Chapter 8
EMERGENCY PROCEDURES

This chapter contains the following sections.

All questions pertaining to this chapter should be directed to the FDA Emergency Operations Center (EOC), HFA-615, 866-300-4374 (24 hour number).

8-1 PURPOSE

To set forth emergency management procedures for the Food and Drug Administration's headquarters and field 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 Policy

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 FDA Emergency Operations Center (EOC), HFA-615, Office of Crisis Management, Office of the Commissioner. This alert system utilizes information from many internal FDA sources (e.g., consumer complaint systems, adverse reactions, product defect, 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). The EOC coordinates the FDA response to emergency situations by facilitating rapid and early

information sharing as well as providing real-time situational awareness to and from FDA Headquarters, Centers, and Field Offices. The EOC is supported by a multi-level network of over 40 FDA Headquarters, Center, Regional, and District Offices.

1. ***Definition Of Emergency***

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

   "An unforeseen combination of circumstances, or the resulting state, that calls for immediate actions."

2. ***This Procedure Was Developed To Provide Guidance For Planning, Monitoring, Coordinating, And Directing FDA Response To:***

   a. national emergencies (e.g., civil disorders; major transportation and industrial strikes; acts of terrorism; refugee crises; etc.);

   b. natural disasters (e.g., hurricanes; floods; earthquakes; tornadoes; volcanic eruptions; etc.);

   c. man-made disasters (e.g., radiological incidents; chemical spills; toxic waste problems; air pollution problems; etc.);

   d. injury and illness complaints or reports of tampering (e.g., foods; drugs; biologics; cosmetics; medical, and radiation emitting devices; veterinary products;

   e. epidemiological investigations (e.g., illness outbreaks associated with foodborne or other pathogens and adverse reactions, etc.); and,

   f. agency emergency preparedness (e.g., planning, development, implementation, and testing of emergency preparedness plans in response to attack).

3. ***Relationship To Recalls***

   Product recalls may occur during an emergency investigation; if so, procedures under Chapter 7 of this manual should be followed as well. A recall of a defective product which is progressing satisfactorily will not by itself activate this 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 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, HFA-615. Any emergencies involving highly transmissible diseases that would include SARS, avian flu,, WNV (West Nile Virus), malaria, etc., chemical, biological or radiological emergencies, contact the EOC at 866-300-4374 or fax to 301-847-8544.

8-3-2 Declaring An Emergency

This procedure includes mechanisms for monitoring investigations leading to an understanding that an emergency exists. It is expected that the involved centers and district 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 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 between any offices or 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 (8-6 3). The Director, Office of Crisis Management along with the Associate Commissioner for Regulatory Affairs or designee, in consultation with ORO and the involved centers, will decide whether to implement the procedure and will notify the appropriate offices.

8-4 NOTIFICATION OF EMERGENCIES

Various terms (i.e., alert, case, suspect, preliminary, etc.) have been used in describing the status of a sample analysis or the stage of an investigation. This has led to confusion and misinterpretation in the identification and management of emergency situations. The following terminology will be used to describe the status of a notification of an emergency:

8-4-1 Alert

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

1. Unconfirmed report of product related illness/injury or unanticipated adverse reaction;
2. Unconfirmed report of the presence of a toxic (chemical, radioactive, or microbial) substance; or,
3. A report of a man-made disaster (oil spill, radiological accident) or a natural disaster (hurricane, flood, tornado).
4. Confirmation of declaration of pandemic influenza (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 which include the following:

1. Epidemiological data has provided a significant association between the illness, injury, or unanticipated adverse reactions and the product;
2. 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;
3. An oil spill has drifted into fishing areas;
4. A radiological incident has occurred and radioactive material has been released, but the extent is unknown; or,
5. Floods have caused property damage in an area where regulated products are being held.
6. Confirmation of widespread outbreak in multiple locations overseas (WHO Phase 6; US Government Response Stage 3).

