTEE

### 10-8-1 Purpose

This section outlines the function, composition, and activities of agency *ad hoc* committees that are convened for enforcement purposes, and lists the responsibilities of the field and headquarters units in recommending and carrying out their goals.

### 10-8-2 Function

There are four principle types of *ad hoc* committees: “strategy,” “referral,” “appeal,” and “seizure/injunction.”

1. Strategy *ad hoc* committees are formed to resolve issues for which agency precedent is lacking on matters that involve complex and difficult enforcement issues, or where there is a dispute between two or more offices over strategy.
2. Referral *ad hoc* committees are formed to consider the referral of a matter to the Department of Justice for further criminal investigations or proceedings. See RPM Chapter 6, “Judicial Actions.”

Note: OCI is responsible for reviewing all matters within FDA’s jurisdiction for which a criminal investigation may be recommended. If the division or center office believes that there is a need for a criminal investigation, they must contact OCI immediately. If OCI concludes that they will not be participating in the matter at the time, the division office or center may then proceed as outlined below under [10-8-4 Procedures](#).

3. Appeal *ad hoc* committees are formed to resolve issues pertaining to a legal, administrative, or regulatory course of action, when enforcement policy is inconsistent, unclear or not fully developed.
4. Seizure/injunction *ad hoc* committees may be convened at any time during the preliminary assessment, case initiation, or concurrent review process (see [RPM Chapter 6](#)) when ORA, the Center Director, or the Deputy Chief Counsel for Litigation, or a designee, cannot agree on the strategy or viability of a seizure or injunction case.

*Ad hoc* committees may be formed at any point in the case development or review process; however, early identification of the need for an *ad hoc* committee enables a more prompt review of the action.

### 10-8-3 Composition

The *ad hoc* committee will be chaired by the Director, DE, and will consist of the appropriate directors of Program Office involved and of the center office of compliance,

the Deputy Chief Counsel for Litigation and, if appropriate, the Director, OCI. The Director, OEIO, should be included when the matter involves a foreign inspection. When a committee member is unable to participate in a scheduled *ad hoc* meeting, he or she must designate an appropriate official to serve in his or her absence.

The committee members or their designated representatives should be prepared to make agency decisions on the issues based upon the evidence presented prior to and during the *ad hoc* committee meeting. The committee members are also responsible for identifying and arranging for the participation of any additional personnel and for other resources that they feel are necessary. Personnel should be limited to those individuals who have knowledge of the events at issue or who can significantly help in the decision making process.

#### **10-8-4 Procedures**

Requests for forming a strategy, referral, appeal, or seizure/injunction *ad hoc* committee may originate from an appropriate division director and program office director, DE; a Director of Compliance; or the Deputy Chief Counsel for Litigation.

If the parties cannot reach an agreement working on their own or with the help of DE, DE will schedule an *ad hoc* committee meeting.

The person who requests an *ad hoc* committee must submit a memorandum via CMS to DE, OSPOP. The memorandum should specify the type of *ad hoc* committee being requested.

- a. The person who requests a strategy *ad hoc* committee should include in the memorandum the recommended outcome of the meeting.
- b. The person who requests a referral *ad hoc* committee should include in the memorandum a description of the evidence expected to be gained through further criminal investigations or proceedings and the reasons it is necessary to refer the matter to the Department of Justice instead of continuing with an FDA investigation.
- c. The person who requests an appeal *ad hoc* committee does not need to summarize the facts and evidence in the memorandum if the committee participants are already familiar with the case; however, if the committee participants are unfamiliar with the case, the person who requests an appeal *ad hoc* should include sufficient background and supporting information in the memorandum.
- d. The person who requests a seizure/injunction *ad hoc* committee should describe any disputed data, information, or views in the memorandum. When an *ad hoc* committee is requested, the clock for reviewing seizure/injunction cases will be tolled. Therefore, the time it

takes to review the *ad hoc* request will not be applied against the timelines for reviewing seizure/injunction cases, described in section 6-1-5 (4). The *ad hoc* committee will immediately establish a time schedule for its review of the case.

At the *ad hoc* committee meeting, the person who requested the meeting will briefly summarize the reason for the request, recommend an outcome of the meeting, describe any foreseeable problems, and provide whatever information may be useful in reaching a decision.

All decisions made by the *ad hoc* committee, including necessary follow-up and strategy, will be recorded, disseminated, and noted in the appropriate section of CMS by the Compliance Officer assigned to the case.

The *ad hoc* committee may reconvene in cases of significant changes, or revisions to the original *ad hoc* supporting material, the discovery of new information or evidence, or when other issues arise that could impact the original decision of the committee. These changes must first be reviewed under the regular review process. If it is necessary to reconvene the *ad hoc* committee, the original *ad hoc* attendees should make every effort to attend any follow-up *ad hoc* meeting.

In most instances, the committee will reach a decision through consensus of the members. When consensus is not possible, the Director, DE will refer the matter to the Associate Commissioner for Regulatory Affairs (ACRA) with a recommendation for making a final decision.

All committee decisions are subject to review by the ACRA and OCC, and the final decision will not be subject to appeal.

#### **10-8-5 Responsibilities**

DE receives the request for convening an *ad hoc* committee review. DE assesses the request to determine if there is a clear indication of a dispute or other issue in need of resolution, determines whether sufficient information was submitted, attempts to obtain a resolution with the parties, and if a resolution cannot be reached, establishes the time and place for the meeting. DE will also disseminate the request and any supporting material to the principal members of the *ad hoc* committee.

The Director, DE, chairs the *ad hoc* committee and issues the final decision based upon the *ad hoc* committee's discussion. If the *ad hoc* committee cannot reach a decision, the Director, DE, refers the matter to the ACRA for a final decision.

The Director, ORO, may recommend convening an *ad hoc* committee based on issues that arise from ORO headquarters based program activities.

The appropriate division directors listed in [subsection 10-8-3 Composition](#) make a final decision on all recommendations for an *ad hoc* committee from the field. The Regional Director serves as a principal on the *ad hoc* committee.

The Division Director may recommend the convening of an *ad hoc* committee and forward the recommendation to DE through the appropriate division directors listed in [subsection 10-8-3](#).

The Director of Compliance of the appropriate Center approves or disapproves all recommendations for an *ad hoc* committee from the center and will serve as a principal on the *ad hoc* committee.

The Deputy Chief Counsel for Litigation will serve as a principal on the *ad hoc* committee to provide legal counsel, and to advise on a particular recommendation.

The ACRA may review all committee decisions.

Committee members who are unable to participate in a scheduled *ad hoc* meeting are responsible for designating an appropriate official to serve in their absence. The committee members are also responsible for identifying and arranging for the participation of any appropriate resource persons they feel are necessary, and for providing necessary background information to those persons.

