

# Regulatory Procedures Manual

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## CHAPTER 8 – Emergency Procedures

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All questions pertaining to this chapter should be directed to the FDA [Office of Emergency Operations Office of Emergency Operations](#) (OEO), [Office of Emergency Management, Emergency Operations Center](#) (EOC), 866-300-4374 (24-hour number). See [SMG 1117.621](#) for more information on OEO.

FDA’s Emergency Operations Plan is the detailed document that should be followed in an emergency. See [Emergency Preparedness > Emergency Response](#) on FDA.gov.

## 8-1 PURPOSE

To set forth emergency management procedures for the FDA's headquarters and personnel resulting from [Executive Order 12656](#), various Presidential Decision Documents, the [Stafford Disaster Relief and Emergency Assistance Act](#), and the [National Response Framework](#).

## 8-2 INTRODUCTION

### 8-2-1 Procedures

These procedures provide guidance for the Agency to act immediately to protect the public from contaminated or defective FDA-regulated products or in situations when FDA-regulated products need to be utilized or deployed. Prompt emergency actions are dependent upon the expeditious reporting and investigation of significant incidents or complaints relating to FDA-regulated products. Examples of such incidents include chemical and biological terrorism, chemical spills affecting food and animal feed supplies, natural disasters, radiological incidents, and food-borne illness outbreaks.

The emergency alert system, which is a part of this procedure, directs telephone notification to the [EOC, Office of Crisis Management, Office of the Commissioner](#). This alert system utilizes information from many internal FDA sources (e.g., systems to report consumer complaints, adverse reactions, product defects, radiological release, and other surveillance reporting systems). The EOC also receives information from outside sources, including other federal or state agencies, foreign health officials, industry and the press.

The FDA conducts response operations under the Incident Command System (ICS) of the [National Incident Management System Implementation](#). The EOC coordinates the FDA response to emergency situations by facilitating rapid and early information sharing as well as by providing real-time situational awareness to and from FDA headquarters, centers, and offices. The EOC is supported by a multi-level network of over 40 offices in FDA headquarters, centers, programs, and divisions.

#### A. Definition of Emergency

For the purpose of this procedure, the following definition of "emergency" shall apply:

An unforeseen occurrence or a combination of circumstances that poses a significant risk to public health, and that involves the safety, efficacy, and security of human and veterinary medicines, biological products, medical devices, food supply, cosmetics, products that emit radiation, or tobacco products, and that calls for immediate actions by FDA staff.

#### B. Scope of Incidents

This procedure was developed to provide guidance for planning, monitoring, coordinating, and directing FDA response to situations which include, but are not limited to:

1. National emergencies (e.g., civil disorders, major transportation and industrial strikes, acts of terrorism, refugee crises, etc.);
2. Natural disasters (e.g., hurricanes, floods, earthquakes, tornadoes, volcanic eruptions, etc.);
3. Man-made disasters (e.g., radiological incidents, chemical spills, toxic waste problems, air pollution problems, technological incidents and associated threats, etc.);
4. Injury and illness complaints or reports of tampering (e.g., foods, drugs, biologics, cosmetics, medical devices, and radiation emitting devices, veterinary products);
5. Epidemiological investigations (e.g., illness outbreaks associated with foodborne or other pathogens and adverse reactions, etc.); and,
6. Agency emergency preparedness (e.g., planning, development, implementation, and testing of emergency preparedness plans in response to attack).

#### C. Relationship to Recalls

Product recalls may occur during an emergency investigation; if so, procedures under Chapter 7 of the [Regulatory Procedures Manual](#) (RPM) should be followed as well. A recall that is for a defective product and that is progressing satisfactorily will not by itself activate this emergency procedure.

## **8-3 RESPONSIBILITY**

### **8-3-1 General**

Alerts to potential emergencies are nearly an everyday occurrence at FDA. The Agency's permanent organizational structure is designed, in part, to accommodate both large and small emergencies. In an emergency situation, it is important that individual assignments and responsibilities be consistent with normal functions and duties as outlined in unit functional statements and position descriptions.