8-4-3 Confirmed

A problem has been confirmed through laboratory analyses, field 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. The first human case of pandemic influenza in U.S. is confirmed (WHO Phase 6; US Government Response Stage 4).

8-4-4 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, given the hazard involved. The depth and extent of FDA activities, at the confirmation of an emergency situation, is based on factors such as:

1. interstate distribution of involved product, and/or,
2. other Federal, state, or local government efforts to control the problem.

When other Federal, state, or local agencies can more effectively deal 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 EOC. EOC contact should be maintained with the investigating agency until a conclusion is reached. 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.

8-5 DISTRICT OPERATING PROCEDURE

8-5-1 24-Hour Communications System

Each regional/district office will maintain a means by which headquarters can communicate emergency situations on a 24-hour, 7-days-a-week basis. Each designated contact should be identified, including home phone number, to the EOC. Changes in contact points should be reported in a timely manner to the EOC. Each region/district will establish and maintain

procedures for internal communications and provide for appropriate liaison and notification systems to city, county, and state governments, and local offices of Federal agencies.

8-5-2 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 or fax, text, or other communication methods would be acceptable if phones are not available..Confirmatory or summary reports may be forwarded by Email to Emergency.Operations@fda.hhs.gov or by FAX (301-847-8544). Report the nature and effect of the emergency including as much of the following information as available:

1. Product description - includes size and type of package; identify manufacturer, lot number, and product code;
2. Probable or actual distribution pattern, if known, for suspect product(s);
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, corrective actions, recalls, or media coverage.

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.

8-5-3 Investigational Instructions

Refer to IOM, Chapter 8, Investigations, for detailed investigative procedures.

8-5-4 Emergency Management

1. ***Coordination with the EOC***

   The Emergency Operations Center will be the focal point for all emergency coordination between the District Office(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.

2. ***Lead District***

As FDA conducts response operations under ICS, the district 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.

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

Any change in the designation of "lead district" 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 district."

The "lead district" will identify an ad hoc emergency management team to be headed by the District Director or a designated district person and a coordinator. The exact number and mix of persons on the team will be determined by the district. Any recommendations for reallocation of field staff between or among districts during emergencies should be directed to the Office of Regional Operations (ORO).

3. ***District 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 district office to facilitate communication and record review. In a widespread emergency, additional coordinators may be named by the involved districts as necessary. The coordinator will be responsible for advising management of actions needed to follow-up on the emergency and channeling all necessary communications.

Any or all of the following steps should be included:

a. Investigation/Analysis

   i. Issuing assignments to district personnel to obtain the information necessary for Agency personnel to evaluate the health hazard of the situation;

   ii. Monitoring assignments to assure timely completion;

   iii. Arranging for continuing contact with investigators for flow of information;

   iv. Seeking technical guidance through the EOC relating to the investigation, samples needed, etc.; and,

   v. Determining in consultation with Division of Field Science, ORA the appropriate laboratory to submit samples to and alerting that laboratory as soon as possible so that necessary preparations may be made.

b. Maintaining Communications

   i. Keeping appropriate District and Regional management informed of

investigational and analytical progress;

ii. Preparing daily status reports;

iii. Contacting the appropriate state and local authorities already involved with the investigation; and,

iv. Serving as local FDA press contact concerning the emergency. The coordinator or other designated official will work with headquarters in preparing statements to the press.

NOTE: FDA field and headquarters employees may be asked to respond to media inquiries about ongoing investigations when not in a position to first seek guidance from the Office of Public Affairs (OPA). 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.

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

Significant emergency press coverage should be reported to EOC promptly. EOC will notify the Office of the Commissioner, OPA, DFSR and other offices of the press coverage. Copies of local press releases by the state and/or the firm should be faxed as soon as possible to EOC.

c. Documentation

i. 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.

ii. Significant telephone conversations involving the emergency should be documented (by the participants) and forwarded to EOC daily.

iii. Statistical data such as numbers of samples analyzed, inspections made, injuries reported, farms quarantined, etc., should begin early in the process and be maintained.