## **10-9 APPEAL PROCESS**

### **10-9-1 Purpose**

This section sets forth a procedure for the appeal of decisions regarding recommendations for legal or administrative actions.

### **10-9-2 Who May Appeal**

Appeals may be originated by the appropriate division directors listed in [subsection 10-8-3](#) or the Center Directors for Compliance (or equivalent).

### **10-9-3 What May Be Appealed**

Appropriate officials may appeal any decision disapproving a proposed action, administrative or legal, which is allegedly inconsistent, or where there is nonexistent enforcement policy. The directors of the involved offices must have attempted to resolve the disagreement prior to submitting an appeal.

### **10-9-4 When An Appeal Is Not Appropriate**

An appeal is not appropriate when additional information that overcomes the basis for the original denial becomes available. In such cases, the recommendation should be

updated to include the new or additional information and resubmitted to the reviewing office with an explanation for the resubmission and a request for reconsideration.

#### **10-9-5 Requests For Appeal**

ORA should submit appeals over the signature of the appropriate division directors listed in [subsection 10-8-3](#). Centers should submit appeals over the signature of the Center Director for Compliance. The appeal memorandum and two copies of relevant supporting material must be identified, indexed, and submitted to the Director, DE.

The appeal memorandum must identify the issues on which the appeal is based, and the reasons for disagreeing with the decision of the declining unit. Recommendations must include a summary of communications regarding attempts to resolve differences of opinion.

#### **10-9-6 Review Of Appeals**

DE will review the appeal package to assure that it is complete, determine that an appeal is appropriate, and will determine whether the appeal deals with policy, regulations, or a statute. DE will initially attempt to gain a resolution of the disagreement by the parties to the appeal.

#### **10-9-7 Decision On Appeals**

If DE cannot get the parties to agree, an *ad hoc* committee meeting to be chaired by the Director, DE, will be scheduled, following the procedures outlined in section 10-6, *ad hoc* Committee.

The meeting will include the appropriate division directors listed in [subsection 10-8-3](#), the Center Director for Compliance, and the Deputy Chief Counsel for Litigation, if appropriate. If the principals are unable to attend, they will designate a senior compliance official to serve in their absence. Usually only one resource person must accompany the senior compliance official.

Resolution of appeals is by consensus of the *ad hoc* committee members. If the *ad hoc* committee can not reach a consensus, the matter will be forwarded to the ACRA for a final decision.

Decisions made by the *ad hoc* committee will be recorded and distributed to meeting participants. The decision may be limited to a decision on the merits of the case or it may include instructions to develop policy in a particular program area. The ACRA or OCC may review all committee decisions.



## **10-10 EXPERT SUPPORT FOR CASES**

### **10-10-1 Purpose**

This section sets out a procedure for assuring that medical, scientific, technical or other specialized (collectively “expert”) support is available for a case. A witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if

1. the testimony is based upon sufficient facts or data,
2. the testimony is the product of reliable principles and methods, and
3. the witness has applied the principles and methods reliably to the facts of the case.

Federal Rules of Evidence, “Rule 702. Testimony by Experts”.

For purposes of this section, the term “case” refers to a matter that is or may become a court case or hearing. The term “experts” is used to describe individuals from within or outside of FDA, who may serve as consultants and/or as expert witnesses in a case. FDA may seek expert support whether or not a case is contested or litigated.

### **10-10-2 Responsibility**

The Centers have the primary responsibility for assuring that FDA has appropriate expert support for a case, if needed to support the particular violation. The initial determination as to the need for expert support shall be included in the approval memorandum. The Center Compliance Office, in consultation with OCC, should determine whether or not FDA needs expert support for a case. If the Center determines that expert support is needed, it should consult with its medical or scientific review staffs to ensure that the Center position on the subject represents the consensus of current informed medical or scientific opinion. If necessary, the Center should also consult ORA to make this determination. See also [FDA SMG 2610.2, Obtaining Services of Expert or Fact Witnesses](#) (7/2/98).

The Center should also determine whether FDA will be able to obtain expert support for a case, when it is necessary to do so. The Center should not send a case forward to institute actual legal proceedings until it makes these determinations about expert support.

### **10-10-3 Criteria For Determining The Level Of Expert Support**

FDA requires outside expert support in precedent-setting cases when FDA does not have sufficient in-house expertise. If in-house experts are available, the Center should

contact them to determine whether it should also contact individuals from outside FDA to assess the consensus of current medical, scientific, or technical opinion.

The Center generally should review unprecedented issues and complex cases involving state-of-the-art and/or current good manufacturing practice to determine whether it should obtain concurrence by the experts.

The Center generally needs only limited additional expert support for cases that are sufficiently similar to previous cases, except where a new court decision, regulation, or policy has sufficiently changed the factors to consider.

The Center generally needs to refer only to recent cases when determining the need for expert support in a current case that is identical to a recent case.

#### **10-10-4 Documentation**

The Center's approval memorandum for a case should include a section regarding expert support, under a separate heading. This section should summarize the Center's effort to provide assurance of expert support and describe significant issues or concerns related to the expert support. It should also include relevant information about prior or pending court cases, testimony or affidavits developed during a recent court case or hearing, information derived during recent processes to propose or finalize rules, advisory committee meetings, literature searches that support the consensus of current opinion, memoranda of conversations with experts, etc.

#### **10-10-5 List Of Individuals For Expert Support**

The Center should develop and maintain a list of experts. The Center might develop this information from a variety of sources, but it is responsible for assuring the adequacy of the expert support for a case. For example, when the Center contacts an expert, it should consider asking that expert to identify other individuals with similar expertise. This may be useful in the case at hand (e.g., if a corroborating witness is needed) as well as in future cases.

#### **10-10-6 Obtaining And Paying For Expert Support**

The Center might determine that FDA needs expert support from outside FDA to review a case and/or to serve as an expert witness. In that event, the Center should consult with other FDA components, e.g., Office of Chief Counsel and ORA division offices, to identify the most suitable witness, obtain the services of that individual, and pay for fees. Further background about obtaining the services of experts and paying for expert support is set out in an August 25, 2003, memorandum, *Obtaining Services of and Paying for Expert Witnesses/Consultants--Policy* from Donald Vasbinder, Acting Director, Office of Enforcement, to FDA Center and ORA managers. A copy of the memorandum can be found on Inside FDA - Home > Policies & Procedures > Guidance & Regulations: Enforcement > Payment/Costs.