The EOC is a focal point for the review of preliminary information about potential emergencies and the EOC assists in the early recognition of incidents, outbreaks and potential acts of terrorism. Primary responsibility for monitoring emergency alert information and coordinating investigations and scientific evaluations rests with the EOC. For any emergencies involving highly transmissible diseases such as Severe Acute Respiratory Syndrome (SARS), highly pathogenic avian influenza, West Nile Virus (WNV), malaria, etc., and for chemical, biological or radiological emergencies, staff should contact the EOC by email at [Emergency.Operations@fda.hhs.gov](mailto:Emergency.Operations@fda.hhs.gov) or by phone at 866-300-4374.

### **8-3-2 Declaring an Emergency**

This procedure includes mechanisms for monitoring investigations before making a determination that an emergency exists. It is expected that the involved centers and division offices will establish the coordination units discussed in this procedure during the course of an investigation as the situation warrants. In some instances, a formal declaration of an emergency may be required in order to activate the appropriate emergency coordinating units within the Agency. On other occasions, a formal declaration of an emergency may not be required because all coordination units are already functioning.

If there is disagreement among offices or if there is uncertainty regarding whether or not FDA should initiate emergency action under this procedure, the issue should immediately (by telephone) be referred to the Office of Crisis Management/EOC. See Chapter [8-6-3 Investigational Instructions](#). The Director, Office of Crisis Management along with the Associate Commissioner for Regulatory Affairs (ACRA) or designee, in consultation with ORA offices and the involved centers, will decide whether to implement the procedure and will notify the appropriate offices.

## **8-4 NOTIFICATION OF EMERGENCIES: TERMINOLOGY**

The terms below (e.g., alert, case, suspect, preliminary, etc.) will be used in providing notification and describing the status of a sample analysis or the stage of an investigation. This consistent terminology can prevent confusion and misinterpretation in the identification and management of emergency situations.

#### **8-4-1 Alert**

Information without support: An alert should be made when the following type of information is received:

- A. An unconfirmed report of product related illness/injury or unanticipated adverse reaction;
- B. An unconfirmed report of the presence of a toxic (e.g., chemical, radioactive, or microbial) substance;
- C. A report of a man-made disaster (e.g., oil spill, radiological accident) or a natural disaster (e.g., hurricane, flood, tornado);
- D. Confirmation of a declaration of pandemic influenza (e.g., WHO Phases 4, 5, and 6; US Government Response Stages 2, 3, 4, and 5).

#### **8-4-2 Presumptive**

Information (analytical, inspectional, investigational, etc.) strongly suggests that a problem exists. Presumptive may be used to describe situations that include:

- A. Epidemiological data has provided a significant association between the illness, injury, or unanticipated adverse reactions and the product;
- B. An original analysis by a reliable laboratory has revealed a significant level of a toxic chemical, radioactive material, or microbial substance in a regulated product, but confirmation is not complete;
- C. An oil spill has drifted into fishing areas;
- D. A radiological incident has occurred and radioactive material has been released, but the extent is unknown;
- E. Floods have caused property damage in an area where regulated products are being held; or
- F. Confirmation of widespread outbreak of a novel strain of influenza in multiple locations overseas (e.g., WHO Phase 6; US Government Response Stage 3).

#### **8-4-3 Confirmed**

A problem has been confirmed through laboratory analyses, investigations, analysis of epidemiological data or a combination of these. Information received from another governmental agency or other source known to be reliable may be accepted for confirmation purposes. An example would be when the first human case of pandemic influenza in U.S. is confirmed (WHO Phase 6; US Government Response Stage 4).

### **8-5 TERMINATION OF EMERGENCY INVESTIGATION**

When it is not possible to obtain information confirming that an emergency situation exists, emergency investigations may be terminated at the Alert

or the Presumptive stages. However, in all cases, the EOC will attempt to identify the source and scope of the problem, and the hazard involved.

The depth and extent of FDA activities, at the confirmation of an emergency situation, is based on factors such as:

- A. Interstate distribution of involved product, and,
- B. Other Federal, state, or local government efforts to control the problem.

When other Federal, state, or local agencies can deal more effectively with a problem, FDA will terminate its emergency investigation, at which time *ad hoc* emergency teams or units established under this procedure may be phased out by the EOC. The investigating agency should maintain contact with the EOC until a conclusion is reached. Likewise, following completion of an FDA emergency investigation, *ad hoc* emergency teams or units established under this procedure may be phased out after consultation with the EOC.