4. ***Location of Field Command Post***

The FDA lead district office (or a large resident post) facility should generally serve as FDA's field 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 field command post at the cooperating lead state agency.

8-5-5 Reporting

1. ***Status Report***

   During the height of an emergency, the district's emergency coordinator should forward daily status reports by E-mail Emergency.Operations@fda.hhs.gov or FAX (301-847-8544) to the EOC with a copy to the responsible emergency coordination unit for the center(s). Copies of such reports should also be forwarded to the "lead districts" by all investigating districts. 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 districts with the appropriate center coordinator.

2. ***Hard Copy Reports***

   Copies of all reports pertaining to the initial alert and subsequent investigation should be forwarded 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/or 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:

   a. CFSAN Food and Drug Administration

      Center for Food Safety and Applied Nutrition
      Office of Food Defense, Communication and Emergency Response
      Supervisor, Emergency Coordination and Response Team (HFS-015)
      5100 Paint Branch Parkway, Room 2B-014
      College Park, MD 20740-3835

   b. CDER Food and Drug Administration

      Center for Drug Evaluation and Research
      Office of Counter-Terrorism & Emergency Coordination
      10903 New Hampshire Avenue
      Building 51, Room 3342
      Silver Spring, MD 20993

   c. CBER Food and Drug Administration

      Center for Biologics Evaluation and Research
      Office of Compliance and Biologics Quality (HFM-650)
      Division of Inspections and Surveillance
      1401 Rockville Pike
      Rockville, MD 20852-1448

   d. CDRH Food and Drug Administration

For all reports:

Center for Devices and Radiological Health
Office of Compliance
10903 New Hampshire Avenue
Building 66
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 4676
Silver Spring, MD 20993

e. CVM Food and Drug Administration

Center for Veterinary Medicine
Office of Compliance and Surveillance
Division of Compliance (HFV-230)
Metro Park North 2, Building #4
7519 Standish Place
Rockville, MD 20855

f. CTP Food and Drug Administration

Center for Tobacco Products
Office of Compliance and Enforcement
Enforcement and Manufacturing
9200 Corporate Blvd
Rockville, MD 20850

g. Food and Drug Administration

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

3. ***Final Reports***

When the investigation of any emergency, (e.g., disaster, or civil disorder) has been terminated, the lead district 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 from previous reports, records of meetings, chronologies, and reports from

cooperating officials.

8-6 HEADQUARTERS OPERATING PROCEDURES

8-6-1 FDA Emergency Operations Center

The FDA Emergency Operations Center 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.

1. ***Emergency Alerts***

   Initial emergency alerts received by FDA headquarters units from consumers and other sources outside FDA will be reported to the EOC. If potential danger to health is involved, the EOC will notify the field by phone immediately. If an investigation is requested by another headquarters unit, procedures established in FMD #17 allow requests to be issued directly to the action district or field office with copies to the appropriate RFDD, ORA unit and other center or office indicated. See also 8-4.

2. ***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 late duty officer (ALDO) by cell phone and/or pager.

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

3. ***Headquarters Coordination***

   The EOC will immediately advise the appropriate field office, the center emergency coordination unit and the Office of Regulatory Affairs of significant emergency alerts or when any investigation reaches presumptive status. The Office of Public Affairs (OPA) will also be notified when public press coverage is ongoing or imminent. The Office of Legislative Affairs (OLA) will be alerted when there is or may be congressional interest. The EOC will forward to DFSR copies of all reports from field offices pertaining to state and local activities/actions/agreements; and any press releases issued. (e.g.: information required under 8-5-1, 8-5-4, 8-5-5-1, etc.). The EOC will prepare periodical updating status reports on such alerts/investigations. These reports will be hand carried to HF-1, HF-4, HFC-1 and HFC-100/101. 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.