As explained in that memorandum, it is important to keep in mind the overall principle that each case is brought on behalf of the FDA, not any particular part of the organization. It is the responsibility of all involved elements of the FDA to cooperate and work together to provide the best possible support for all cases, regardless of which particular office may be the lead. Thus, it is the joint responsibility of the Center and field offices to identify and obtain the best witnesses and other case support, with the Office of Chief Counsel responsible for the final determination of use of witnesses if we anticipate a contest or litigating a case. Although the Centers have primary responsibility for assuring the availability of expert support, field offices should work closely with the Centers and provide any possible assistance in the process, such as identifying and suggesting to the Center possible good local experts. Field/Center consultation and cooperation on considering the possible need for and the obtaining of expert support should start as soon as necessary and feasible in the case development process and continue throughout each stage.

The following procedures are to be followed for obtaining and paying for the services of experts when needed for support of court cases or hearings:

1. Decisions are to be made jointly by the responsible Center and field offices on the type and scope of expert support needed for support of cases and hearings. It is also important that, if the agency anticipates that a case will be contested, the Office of Chief Counsel be consulted as to the use of expert witnesses. The office that first identifies the need to obtain expert support is responsible for contacting and consulting with the other offices responsible for the case.
2. For outside (non-FDA) consultants and expert witnesses agreed upon as necessary by all parties to support cases or hearings at any stage (including support for a recommendation, review and approval, and litigation), all costs associated with such services will be shared equally among each major office (other than OCC) having responsibility for the case (e.g., each Center and Division involved). This includes all necessary expenses for such expert services, such as contracting for and consulting with experts, travel and per diem, and other associated expenses necessary for this purpose.
  - a. For outside experts, the responsible Center and field offices involved shall also consult and agree with one another on which office will be designated to take the lead role in actually contacting the expert, negotiating a contract for services, and making sure the necessary paperwork is completed.
  - b. Normally, unless mutually agreed otherwise, the designated lead office for these administrative purposes will be the one having primary responsibility for the aspect of the case that requires the expert support. For example:

- i. The Division would normally be the administrative lead for expert support (such as declarations) required for its regulatory action recommendations, or for expert witnesses needed for testimony for a trial or hearing under the Division's purview.
  - ii. The Center would normally be the administrative lead if either the Center or OCC concluded in reviewing a recommended case that outside expert review is required to ensure adequate scientific support is available before proceeding with the case, or for expert witnesses needed for testimony at a hearing under the Center's purview.
- c. The designated lead office that prepares the necessary paperwork to procure the services for outside expert support is also responsible for ensuring timely payment of all invoices related to the services provided. In order to accommodate the shared- funding arrangement, the following accounting procedures should be employed:
  - i. When an ORA field office is designated as the lead for an outside expert:

The total expense should be charged to the applicable ORA field central funding CAN using category E. Accounting technicians should code field "N" of the DHR as follows:

"E (Last name of witness)"

Copies of each obligating document, including information concerning the Center with which the cost will be shared, should be sent to ORA's, Division of Management Operations (DMO) using the contact information on the division's intranet page. DMO will provide the respective Center a copy of the obligating document for tracking purposes. Each quarter, DMO will contact the budget personnel in the applicable Center to request a transfer of funds to recover half of the total cost.

- ii. When a Center is designated as the lead for an outside expert:

The total expense should be charged to the applicable Center's accounting point. Copies of each obligating document, including information concerning the field location with which the cost will be shared, should be sent to DMO at using the contact information on the division's intranet page. Each quarter, the applicable Center will contact the budget personnel in DMO to request a transfer of funds to recover its half of the total cost.

3. For expert support provided by FDA employees, all such expenses (including travel and per diem) will be borne by the office of the employee involved. Expenses should be paid by the employee's office in accordance with its normal procedures.

**NOTE:** For expert support by FDA employees, this changes some provisions in sections 5.b. and 7.b.iii. of [FDA SMG 2610.2, Obtaining Services of Expert or Fact Witnesses](#), which are somewhat in conflict.)

## 10-11 TESTIMONY; PRODUCTION OF RECORDS; CERTIFICATION OF RECORDS

Although FDA receives requests for information orally, in writing, and even in person at FDA offices, from parties including litigants, Congressional representatives and their staffs, and state and other federal officials, only written requests can be processed. Any FDA employee receiving a request should let the requestor know to file it in writing and preferably electronically. Before releasing any information to any person, FDA staff must carefully review the procedures in this Chapter including the special considerations described on [10-11-5 Requests Involving Special Circumstances](#) and in the instructions for ORA employees in [10-12, U. S. Congressional Requests](#) and in [10-13, Requests from State and Federal Officials](#).

### 10-11-1 Requests for Testimony

FDA regulations at 21 CFR § 20.1 require that requests for testimony of FDA employees in non-FDA proceedings be handled in a specific manner. FDA employees are not permitted to provide testimony, whether written or oral, pertaining to any function of the FDA, or with respect to any information acquired in performing their official duties, unless authorized by the FDA Commissioner or another FDA official to whom this authority has been delegated. The FDA may authorize current FDA employees to provide testimony in any proceeding when the testimony will be in the public interest and promote FDA's objectives and the laws it enforces. 21 CFR § 20.1. While interrupting the normal duties of FDA employees to provide testimony in a proceeding to which the agency is not a party is generally not considered to be in the public interest, FDA may be able to honor a request for testimony by providing responsive documents. The FDA can also certify these documents for presentation in court.

The FDA processes written requests for testimony in accordance with 21 CFR § 20.1. Affidavits, declarations, and employees' responses to depositions, interrogatories, or rogatory letters are considered to be testimony covered by 21 CFR § 20.1. See [10-11-8 Definitions](#). Under no circumstances does the FDA process verbal requests for testimony.

The Director, OSPOP, ORA has been delegated the authority to authorize the giving of testimony under 21 CFR § 20.1<sup>1</sup>, and is the agency lead for authorizing all testimony. In addition to the Director, OPSPO, the following officials have the authority to authorize the giving of testimony under 21 CFR § 20.1: the ACRA; and the Deputy ACRA, ORA See [SMG 1410.24](#) for these delegations.

ORA's Office of Partnerships and Operational Policy (OPOP)/ Office of Strategic Planning and Operational Policy (OSPOP)/Division of Information Disclosure Policy Information (DIDP)/Disclosure Policy Branch (DPB) conducts the initial review of all requests for testimony , and DPB then prepares a 21 CFR § 20.1 package for the review and signature of the Director, OSPOP.

FDA employees may be asked to assist DPB in responding to a request for testimony, by identifying suitable individual(s) to testify, drafting authorized testimony, or identifying records (instead of testimony) that are responsive to the request.