## **8-6 OPERATING PROCEDURE**

### **8-6-1 24-Hour Communications System**

Each program and division office will maintain a means by which headquarters can communicate emergency situations on a 24-hour, 7-days-a-week basis. Each designated contact, including an after hours phone number, should be identified to the EOC. Changes in contact points should be reported in a timely manner to the EOC. Each program and division will establish and maintain procedures for internal communications and will provide for appropriate liaison and notification systems to city, county, and state governments, and to local offices of Federal agencies.

### **8-6-2 Emergency Alerts**

All reports of natural or man-made disasters and significant alleged or actual adverse effects associated with FDA-regulated products require prompt reporting to the EOC by phone, but e-mail, fax, text, or other available communication methods will be acceptable if telephones are not available. Confirmatory or summary reports may be forwarded by Email to [Emergency.Operations@fda.hhs.gov](mailto:Emergency.Operations@fda.hhs.gov) .

- A. Report the nature and effect of the emergency including as much of the following information as is available:
  - 1. Product description, e.g., product name (proprietary and generic), dosage form (tablet, injectable, suspension, etc.), strength, expiration date, size and type of package, manufacturer, lot number, and product code;
  - 2. Probable or actual distribution pattern, e.g., state or nationwide;

3. Description of product-related illnesses or injuries, including symptoms, onset times, and duration; where applicable, include name, address, age, sex of affected parties, and identify hospital and medical personnel that are involved, including telephone numbers;
  4. Steps taken to coordinate FDA actions with state, local and other Federal officials; also, any independent actions taken by state and/or local officials; and
  5. Actions taken by firms to mitigate risk including corrective actions, recalls, public outreach or media coverage.
- B. In addition to the above, disasters related to fires, high winds, floods, wrecks, explosions, strikes, civil disorders, covert actions, pandemic influenza, radiological incidents, etc., also require the reporting of:
1. The magnitude of health hazards or other problems related to FDA activities; and
  2. The extent to which FDA facilities are or may be affected.

### **8-6-3 Investigational Instructions**

Refer to [IOM](#), Chapter 8 — Investigations for detailed investigative procedures.

### **8-6-4 Emergency Management**

#### **A. Coordination with the EOC**

The [EOC](#) will be the focal point for all emergency coordination between the division(s) involved, the center(s) involved, HQ offices, and other federal, state and local agencies. A member of the EOC staff will be designated to oversee each emergency situation. However, all EOC staff members are kept abreast of the situation and should be able to serve as a backup as necessary.

Other offices and agencies involved in an emergency situation will identify a contact for all communications.

#### **B. Lead Office**

As FDA conducts response operations under ICS, the office in which the emergency is occurring (e.g., where people are becoming ill or where a disaster has occurred) will assume the lead investigative role in determining the cause of the emergency, managing on-scene operations, and obtaining necessary information for the Agency to confirm the health hazard. This lead would generally be the division, but may be the program.

If it becomes apparent during the course of the investigation that a firm in another division is responsible for the product involved in the emergency, the lead division designation will be transferred to the home division of the responsible firm.



Any change in the designation of lead division should be concurred with by the EOC. In certain widespread emergencies involving more than one responsible firm, the EOC may assume the lead role without designation of a lead division.

The lead division will identify an ad hoc emergency management team to be headed by the division director or a designated division person and a coordinator. The exact number and mix of persons on the team will be determined by the division. Any recommendations for reallocation of staff between or among divisions during emergencies should be directed to the Office of Operations (OO).

C. Office Emergency Coordinator

A senior staff employee should be promptly named as coordinator of the emergency response activities. This person should generally be located at the lead division office to facilitate communication and review of records. In a widespread emergency, additional coordinators may be named by the involved division as necessary. The coordinator will be responsible for advising management of actions needed to follow-up on the emergency and for channeling all necessary communications.

D. Any or all of the following steps should be included:

1. Investigation/Analysis
2. Issuing assignments to division personnel to obtain the information necessary for Agency personnel to evaluate the health hazard of the situation;
3. Monitoring assignments to assure timely completion;
4. Arranging for continuing contact with investigators for flow of information;
5. Seeking technical guidance through the EOC relating to the investigation, samples needed, etc.;
6. Determining in consultation with the [Office of Regulatory Science](#), ORA the appropriate laboratory for submitting samples; and
7. Alerting that laboratory as soon as possible so that necessary preparations may be made.