4. ***Interagency Liaison***

   The EOC will coordinate information concerning emergencies with headquarters

offices of other Federal agencies in accordance with Section 8-7 of this chapter. 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.

8-6-2 Center Emergency Coordination Units

All centers will maintain an emergency coordination function which 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.

Each center has identified the office listed in 8-5-5 to serve as its coordination unit. These units (except for CDRH/Radiation Programs Branch) are located in the center's Office of Compliance to facilitate any recall and/or case development activities which may be associated with an emergency. The Radiation Programs Branch is a focal point for radiological emergencies involving releases of radiation or radioactive materials which could impact FDA-regulated products or require the use of FDA-regulated products to mitigate the impact of the release. The Radiation Programs Branch is located in the Division of Mammography Quality and Radiation Programs/CDRH.

1. ***Inter-Office Communications***

   The center's emergency coordination function will provide a telephone number which will be the contact number for communications with the EOC during any stage of an emergency. It shall be equipped with a speaker phone and situated in a room or office suitable for a small meeting.

2. ***After Hours Communication***

   Each center emergency coordination function will provide the EOC with a call list, which will provide 24 hour/7 day coverage. (A continuing effort will be made to evaluate various electronic communications systems to supplant the call lists.)

3. ***Reporting***

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

8-6-3 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, Commissioner and Deputy Commissioner for Operations and with other Deputy Commissioners both during business and non-business hours. ***This does not, when appropriate, preclude the immediate reporting of significant emergency information to the Commissioner/Deputy***

Commissioner for Operations by the Director of Office of Regional Operations, Center Directors, or by the Director or Deputy Director, EOC.

1. ***Policy Statements***

   The Office of Crisis Management and the Associate Commissioner for Regulatory Affairs or designee, working with the responsible centers and ORO, will develop/issue/approve any new or revised regulatory policy which is required by an emergency situation.

2. ***ORA Call List***

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

   a. Associate Commissioner for Regulatory Affairs

   b. Director, Office of Regional Operations

   c. Deputy Associate Commissioner for Regulatory Affairs

   d. Assistant Commissioner for Regulatory Affairs

   e. Director, Office of Enforcement

   f. Director, Office of Resource Management

8-6-4 Federal-State Relations/ORO

The Division of Federal-State Relations (DFSR), in cooperation with the regions or districts, will coordinate Agency interaction with state and local agencies in emergency situations.

DFSR will maintain FDA's rapid communication system to state governments, major municipalities and poison control centers. DFSR will also continue the ORO/State Association efforts to develop uniform emergency operational guidelines.

1. ***In emergency situations, DFSR will***:

   a. Ensure that the governors' offices have been notified of significant confirmed emergencies in their states;

   b. Notify all states of confirmed emergencies involving two or more states. Indicate potential or problem products entering commerce; and,

   c. 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.

2. ***As routine functions, DFSR will***:

   Maintain a directory showing the responsibilities of major state organizations; names, telephone numbers, and addresses of key state personnel, and other information needed to quickly enlist nation-wide state and local assistance to FDA's

emergency operations.

8-7 INTERAGENCY COORDINATION

Liaison with responsible government agencies at the federal, state, and local levels must be effective during emergency situations to ensure that resource allocations are efficient and 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 depends on the problem and its location as well.

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 district will establish communications with field 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 district and other investigating districts 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 district offices to work directly with such local units.