If a request involves Congress, employee personnel records, the DHHS Office of Equal Employment Opportunity, the investigation of an FDA employee by the DHHS Inspector General, the testimony of an FDA employee as a private citizen, or the testimony of a former employee regarding FDA-related matters, see the instructions in "Requests involving Special Circumstances" below. Otherwise,

- 1. If you receive a written request for testimony (whether by letter, subpoena, or in any other form) that was submitted by, or on the behalf of any person, contact DPB immediately and send the original request to that office at the address below.**

U.S. Food and Drug Administration  
Office of Partnerships and Operational Policy  
Office of Strategic Policy and Operational Policy  
Division of Information Disclosure Policy

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<sup>1</sup> Pursuant to Staff Manual Guide (SMG) [1410.24](#), Disclosure of Official Records and Authorization of Testimony, dated April 27, 2007, the Commissioner of Food and Drugs (Commissioner) has delegated to "Director, Division of Compliance Policy" (DCP), among others, the authority to make determinations to authorize the testimony of an FDA employee in litigation in which the FDA is not a party pursuant to 21 C.F.R. § 20.1. It is well established that DCP was reorganized into the Office of Strategic Planning and Operational Policy (OSPOP) and kept the same functions. According to SMG 1401.1, Policy and Procedures Governing Regulatory and Administrative Delegations of Authority (DOAs), paragraph G, delegations to an organization remain in effect in a successor organization with the same functions. Therefore, as the successor organization to DCP, Director of the Office of Strategic Planning and Operational Policy (OSPOP) has the authority to grant requests for testimony pursuant to 21 C.F.R. 20.1. The OSPOP Director will have primary responsibility for ORA's 20.1 authorizations.

Note: Per the SMG, the Deputy Associate Commissioner for Regulatory Affairs (Deputy ACRA), ORA; the Director and Deputy Director, Office of Enforcement OE, ORA; and the Director, Division of Compliance Policy, OE, ORA are all delegated the authority to grant requests for testimony or to authorize the giving of testimony under Sec. 20.1 of 21 CFR. These officials may not further redelegate this authority.

Disclosure Policy Branch  
c/o Testimony Specialist  
12420 Parklawn Drive  
(Element Bldg., RM. 4042)  
Rockville, MD 20857

To expedite processing, a scanned copy of the testimony request should also be sent to the FDA Outlook address for the ORA OSPOP Testimony – Info Sharing Team at [ORAINfoshare@fda.hhs.gov](mailto:ORAINfoshare@fda.hhs.gov).

**2. If you are contacted by individuals requesting testimony:**

- a. Either refer the individuals to a Testimony Specialist at the FDA Outlook address for the ORA OSPOP Testimony – Info Sharing Team in DIDP/DPB, or advise them that FDA does not process verbal requests for testimony and that they should submit a written testimony request to the address for DPB shown above, well in advance of their desired due date to allow time for evaluating and processing the request; and that they should include information about the hearing body, date, location, and purpose of the proceeding; the nature and scope of the testimony the FDA is being asked to provide and the use to which it will be put; the name(s) of the FDA employees, if known, being asked to testify; the requester's interest in the matter sought to be disclosed; the requester's rationale for considering that the testimony is in the public interest and will promote the objectives of FDA and the laws it enforces; and any other relevant background. Refer them to 21 CFR § 20.1(c) for FDA's procedures on how to make these requests.
- b. Do not make any commitment regarding the availability or willingness of a witness to testify in any particular case.
- c. Document the conversation, and send DIDP/DPB a memorandum by email and contact that office to confirm receipt.

**3. If you have been authorized to testify:**

- a. Before presenting testimony, contact the assigned OCC attorney, to obtain legal advice; and the appropriate FDA component, to obtain any technical advice you believe you need and, if needed, information about funding travel.
- b. After presenting testimony, submit a summary memorandum or copy of the testimony or a transcript of the testimony to the Testimony Specialists in DPB and to OCC. If the Director, OSPOP, authorizes the testimony for a hearing in a state court, the summary memorandum

you prepare should address not only the individual's testimony, but also any other portions of the hearing that the individual attended.

### **10-11-2 Requests for Production of Records**

The Director, OSPOP, is the agency official with delegated authority who is the lead for responding to subpoenas for the production of records made pursuant to 21 CFR § 20.2<sup>1</sup>.

If a request involves Congress, employee personnel records, the DHHS Office of Equal Employment Opportunity, the investigation of an FDA employee by the DHHS Inspector General, the testimony of an FDA employee as a private citizen, or the testimony of a former employee regarding FDA-related matters, see the instructions for ORA employees in [10-12, U.S. Congressional Requests](#) and in [10-13, Requests from State and Federal Officials](#). Otherwise,

**1. If you receive a written request or a subpoena, including a subpoena duces tecum, for the production or certification of records:**

Send the request to the address for the Testimony Specialist, DPB shown above.

**2. If you are contacted by an individual requesting the production or certification of records:**

- a. Either refer the individuals to the Testimony Specialist, DPB; or advise them that FDA does not process verbal requests for records and that they should submit a written request to the address for the Testimony Specialist, DPB (shown above in "If you receive a written request for testimony") well in advance of their desired due date to allow time for evaluating and processing the request; and that they should include

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<sup>1</sup> Pursuant to Staff Manual Guide (SMG) [1410.24](#), Disclosure of Official Records and Authorization of Testimony, dated April 27, 2007, the Commissioner of Food and Drugs (Commissioner) has delegated to "Director, Division of Compliance Policy" (DCP), among others, the authority to make determinations to authorize the testimony of an FDA employee in litigation in which the FDA is not a party pursuant to 21 C.F.R. § 20.2. It is well established that DCP was reorganized into the Office of Strategic Planning and Operational Policy (OSPOP) and kept the same functions. According to SMG 1401.1, Policy and Procedures Governing Regulatory and Administrative Delegations of Authority (DOAs), paragraph G, delegations to an organization remain in effect in a successor organization with the same functions. Therefore, as the successor organization to DCP, Director of the Office of Strategic Planning and Operational Policy (OSPOP) has the authority to grant requests for testimony pursuant to 21 C.F.R. 20.2. The OSPOP Director will have primary responsibility for ORA's 20.2 authorizations.

Note: Per the SMG, the Deputy Associate Commissioner for Regulatory Affairs (Deputy ACRA), ORA; the Director and Deputy Director, Office of Enforcement OE, ORA; and the Director, Division of Compliance Policy, OE, ORA are all delegated the authority to grant requests for testimony or to authorize the giving of testimony under Sec. 20.2 of 21 CFR. These officials may not further redelegate this authority.



specific information about the records requested, the requested due date, and any other relevant background. Refer them to 21 CFR § 20.2 for FDA's procedures for processing these requests.

- b. Do not make any commitment regarding the availability of records.
- c. Document the conversation, and send DPB a memorandum by email or and contact that office to confirm receipt.