E. Maintaining Communications

1. Keeping appropriate division and program management informed of investigational and analytical progress;
2. Preparing daily status reports;
3. Contacting the appropriate state and local authorities already involved with the investigation; and,



4. Serving as a local FDA press contact concerning the emergency, working with headquarters in preparing statements to the press.

**NOTE:** FDA employees may be asked by media or other outside organizations to respond to inquiries about ongoing investigations when the employees are not in a position to first seek guidance from the [Office of Media Affairs](#) (OMA). Such employees must assess these situations and the media requests on an individual basis and respond appropriately. When possible, media requests should be referred to first line supervisors or above. Unless specifically authorized to do so, only those employees whose position descriptions include communications with the press should provide statements to the press. See [8-9, Press Relations](#).

Care must be taken to ensure that timely, accurate, complete and authorized information is issued.

Significant emergency press coverage should be reported to the EOC promptly. The EOC will notify the Office of the Commissioner, [Office of Communications and Quality Program Management](#) (OCQPM), [Office of Partnerships](#) (OP), and other offices of the press coverage. Copies of local press releases by the state and/or the firm should be sent to EOC at [Emergency.Operations@fda.hhs.gov](mailto:Emergency.Operations@fda.hhs.gov) as soon as possible.

#### F. Documentation

1. A chronology of the emergency situation should be kept, starting with the original alert. It should be updated frequently since this information is often needed on short notice by Agency or Department personnel.
2. Significant telephone conversations involving the emergency should be documented by the participants and forwarded to the EOC daily.
3. Statistical data such as numbers of samples analyzed, inspections made, injuries reported, farms quarantined, etc., should begin early in the process and should be maintained.

#### G. Command Post Location

The FDA lead division office facility should generally serve as the site of FDA's command post because of the available communications equipment. If the emergency is in a state without a well- equipped FDA office, consideration may be given to locating FDA's command post at the cooperating lead state agency.

### 8-6-5 Reporting

#### A. Status Report

During the height of an emergency, the division's emergency coordinator should forward daily status reports to the EOC by e-mail to [Emergency.Operations@fda.hhs.gov](mailto:Emergency.Operations@fda.hhs.gov), with a copy to the responsible

emergency coordination unit for the center(s). Copies of such reports should also be forwarded to the lead division(s) (see [8-6-3 Investigational Instructions](#)) by all investigating divisions. The EOC will specify when status reports are needed less frequently. Status reports should be in bullet format, highlighting significant information concerning the emergency (e.g., investigations, analyses, public affairs, cooperating agencies, scientific, and court matters).

The EOC will facilitate contact between divisions with the appropriate center coordinator.

#### B. Hard Copy Reports

The division's emergency coordinator should forward copies of all reports pertaining to the initial alert and subsequent investigation to the responsible center(s) and to the EOC. Each submission must include product name and product code to enable proper filing by the EOC. Copies of complaint reports, memos, collection reports, establishment inspection reports, reports of analyses, follow-up investigations, recommendations for regulatory action and recalls, when generated by an emergency, should be submitted. Unless a specific center office is identified to receive hard copy, hard copy reporting to the centers for emergencies is as follows:

1. Center for Food Safety and Applied Nutrition:

Center for Food Safety and Applied Nutrition  
Office of Analytics and Outreach  
Supervisor, Emergency Coordination and Response Team  
5100 Paint Branch Parkway, Room 2B-014  
College Park, MD 20740-3835

2. Center for Drug Evaluation and Research:

Counter-Terrorism & Emergency Coordination Staff (CTECS)  
10001 New Hampshire Avenue, Room 2155  
Silver Spring, MD 20993-1707

3. Center for Biologics Evaluation and Research:

Center for Biologics Evaluation and Research  
Office of Compliance and Biologics Quality  
Division of Inspections and Surveillance  
10903 New Hampshire Avenue  
Building 71, Room 5141  
Silver Spring, MD 20993

4. Center for Devices and Radiological Health

For all reports:

Center for Devices and Radiological Health  
Office of Compliance  
10903 New Hampshire Avenue  
Building 66, Room 2621  
Silver Spring, MD 20993

For reports of incidents involving radiation or radioactive material releases:

Center for Devices and Radiological Health  
Office of Communication, Education and Radiation Programs  
Division of Mammography Quality and Radiation Programs  
10903 New Hampshire Avenue  
Building 66, Room 0609  
Silver Spring, MD 20993