8-7-1 Agencies FDA Cooperates With In Emergency Situations

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

1. Overall emergency management;
2. Consumer products;
3. The environment;
4. Human health; and,
5. Animal health.

8-7-2 Federal Agency Checklist

1. ***Overall Emergency Management***
    a. Federal Emergency Management Agency (FEMA)/Department of Homeland Security (DHS);
    b. Public Health Service Emergency; and,
    c. Coordinator (PHS)
2. ***Consumer Products***
    a. Food Safety and Inspection Service (USDA);
    b. Consumer Product Safety Commission (CPSC);

c. National Marine Fisheries Service NOAA/USDC;

d. Defense Logistics Agency;

e. Department of Defense (DOD);

f. Contract Compliance Service;

g. Veterans Administration (VA);

h. Environmental Protection Agency (EPA);

i. (FIFRA Products) (EPA); and,

j. Federal Bureau of Investigation (FBI).

3. ***The Environment***

a. Environmental Protection Agency (EPA);

b. National Oceanic and Atmospheric Administration (NOAA)

c. U.S. Coast Guard (Oil Spills) (USCG);

d. Nuclear Regulatory Commission (NRC);

e. Department of Energy (DOE); and,

f. Department of Transportation (DOT).

4. ***Human Health***

a. Department of Health and Human Services – Secretary's Operations Center (SOC);

b. Centers for Disease Control and Prevention (CDC);

c. National Institute of Environmental Health Sciences;

d. Occupational Safety & Health Administration (OSHA); and,

e. U.S. Department of Defense (DOD).

5. ***Animal Health***

a. Animal and Plant Health Inspection Service (USDA);

b. National Animal Disease Laboratory (USDA);

c. U.S. Fish & Wildlife Service (USDI); and,

d. Centers for Disease Control and Prevention (CDC).

8-7-3 State And Local Agency Checklist

1. ***Overall Emergency Management***

a. Governor's Office (or Governor's Designated Emergency Contact)

2. ***Consumer Products***
3. ***The Environment***
4. ***Human Health***
5. ***Animal Health***
6. ***Agriculture***

8-8 PRESS RELATIONS

The Office of Public Affairs is responsible for issuing publicity and preparing answers to press inquiries about emergencies. OPA, in cooperation with the appropriate center and other Agency components, will:

1. Prepare and approve all talk papers and press releases;
2. Provide guidance to the lead and investigating districts concerning the handling of local press inquiries;
3. Notify the department of pending media coverage;
4. Coordinate with the press operations of other agencies involved in an emergency;
5. Counsel FDA management about necessary public statements; and
6. Provide all Associated Press and United Press International wire copy about emergencies to EOC.

8-8-1 Notification Of Press Office

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

8-9 REFERENCES

8-9-1 General

1. FMD NO. 17 - Assignments from Headquarter Offices
2. FMD NO. 141 - Infant and Toddler Products
3. IOM CHAPTER 3 - Federal - State Cooperation
    a. Subchapter 3.2 - Federal Agency Interaction
4. IOM CHAPTER 8 - Investigations
    a. Subchapter 8.3 - Investigation of Foodborne Outbreaks

b. Subchapter 8.4 - Investigation - Injury and Adverse Reactions

5. Bovine Spongiform Encephalopathy (BSE) Response Plan, version 2.1, September 2002

8-9-2 Standard Operating Procedures

1. Field Management Directive (FMD) No.64, "Epidemiological Investigations Alert Reporting Procedures," June 1, 1995, revision.
2. Field Management Directive (FMD) No.119, "Consumer Products Complaint System," January 12, 1994, revision.
3. Field Management Directive (FMD) No.141, "Infant and Toddler Products," May 16, 1995, revision.
4. Memorandum of Understanding between the Centers for Disease Control and the Food and Drug Administration, April 1, 1982.
5. Bovine Spongiform Encephalopathy (BSE) Response Plan, version 2.1, September 2002
6. Multistate Foodborne Outbreak Investigations: Guidelines for Improving Coordination and Communication, National Food Safety System Project, Outbreak Coordination and Investigation Workgroup, February 2001.
7. Guide to Traceback of Fresh Fruits and Vegetables Implicated In Epidemiological Investigations, April 2001.
8. MOU between the Centers for Disease Control and the Food and Drug Administration, dated 6/26/00.