### **10-11-3 Multi-issue Subpoena - Requests for Samples**

If you receive a subpoena or a request that seeks FDA records, testimony, and actual samples for litigation (not for first party request for a 702(b) sample), you should: (1) refer the sender of the request/subpoena for the samples to the Testimony Specialist, DPB, who, if needed, will consult with OCC for a response pursuant to 21 CFR § 2.10, and if involved, OCI; and (2) process the remaining portion of the request/subpoena as a request for testimony and for records.

FDA considers a request/subpoena for analytical results to be a request for records.

### **10-11-4 Requests for Certification of Records**

FDA processes requests for certification of records in accordance with 21 CFR § 20.3. If you are asked to certify records, contact DPB by email at the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team*. DPB will forward requests for the certification of records to the appropriate component for direct response.

### **10-11-5 Requests involving Special Circumstances**

If you receive a request that involves:

1. An FDA proceeding or a DHHS proceeding where FDA is involved – contact DPB, if that office is not already involved or aware of the request. DPB will coordinate with other entities as needed.
2. Congress – contact FDA's Office of Legislation, except as noted in instructions for ORA staff in sections [10-12, Congressional Requests](#) and in [10-13, Requests from State and Federal Officials](#) below.
3. Employee personnel records related to litigation – contact DPB. DPB will coordinate with other entities as needed.
4. An investigation of an FDA employee by the DHHS Inspector General - contact FDA's Office of Internal Affairs (HFH-560) in the Office of Criminal Investigations.

5. The DHHS Office of Equal Employment Opportunity – contact FDA’s EEO and Diversity Management Office (HF-15), in the Office of Shared Services.
6. Testimony as a private citizen - Some testimony as a "private citizen" (i.e., not in one's official FDA capacity) may raise special concerns such as possible conflict of interest or may require approval as an outside activity.

**NOTE:** If the individual’s planned testimony is based on information derived during FDA employment, the employee must contact DIDP/DPB for clearance of this testimony under 21 CFR § 20.1. For testimony as a private citizen, employees also should refer to the Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR § 2635.805, and the HHS Supplemental Standards of Ethical Conduct, 5 CFR § 5501.106. Contact FDA’s Ethics and Integrity Staff for further information regarding approval of the testimony as an outside activity.

7. Testimony by former FDA employees - Requests for the testimony of former FDA employees are not covered specifically by 21 CFR § 20.1. However, we encourage former employees to contact DPB if they receive a request or subpoena to provide testimony regarding FDA-related matters, because FDA may assist that individual on behalf of FDA. Advise former employees that there may be other restrictions on their ability to provide the requested testimony, including possible conflict of interest concerns and statutory and regulatory restrictions on the release of trade secrets and other kinds of confidential information.

### **10-11-6 Disclosure of Non-public information**

FDA generally discloses information pursuant to a request or subpoena if that information is neither exempt from disclosure under FOIA nor prohibited from disclosure by other law, and the disclosure is consistent with FDA’s [part 20](#) regulations.

In certain circumstances, with the appropriate authorization, transmittal procedures, and disclosure reviews, FDA may share certain non-public information that is otherwise exempt or prohibited from disclosure, e.g., 21 CFR § 20.85 (disclosure to other federal agencies), 21 CFR § 20.88(d) (disclosure to state and local agencies), or 21 CFR 20.89(c) (disclosure to foreign agencies). Any request for non-public information from a federal or state agency must be sent to the Testimony Specialists in the Division of Information Disclosure Policy/Office of Strategic Policy and Operational Planning/ORA at the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team*. See also RPM [Chapter 3 Commissioning > Confidentiality](#). Any request for non-public information from a foreign agency must be sent to the Office of Partnerships International and Federal Engagement staff at the FDA Outlook address for ORA OP DI International and Federal Group.

Other examples of instances in which FDA may share non- public information are set forth below.

1. FDA may share under 21 U.S.C. § 372(a) certain non-public information, including trade secrets, personal privacy, open investigatory, and confidential commercial information, , with federal or state officials commissioned by FDA under law. For questions contact Office of Partnerships at the FDA Outlook address for *ORA State Commissioning* . See also RPM [Chapter 3 Commissioning](#) > *Confidentiality*.
2. FDA may share under 21 CFR § 20.90 certain non-public information with other government officials under agreements or contracts that contain appropriate confidentiality provisions. For questions contact Office of Partnerships at the FDA Outlook address for *ORA OP Feedback*.

### **10-11-7 Other Requests for Information – Informal Meetings**

A person (individual, company, corporation, etc.) might request an informal meeting with an FDA employee to discuss information the employee obtained during the course of his or her employment.

1. If the requester is not an official from another government agency, and if private civil litigation is involved, decline the request and suggest that the requester submit a request for testimony under 21 CFR 20.1. Also, advise the requester that FDA has a long- standing practice against granting one-sided interviews or informal testimony to avoid creating the impression that FDA is biased toward a party.
2. If the requester is not an official from another government agency, and if the request relates to a matter other than private civil litigation (e.g., the requester seeks general information about FDA’s activities), advise the requester to submit a written request to FDA, to be handled as general correspondence under routine office procedures.
3. If the requester is an official from another government agency, advise the requester to submit a written request to FDA to be handled under appropriate agency procedures for the sharing of publicly releasable or non-public information under RPM Chapter 3 Commissioning > Confidentiality and in Instructions for ORA employees in 10-12, U. S. Congressional Requests and in 10-13, Requests from State and Federal Officials. Contact OCI’s information disclosure senior investigator if the request is from a law enforcement agency and the request is for non-public information.

Consult with DIDP if needed at the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team*.

## 10-11-8 Definitions

The following list contains definitions of commonly used terms in the context of testimony, subpoenas, or production of records.

**Affidavit** - A written document signed in the presence of a notary public under a sworn oath that the statement is true. FDA considers an affidavit to be testimony covered by 21 CFR 20.1.

**Certification (also known as “certificate”)** - A written assurance, or official representation, that some act has or has not been done, or some event occurred, or some legal formality has been complied with. Typically, a requester will ask that FDA certify as to the authenticity of an FDA record as a true copy. FDA processes requests or subpoenas for certification under 21 CFR 20.3.

**Declaration** - A written statement signed under the penalty of perjury. A declaration can substitute for an affidavit in federal court proceedings. 28 U.S.C. 1746. FDA considers a declaration to be testimony covered by 21 CFR 20.1.

**Deposition** - The taking and recording of testimony of a witness under oath, in front of a court reporter prior to trial and away from the courtroom. FDA considers an employee’s responses in a deposition to be testimony covered by 21 CFR 20.1.