5. Center for Veterinary Medicine:

Center for Veterinary Medicine  
Office of Compliance and Surveillance  
Division of Compliance  
Metro Park North 2, Building #4  
7519 Standish Place  
Rockville, MD 20855-7707

6. Center for Tobacco Products:

Center for Tobacco Products  
Office of Compliance and Enforcement  
Division of Enforcement and Manufacturing  
10903 New Hampshire Avenue  
Building 75, Room 7464  
Silver Spring, MD 20993

7. Emergency Operations Center:

FDA Emergency Operations Center, OC/OCM  
10903 New Hampshire Avenue  
Building 32, Room 1359  
Silver Spring, MD 20993

C. Final Reports

When the investigation of any emergency, (e.g., disaster, or civil disorder) has been terminated, the lead division will submit a final written summary to OC/OCM/EOC with a copy to the responsible center emergency coordination unit. This summary will be prepared using previous reports, records of meetings, chronologies, and reports from cooperating officials.

## 8-7 HEADQUARTERS OPERATING PROCEDURES

### 8-7-1 FDA Emergency Operations Center

The FDA [EOC](#) will monitor all emergency alerts/investigations and serve as the agency-wide and inter-agency focal point for 24-hour, 7-day communications concerning developing and active emergency situations.

#### A. Emergency Alerts

FDA headquarters units that receive initial emergency alerts from consumers and other sources outside FDA will report the information to the EOC. If potential danger to health is involved, the EOC will notify the affected program and district director(s) immediately at the telephone number listed in the “ORA Directory” in the [IOM](#). If an investigation is requested by another headquarters unit, the procedures established in [FMD 17, Field Assignment Issuances Guidelines for Headquarters Offices](#) allow requests to be issued directly to the action division or office with copies to the appropriate Program Director, ORA unit, and other center or office indicated. See also [8-4, Notification of Emergencies – Terminology](#).

#### B. EOC 24-Hour Telephone Contacts

After hours, or when the command center is not in operation, calls can be made to the 24-hour emergency number handled by the answering service. In the event that calls are designated as an emergency by the caller, the answering service will contact the late duty officer (LDO) or alternate LDO (ALDO) by cell phone or pager or both.

FDA Emergency Operations 24-hour telephone number is 866-300-4374.

#### C. Headquarters Coordination

The EOC will immediately advise the appropriate ORA offices, the center emergency coordination unit and ORA of significant emergency alerts or when any investigation reaches presumptive status. [OMA](#) will also be notified when public press coverage is ongoing or imminent. The [Office of Legislation](#) (OL) will be alerted when there is or may be congressional interest. The EOC will forward to OPOP copies of all reports from ORA offices pertaining to state and local activities, actions, and agreements; and any press releases issued, e.g., information required under [8-5, Termination of Emergency Investigation](#).

The EOC will prepare updated, periodic status reports on such alerts and investigations. These reports will be expedited to the Office of the Commissioner, the ACRA, and the ORA Office of Operations. Electronic mail will be used to distribute additional copies to other headquarters offices, responsible centers and to other appropriate units.

All reports required by the Department on disasters, civil disorders, or other emergencies will be prepared by the EOC for distribution within ORA Headquarters and the appropriate office within DHHS.

#### D. Interagency Liaison

The EOC will coordinate information concerning emergencies with headquarters offices of other Federal agencies in accordance with RPM Section [8-7, Interagency Coordination](#). When commerce with

Canada or Mexico is involved, coordination will be by the EOC in cooperation with the [Office of International Programs](#) (OIP). When other foreign governments are involved, the EOC will advise OIP so that office may establish and coordinate with the EOC the maintenance of communication channels.

### **8-7-2 Center Emergency Coordination Units**

All centers will maintain an emergency coordination function that will serve as the focal point for intra-center communications with the EOC. Centers will be responsible for scientific evaluations and for policy decisions, in cooperation with ACRA, in their respective program areas. Centers will continue ongoing interagency liaison activities to the extent possible as emergency coordination with other agencies is managed pursuant to [8-7, Interagency Coordination](#).

Each center has identified the office listed in [8-6-5, Reporting](#), to serve as its coordination unit. These units facilitate any recall and case development activities that may be associated with an emergency.

#### **A. Inter-Office Communications**

Each center's emergency coordination unit will provide the EOC with a telephone number that will be the contact number for communications with the EOC during any stage of an emergency. The phone shall be suitable for conference calling.

#### **B. After Hours Communication**

Each center emergency coordination unit will provide the EOC with a call list that will provide 24-hour/7-days a week coverage. (A continuing effort will be made to evaluate various electronic communications systems to supplant the call lists.)

#### **C. Reporting by Center and on-site emergency coordinators**

Center emergency coordinators will maintain concise chronology of center activities similar to that which coordinators maintain (see [8-6-4, Emergency Management](#)). When the copy of the final report (see [8-6-5, Reporting](#)) is received from the lead division, the center will use its chronology during its review of the division report. The Center will then send any comments to the EOC before the EOC prepares a final report on the emergency.

### **8-7-3 Office of Regulatory Affairs**

The [Office of Crisis Management/EOC](#) will serve as the focal point for emergency operations and communications within the [Office of the Commissioner](#). Any information received by ORA will be discussed as appropriate with the Office of Crisis Management, the Commissioner, the Deputy Commissioner for Operations, and with other Deputy Commissioners both during business and non-business hours.

This does not preclude the immediate reporting of significant emergency information to the Commissioner/Deputy Commissioner for Operations by

the Director of Office of Operations, the Center Directors, or the Director or Deputy Director, EOC.

D. Responsibility for Policy Statements

The [Office of Crisis Management](#) and the ACRA or the ACRA's designee, working with the responsible centers and ORA, will develop, issue, and approve any new or revised regulatory policy that is required by an emergency situation.

E. ORA Call List

The order in which EOC staff should call ORA personnel during non-business hours is:

1. [Associate Commissioner for Regulatory Affairs](#)
2. [Assistant Director for Management](#)
3. [Deputy Associate Commissioner for Regulatory Affairs](#)
4. [Director, Office of Enforcement and Import Operations](#)
5. [Director, Office of Partnerships and Operational Policy](#)

**8-7-4 Office of Partnerships (OP)**

The [Office of Partnerships](#) (OP), in cooperation with the programs or divisions, will coordinate Agency interaction with state and local agencies in emergency situations.

OP will maintain FDA's rapid communication system to state governments, major municipalities and poison control centers. OP will also continue the ORA OPOP/state association efforts to develop uniform emergency operational guidelines.

A. In emergency situations, OP will:

1. Ensure that the governors' offices have been notified of significant confirmed emergencies in their states;
2. Notify all states of confirmed emergencies involving two or more states.
3. Indicate potential or problem products entering commerce; and,
4. Prepare (or distribute) information requested by states for their emergency roles, and assure that states are fully advised as to what action the Agency can recommend to them under the circumstances of the specific emergency.

B. As routine functions, OPOP will:

Maintain a directory showing

1. the responsibilities of major state organizations;
2. names, telephone numbers, and addresses of key state personnel; and

3. other information needed to quickly enlist nation-wide state and local assistance to FDA's emergency operations.

## **8-8 INTERAGENCY COORDINATION**

Liaison activities with responsible government agencies at the federal, state, and local levels must be effective during emergency situations to help ensure that resource allocations are efficient, that policy is understood, and that roles are well defined. Considering that federal agency responsibility varies from one emergency to another and that state and local government organizations differ from the federal model, the specific agencies that should cooperate in a given situation will depend on the problem and its location.

The EOC will coordinate all interagency liaison activities during emergencies and will establish communications with the headquarters office of the responsible federal agencies. The lead division will establish communications with offices of the responsible federal agencies. The EOC and the Division of Mammography Quality and Radiation Programs, CDRH, will share radiological emergency interagency liaison in accordance with attachment A.

Both the lead division and other investigating divisions will establish communications with responsible state agencies. State agencies often receive assistance from local agencies, universities, and other units in carrying out their responsibilities. Usually FDA will work through the state in coordinating efforts on the local level. Depending upon the state, it may be more appropriate for FDA division offices to work directly with such local units.

### **8-8-1 Agencies FDA Cooperates With In Emergency Situations**

These agencies may be grouped under five broad areas of responsibility, as follows:

- A. Overall emergency management;
- B. Consumer products;
- C. The environment;
- D. Human health; and,
- E. Animal health.

### **8-8-2 Federal Agency Checklist**

The following agencies and position titles should be considered for the appropriately relevant emergency:

- A. Overall Emergency Management

Federal Emergency Management Agency (FEMA)/Department of Homeland Security (DHS).