**Interrogatories** - Written questions sent by one party in a lawsuit to the other party during the discovery process prior to trial. Interrogatories must be answered in writing under oath or under penalty of perjury. FDA considers the employee’s response to interrogatories to be testimony covered by 21 CFR 20.1.

**Notary Public** - A person authorized by the state in which they reside to administer an oath of truth to a person making an affidavit, and to apply their signature and seal or stamp to attest to the oath.

**Rogatory Letters** - A written request from a judge in one state to a judge in another, asking that the latter take the testimony of a witness. FDA considers testimony in response to rogatory letters to be covered by 21 CFR 20.1.

**Subpoena** - A court order commanding a witness to appear at a certain time and place to testify on a certain matter. For purposes of this section, a “subpoena” means a subpoena for verbal or written testimony (e.g., an affidavit). A subpoena for testimony also might include a request for records. In that case, FDA would process the subpoena under 21 CFR 20.1 and 20.2.

**Subpoena Duces Tecum** - A court order commanding a witness to produce documents at a certain time and place. FDA processes these subpoenas, which are intended for the production of records, under 21 CFR 20.2.

**Testimony** - For purposes of this section, testimony is an individual's statement given in writing (such as an affidavit or a declaration) or by appearance under oath at a proceeding. The statement might be in response to a deposition or interrogatories. Testimony is covered by 21 CFR 20.1.

### **10-11-9 References**

The following list contains references commonly used in the context of testimony, subpoenas, or production of records.

1. "Enforcement Notes," Issue No. 85, September 18, 2002, Testimony, available on ORA's Intranet
2. Staff Manual Guide 1410.21 (General Redelegations of Authority from the Commissioner to other Officers of the Food and Drug Administration)
3. Staff Manual Guide 1410.23 (Certification of True Copies and Use of Department Seal)
4. Staff Manual Guide 1410.24 (Disclosure of Official Records and Authorization of Testimony)
5. Staff Manual Guide 2127.1 (Attendance by FDA Employees at Congressional Hearings)
6. Staff Manual Guide 2127.2 (Requests for Testimony of FDA Personnel in Non-FDA Proceedings)
7. Staff Manual Guide 2460.7 (Procedures for Implementing the Freedom of Information Act) (Not on Intranet)
8. 5 U.S.C. § 552a (Privacy Act); 21 CFR Part 21 (Privacy Act regulations)
9. 5 U.S.C. § 552(b) (Freedom of Information Act (FOIA)); 21 CFR Part 20 (FOIA regulations), particularly 21 CFR 20.1, 20.2, and 20.3
10. 5 CFR § 2635.805 (Standards of Ethical Conduct for Employees of the Executive Branch; Service as an expert witness)
11. 5 CFR § 5501.106 (HHS Supplemental Standards of Ethical Conduct; Outside employment and other outside activities)
12. Information Disclosure Manual on ORA's Intranet Information Disclosure Main Page
13. FDA's FOIA Page on FDA's Intranet

## 10-12 U. S. CONGRESSIONAL REQUESTS – INSTRUCTIONS FOR ORA EMPLOYEES

Whether any ORA field or headquarters employees may directly answer an inquiry from U.S. Congressional staff (House or Senate) in their district's geographical area or must refer the inquiry to ORA's Executive Secretariat Staff (ESS) depends on the source and subject matter of the inquiry, as detailed below.

1. The following type of U.S. Congressional (House or Senate) inquiries may be answered directly by ORA field or headquarters employees:
  - a. Inquiries from Congressional staff located in a district's geographical area that concern issues of general interest and can be answered using approved information already available to the public (e.g., copies of public documents, FDA publications, talking points, press releases, Federal Register notices, or other published materials).
    - i. ORA employees should refer the Congressional staff located in their district's geographical area to FDA's public websites, where many of these materials are available online.
  - b. Inquiries from Congressional staff located in a district's geographical area that request information about an import entry in "may proceed" status that is "closed" for ORA.
    - i. ORA employees may refer these inquires to FDA's public website for its import entry system - Import Trade Auxiliary Communication System (ITACS):  
<https://itacs.fda.gov/app/welcomeToITACS.jsf>.

**Note:** "May Proceed" status indicates that the entry has been released without any further action by FDA and is considered "closed."

"May Proceed" status does not include entries in which there was an examination, sampling, detention, etc. Those inquiries must be referred to FDA's Office of Legislation (OL) through ESS.

2. The following types of U.S. Congressional (House or Senate) inquiries *must be* referred to ESS:
  - a. Inquiries that originate from the staff of a Congressional office located in Washington, D.C.

- b. Inquiries involving legislative, policy, or budget issues that are national in scope (e.g., issues that are receiving major press coverage, are the subject of pending Federal legislation, involve FDA expenditures, etc.).
- c. Inquiries regarding FDA inspections, investigations, sample collection/analysis, litigation, or pending product approvals.
- d. Inquiries that involve import entries in any status other than “may proceed,” as defined in section 1(b) above.
- e. Inquiries regarding cases in litigation or pending product approvals.
- f. Any inquiries that require a formal, written response.

Submit the inquiry or refer the requesters to ESS via the FDA Outlook address for the *ORA OCPM Executive Secretariat Staff* within one business day of receiving the inquiry. To ensure the expeditious handling of the inquiry, please include “Congressional Inquiry” in the subject line of your email.

Upon receipt, ESS will refer the inquiry to OL’s Congressional Correspondence Team to collect information/data and issue the official agency response to the requester.

Federal (non-congressional) inquiries are processed by ORA’s Federal-State Health Communications and Relations (FSHCR) program manager. Submit federal (non-congressional) inquiries to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA*’s per [RPM 10-13-3, \*Procedures for Handling Inquiries from Federal Agencies\*](#). Additionally, if the federal request is for non-publicly available records, forward the request to the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team* in DIDP/DPB with a copy to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA*.

Inquiries from state, local, tribal, and territorial government officials *must* be processed per [RPM 10-13-4 \*Procedures for Handling Inquiries from Other State, Local, Tribal, and Territorial Government Officials\*](#) unless the inquiry concerns non-publicly available information or is solely a records request; in those cases, forward the request to the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team* in DIDP/DPB with a copy to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA*.