B. Consumer Products

1. Food Safety and Inspection Service (USDA/FSIS);
2. Consumer Product Safety Commission (CPSC);
3. National Oceanic and Atmosphere Administration (NOAA) National Marine Fisheries Service (NOTE: The NOAA Seafood Inspection Program is often referred to as the U.S. Department of Commerce (USDC) Seafood Inspection Program and uses marks and documents bearing the USDC moniker);
4. Defense Logistics Agency (DLA);
5. Department of Defense (DOD);
6. Contract Compliance Service, Veterans Administration (VA);
7. Environmental Protection Agency (EPA), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Products; and,
8. Federal Bureau of Investigation (FBI).
9. The Environment
10. Environmental Protection Agency (EPA);
11. National Oceanic and Atmospheric Administration (NOAA);
12. U.S. Coast Guard (USCG) (Oil Spills);
13. Nuclear Regulatory Commission (NRC);
14. Department of Energy (DOE); and,
15. Department of Transportation (DOT).

C. Human Health

1. Department of Health and Human Services – Secretary's Operations Center (SOC);
2. Centers for Disease Control and Prevention (CDC);
3. National Institutes of Health (NIH), National Institute of Environmental Health Sciences (NIEHS);
4. Occupational Safety & Health Administration (OSHA); and,
5. U.S. Department of Defense (DOD).

D. Animal Health

1. US Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS);
2. USDA National Animal Disease Laboratory (NADL);
3. US Department of the Interior, U.S. Fish & Wildlife Service; and,
4. Centers for Disease Control and Prevention (CDC).

### **8-8-3 State and Local Agency Checklist**

- A. Overall Emergency Management  
Governor's Office (or Governor's Designated Emergency Contact).
- B. Consumer Products  
Appropriate state consumer protection counterpart.
- C. The Environment  
Appropriate state environmental protection counterpart.
- D. Human Health  
Appropriate state health counterpart.
- E. Animal Health  
Appropriate state animal and agricultural counterpart.
- F. Agriculture  
Appropriate state agricultural counterpart.

## **8-9 PRESS RELATIONS**

The [Office of Media Affairs](#) (OMA) is responsible for issuing publicity and preparing answers to press inquiries about emergencies. OMA, in cooperation with the appropriate center and other Agency components, will:

- A. Prepare and approve all talk papers and press releases;
- B. Provide guidance to the lead and investigating divisions concerning the handling of local press inquiries;
- C. Notify the department of pending media coverage;
- D. Coordinate with the press operations of other agencies involved in an emergency;
- E. Counsel FDA management about necessary public statements; and
- F. Provide all Associated Press and United Press International wire copy about emergencies to EOC.

### **8-9-1 Notification of the Office of Media Affairs (OMA)**

The OMA should be notified by any FDA unit that publicity has occurred relating to the emergency condition, as well as receipt of pending requests for information from the media or the public. The Director or any Deputy Director of OMA may communicate directly with the officials closest to the scene to ascertain what information needs to be released.

## 8-10 REFERENCES

### 8-10-1 General references

- A. FMD 17 – [Field Assignments from Headquarter Offices.](#)
- B. FMD 141 – [Infant and Toddler Products.](#)
- C. [IOM](#) CHAPTER 3 – Federal - State Cooperation [Subchapter 3.2 - Federal Agency Interaction](#)
- D. [IOM](#) CHAPTER 8 – Investigations
  - a. Subchapter 8.3 – [Investigation of Foodborne Outbreaks](#)
  - b. Subchapter 8.4 – [Investigation - Injury and Adverse Reactions.](#)
- E. Bovine Spongiform Encephalopathy (BSE) Response Plan, version 2.1, September 2002.
- F. FDA's Emergency Operations Plan (EOP) available on [Emergency Preparedness > Emergency Response](#) on FDA.gov. The current plan is FDA EOP, version 2.0, March 2014.