If you have any questions regarding U.S. Congressional inquiries, call or email ESS or OL. Contact information below:

Executive Secretariat Staff

Email address: use the FDA Outlook address for *ORA OCPM Executive Secretariat Staff*  
Phone: (301) 796-5231  
Fax: (301) 827-0963

Office of Legislation  
Congressional Correspondence Team  
Email address: use the FDA Outlook address for *legislation*  
Phone: (301) 796-8900  
Fax: (301) 827-8602 or (301) 847-8603

## **10-13 REQUESTS FROM STATE AND FEDERAL OFFICIALS – INSTRUCTIONS FOR ORA EMPLOYEES**

### **10-13-1 Background**

Be aware of changes in 2014 in the handling of inquiries and requests for information and reports (henceforth referred to as inquiries) originating from state government officials and national associations representing state government officials (State government officials include governors, attorneys general, state legislators, and other officials in state, local, tribal, and territorial governments.) Historically, these inquiries were handled by the Office of Partnerships (OP) in ORA. These requests included most inquiries involving actions and matters that were policy-related and operational in nature. In addition, ORA's district and regional offices responded directly to inquiries from state legislatures within their boundaries when the inquiries involved issues of general interest that could be answered using cleared information available to the public.

With the exception of testimony and subpoena requests that fall under 21 C.F.R §§ 20.1, 20.2 and non-public information and records requests that fall under 21 CFR §§20.85, and 20.88 (all of which are managed by DIDP), responsibility for handling and coordinating agency responses to policy-related and operational-type inquiries from these entities was moved from the OP to ORA's Division of Communications in March 2014 as part of ORA's realignment and consolidation of all communications and public affairs staff and functions into a newly established Division of Communications. Under this ORA realignment, the FSHCR program manager in ORA's Division of Communications was charged with handling and coordinating responses to policy-related and operational-type inquiries from state congressional officials, other state, local, tribal, and territorial government officials, and national associations representing state government officials.

In September 2014, FDA's Office of Policy, Planning, and Legislation (OPPL) signed a Service Level Agreement (SLA) with ORA that outlined the responsibilities of ORA and of OPPL's newly created Intergovernmental Affairs (IGA) staff, with new procedures for



handling inquiries from state congressional officials and the national associations that represent state government officials.

1. Under the SLA, IGA is responsible for handling responses to policy-related inquiries from state congressional officials and the national associations representing state government officials. ORA, however, retains responsibility for handling and coordinating operational-type responses to inquiries from those groups.
  - a. Inquiries that are policy-related generally pertain to questions regarding FDA laws, regulations, policies, guidance, and rulemaking.
  - b. Inquiries that are operational in nature usually involve regulatory actions such as FDA investigations and compliance/enforcement activities. Examples include warning letters, embargos, injunctions, seizures, etc.) as well as information on illness outbreaks and injury-related events involving FDA-regulated products.
2. The SLA designates the following as points of contact and liaisons in ORA and OPPL: the director and staff of IGA, which is part of OPPL, and the FSHCR program manager. They are variously responsible for handling and coordinating different kinds of policy-related and operational inquiries from state congressional officials and the national associations representing state government officials.

### **10-13-2 Procedures for Handling Inquiries from State Congressional Officials and their Staff**

In accordance with the SLA, all inquiries, unless solely a request for records or a request for non-public information, that originate from state congressional officials (e.g., state senator, state representative, state assemblyman) and their staff must be referred either to the FSHCR program manager in ORA's Division of Communications or IGA Staff for further processing as detailed below. If solely records are requested, or the release of non-public information is implicated, contact DBP/DIDP at the FDA Outlook address for *ORA OSPOP Testimony – Info Sharing Team*.

1. The FSHCR program manager will handle responses to inquiries that are operational in nature and involve regulatory actions such as FDA inspections, investigations, and compliance/enforcement actions (e.g., warning letters, embargos, injunctions, seizures, inspections, etc.) and activities like work planning, emergency response, and sample collection. This responsibility includes coordinating with the responsible FDA center/office and the Office of Chief Counsel (OCC) to develop and clear the response as required. It also entails coordinating with DBP/DIDP if records are requested or if non-publicly available information may be released pursuant to 21 CFR § 20.88.

- a. ORA field and headquarters employees must refer the inquiry to the FSHCR program manager for further processing within one business day of receipt of the inquiry. To ensure the expeditious handling of the inquiry, “State Congressional Inquiry” should be in the subject line of the email.
  - i. The FSHCR program manager referenced above must contact the requester to acknowledge receipt of the inquiry and provide a projected time frame when a response will be provided.
  - ii. The FSHCR program manager will provide the cleared response to the requestor as expeditiously as possible after receipt of the inquiry. If significant delays are encountered with coordinating or clearing the response, the FSHCR program manager will inform the requestor of the delay, along with a projected date or time frame when the cleared agency response will be provided to them.
2. The IGA staff will handle inquiries that are policy-related and involve FDA legislation, legislative testimony, guidances and rulemaking, FDA-regulated products, and tobacco.
  - a. ORA field and headquarters employees must forward the inquiry to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA* for further processing within one business day of receipt of the inquiry. To ensure the expeditious handling of the inquiry, “State Congressional Inquiry” should be in the subject line of the email.
  - b. The FSHCR program manager will forward the inquiry within one business day of receipt to the IGA Staff to handle and coordinate the response to the inquiry.
3. The IGA staff will handle responses to inquiries that are policy-related and involve pharmacy compounding issues.
  - a. ORA field and headquarters employees must forward the inquiry within one business day of receipt directly to the IGA staff at the FDA Outlook address for the *IGA*, with copies sent to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA* and to the Outlook address for *ORA Compounding ICS*.
4. For inquiries that are a combination of policy-related and operational in nature, the IGA staff and FSHCR program manager will collaboratively review the inquiry to determine who will take the lead in handling and coordinating the response to the inquiry.

5. ORA field and headquarters employees who have questions regarding whether an inquiry is policy-related or operational in nature may forward the inquiry to the [FSHCR program manager](#) to determine how it should be handled.

### **10-13-3 Procedures for Handling Inquiries from Federal Agencies**

With the exception of inquiries from the HHS Office of the Inspector General (OIG) and U.S. Government Accountability Office (GAO), the FSHCR program manager handles all inquiries for publicly available information from other federal agencies sent to any ORA employee. If records are requested or the release of non-public information is contemplated, coordination must be made with the DPB/DIDP to determine if non-publicly available information may be released pursuant to 21 CFR § 20.85. Additionally, OSPOP is responsible for coordinating ORA's response to inquiries involving GAO studies and OIG audits.

1. ORA field and headquarters employees must forward the federal agency inquiry directly to the FSHCR program manager at the FDA Outlook address for DivComm-ORA for further processing within one business day of receipt of the inquiry. To ensure the expeditious handling of the inquiry, "Federal Agency Inquiry" should be in the subject line of the email.
2. For federal inquiries from the HHS OIG and US GAO, ORA field and headquarters employees must forward the inquiry to the FDA Outlook address for the GAO ORA Liaison in ORA's OSPOP with a copy to the FSHCR program manager at the FDA Outlook address for DivComm-ORA within one business day of receipt of the inquiry.
3. If solely records are requested, or the release of non-public information is implicated, the FSHCR must contact DBP/DIDP at the FDA Outlook address for the ORA OSPOP Testimony – Info Sharing Team.

### **10-13-4 Procedures for Handling Inquiries from Other State, Local, Tribal, and Territorial Government Officials and National Associations**

Regarding inquiries from other state, local, tribal, and territorial government officials and the national associations representing these officials: The source and subject matter determine whether the inquiry should be handled by ORA field employees or be referred to the FSHCR program manager or IGA staff for further processing. See details below.

1. The following types of inquiries from non-elected state, local, tribal, and territorial government officials and national associations representing these officials may be answered directly by ORA field and headquarters employees:

- b. Inquiries that deal with issues of general interest that can be answered with approved information and reports available to the public (e.g., copies of public documents, FDA publications, Field Alert Reports, talking points, press releases, Federal Register notices, or other published materials). When applicable, ORA employees should refer the requestor to FDA's public website, where many of the materials are available online.
  - c. Inquiries involving operational matters such as requests for information about pending or recommended compliance/enforcement actions, within five working days of completion of a violative inspection, events related to illness and injury involving regulated products, and emergency situations subject to appropriate information disclosure requirements. If solely records are requested or the release of non-public information is implicated, ORA employees must contact DBP/DIDP at the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team*.
  - d. Field or headquarters employees must provide a cleared response to the requestor as expeditiously as possible after receipt of the inquiry. If significant delays are encountered with coordinating or clearing the response, the requestor must be informed of the delay along with a projected date or time frame when the cleared agency response will be provided to them.
2. The following types of inquiries from elected and high-level other state, local, tribal, and territorial government officials and their staff, as well as the national associations representing these officials, must be referred to the FSHCR program manager or IGA staff for further processing as detailed below:
- a. The FSHCR program manager will handle responses that involve operational issues.
    - i. ORA field and headquarters employees must forward the inquiry to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA* for further processing within one business day of receipt of the inquiry. To ensure the expeditious handling of the inquiry, "State Government Inquiry" should be in the subject line of the email. If solely records are requested or the release of non-public information is implicated, ORA employees must contact DBP/DIDP at the FDA Outlook address for the *ORA OSPOP Testimony – Info Sharing Team* with a copy to FSHCR program manager at the FDA Outlook address for *DivComm-ORA*.

- b. IGA staff will handle responses to inquiries that involve legislative, policy, budget matters, and high interest issues that are national in scope (e.g., issues that are receiving major press coverage, are the subject of pending federal legislation, involve FDA expenditures, etc.) However, send the inquiries to the FSHCR project manager for initial handling.
  - i. ORA field and headquarters employees must forward the inquiry to the FSHCR program manager for further processing within one business day of receipt of the inquiry. To ensure the expeditious handling of the inquiry, “State Government Inquiry” should be in the subject line of the email.
  - ii. The FSHCR program manager will forward the inquiry within one business day of receipt to the IGA Staff at the FDA Outlook address for *IGA* to handle and coordinate the response to the inquiry.
- c. The IGA staff will handle the response to policy-related pharmacy compounding inquiries.
  - i. ORA field and headquarters employees must forward the inquiry within one business day of receipt directly to the IGA staff at the FDA Outlook address for the *IGA* to handle and coordinate the response to the inquiry, with copies sent to the FSHCR program manager at the FDA Outlook address for *DivComm-ORA* and to the Outlook address for *ORA Compounding ICS*. To ensure the expeditious handling of the inquiry, “State Pharmacy Compounding Inquiry” should be in the subject line of the email.

## 10-14 APPLICATION INTEGRITY POLICY

The Application Integrity Policy (AIP) describes the agency's approach regarding the review of applications that may be affected by wrongful acts that raise significant questions regarding data reliability. FDA published this policy, formally titled, "[Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy](#)" in the Federal Register on September 10, 1991 (56 FR 46191), and in Compliance Policy Guide (CPG) 7150.09. See Sec. 120.100 of the Compliance Policy Guides publication. These documents, procedures to implement the AIP, and AIP information are available on the FDA [Application Integrity page](#).

## 10-15 EXHIBIT

### Exhibit 10-1 – SECTION 414 OF THE FD&C ACT RECOMMENDATION MEMORANDUM

**To:** Director, Division of Enforcement, Office of Regulatory Affairs

**From:** Program Division Director or Designee

**Date:**

**Re:** Formal Recommendation for Invoking Records Inspection Authority under Section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 350c]

**Firm Identification #(s):** Insert firm name, address, and FEI number (may not be a farm or restaurant)

**Dates of Inspection:**

**Details of Record Refusal:** Provide information on the facts of the records refusal and FDA's attempts at obtaining the necessary records or provide the background of past experiences with the firm, if the Division anticipates the firm may refuse to provide access to records.

**Section 414 of the FD&C Act Statutory Requirements:** Outline evidence supporting why the Division believes the current situation meets the statutory requirements of section 414 of the FD&C Act. This may be done with a bulleted list to describe how the requirements are met under either section 414(a)(1) or 414(a)(2) of the FD&C Act. Examples include but are not limited to: Description of foodborne outbreak; sample results; or inspectional observations.

- Section 414(a)(1) of the FD&C Act: FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (SAHCODHA).
- Section 414(a)(2) of the FD&C Act: FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause SAHCODHA.

**Records to Request:** Include a bulleted list of records to request and summarize, in one to two sentences, the rationale for why section 414 of the FD&C Act authorizes FDA to access and copy these records.

- The records should relate to the article in question and to any other article of food believed to be affected in a similar manner.
- The records should be necessary to assist in determining whether the food is adulterated and presents a threat of SAHCODHA, or there is a reasonable probability that use of or exposure to the food will cause SAHCODHA.
- Examples include: Receiving records for raw materials or finished product; production records; sanitation records; testing records; inventory; distribution records; and complaints and adverse event reports.

- Section 414 records inspection authority excludes recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

**Timeframe for Issuance of Form FDA 482c:** Provide a timeframe for when the Division could issue Form FDA 482c, if approved. Include any concerns surrounding issuance (e.g. personal safety during issuance).

*Program Division Director or designee Signature Block*

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**Center Concurrence:**

As an official delegated with the authority to make determinations under section 414(a) of the FD&C Act, I have determined there is a reasonable belief, based on the information noted above and facts presented to date, that [*an article of food*] [*manufactured, processed, packed, distributed, received, held, or imported*] by [*firm name*] is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (SAHCODHA) or that there is a reasonable probability that use of or exposure to the food will cause SAHCODHA.

I concur with the recommendation to invoke records inspection authority under section 414 of the FD&C Act.

*Delegated Official per [SMG 1410.306](#) Signature Block*