### 8-10-2 Specific references

- A. FMD 64 -- [Epidemiological Investigations Alert Reporting Procedures](#), June 1, 1995, revision.
- B. FMD 119 -- [Consumer Products Complaint System](#) March 5, 20122012 January 12, 1994, revision.
- C. FMD 141-- [Infant and Toddler Products](#), May 16,1995, revision.
- D. [Memorandum of Understanding between the Centers for Disease Control and the Food and Drug Administration](#), April 1, 1982.
- E. [MOU between the Centers for Disease Control and the Food and Drug Administration](#), 225-14-0017, 2014.
- F. [Multistate Foodborne Outbreak Investigations: Guidelines for Improving Coordination and Communication](#), National Food Safety System Project, Outbreak Coordination and Investigation Workgroup, February 2001.
- G. [Guide to Traceback of Fresh Fruits and Vegetables Implicated In Epidemiological Investigations](#), June 2006.
- H. [FDA's Coordinated Outbreak Response and Evaluation \(CORE\) Network.](#)
- I. [FDA Emergency Operations Plan](#), version 2.0, March 2014, Office of Crisis Management.
- J. [Office of Emergency Operations](#), [Office of Crisis Management](#), [Office of the Commissioner.](#)

## 8-11 Attachment A - Guidelines for Follow-up of Tampering

### A. Introduction

The [Federal Anti-Tampering Act \(FATA\)](#) passed by Congress in 1983 makes it a Federal crime to tamper with certain consumer products and to commit certain other related acts. The Act provides specific statutory authority to the FDA to investigate tampering and alleged tampering of products that the agency regulates. There are five violations of the FATA:

1. Tampering, or attempted tampering, with a consumer product with reckless disregard for the risk of death or bodily injury.
2. Tainting a consumer product with intent to cause serious injury to the business of any person.
3. Knowingly communicating false information that a consumer product has been tainted.
4. Knowingly threatening to tamper with a consumer product.
5. Conspiracy to tamper with a consumer product.

A more detailed discussion of these violations can be found in the FATA (Title 18, United States Code, Section 1365).

### B. Guidelines

1. The FDA [Emergency Operations Center](#) (EOC), 866-300-4374 (HFA-615), must be promptly alerted to all tampering/threat incidents. This is in addition to the prompt reporting of incidents outlined in the Emergency Procedures section of the RPM, Chapter 8.
2. Division and other ORA offices should immediately notify the appropriate Office of Criminal Investigations (OCI) office upon receiving information concerning a tampering/threat incident. This notification will enable the OCI office and the Division office to coordinate operations.
3. OCI offices have primary responsibility for liaison with law-enforcement agencies (i.e., FBI, state police, sheriff departments, and local police). In certain situations OCI may request ORA offices to maintain contact with and offer assistance to cooperating officials who investigate tampering incidents (i.e., FBI, USDA, state and local police, health department, coroner, and medical examiners).
4. The FBI expressed an interest in being notified in all tampering investigations involving extortion, serious injury or death, terrorism, and significant false reports. In all but critical circumstances such notifications will be done through the OCI office. In some situations the Division office may be asked by OCI to notify the FBI.

5. All requests for assistance from other law-enforcement agencies, including status briefings and notifications, regarding criminal investigations must be coordinated through OCI office.
  6. Complaints/reports concerning products subject to USDA regulations should be immediately referred to their local contact of USDA for their follow-up. The Division office should promptly notify the OCI office and EOC of all such referrals.
- C. When an alleged or suspected tampering incident is reported to FDA, the Agency must attempt to determine whether tampering has actually occurred or whether some other problem such as a manufacturing or distribution defect is involved. EOC and the centers are available to offer expert advice on possible manufacturing defects. The manufacturer can also provide information on defects. In addition, we should seek to determine where the tampering occurred (e.g., in the retail store, at the manufacturing site, etc.)
- D. The OCI office will have primary responsibility for all criminal investigations of tampering/threats incidents. In those incidents where OCI does not or cannot initiate a criminal investigation because of resource limitations, the Division offices must continue the investigation. Division offices must closely coordinate their efforts with OCI offices. In these special situations the Division office must keep the EOC and OCI office advised of their progress. Any referrals to law-enforcement agencies, other than OCI, may be made only after obtaining the concurrence of OCI office. The OCI Headquarters will provide details on tampering cases investigated by the OCI office to EOC for forwarding to the proper centers for their information and any action they may have to take.
- E. The Office of Chief Counsel/FDA (OCC) should be notified as soon as an FDA component determines that a case will be referred to a United States attorney in the following circumstances:
- F. Where there is a conspiracy.
- G. When an FDA regulated entity is included as a defendant.
- H. When Title 21 charges are contemplated.

In the absence of one of these three circumstances OCC need not be notified prior to referral to a United States attorney; however, OCC should be sent a copy of the charging document that is filed with the court.