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), HFC-160, 301-443-1240 (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 Assistance Act, and the Federal Response Plan.

8-2 INTRODUCTION

A. POLICY

These procedures provide guidance for the Agency to act immediately to protect the public from contaminated or defective FDA-regulated products. 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) HFC-160, Office of Crisis Management, Office of the Commissioner). This alert system utilizes information from many internal FDA sources (e.g., consumer complaints, 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 EOC coordinates the FDA response to emergency situations by facilitating early notification to FDA headquarters, Centers, and appropriate field offices and the Office of The Commissioner.

B. 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."

This procedure was developed to provide guidance for planning, monitoring, coordinating, and directing FDA investigations in response to national emergencies (e.g., civil disorders; major transportation and industrial strikes; acts of terrorism; refugee crises; etc.); natural disasters (e.g., hurricanes; floods; earthquakes; tornadoes; volcanic eruptions; etc.); man-made disasters (e.g., radiological incidents; chemical spills; toxic waste problems; air pollution problems; etc.); injury and illness complaints or reports of tampering (e.g., foods; drugs; biologics; cosmetics; medical, and radiation emitting devices; veterinary products; epidemiological investigations (e.g., illness outbreaks associated with foodborne or other pathogens and adverse reactions, etc.); and 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 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

A. 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, HFC-160. Any emergencies involving BSE/TSE, chemical, biological or radiological emergencies, contact the EOC at 301-443-1240 or fax to 301-827-3333.

B. 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 (8-10-50 C). 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:

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;
3) A report of a man-made disaster (oil spill, radiological accident) or a natural disaster (hurricane, flood, tornado).

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.
5) Floods have caused property damage in an area where regulated products are being held.

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.

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

A. 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.

B. 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 and appropriate follow-up. Confirmatory or summary reports may be forwarded by Email Emergency.Operations@fda.gov or by FAX (301-827-3333). 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.
(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, radiological incidents, etc., also require the reporting of:
(6) The magnitude of health hazards or other problems related to FDA activities.
(7) The extent to which FDA facilities are or may be affected.

C. INVESTIGATIONAL INSTRUCTIONS

Refer to IOM, Chapter 9, Investigations, for detailed investigative procedures.

D. 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 in order to be able to serve backup, as necessary.

Other Offices and Agencies involved in an emergency situation will identify a contact for all communications.

(2) Lead District

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 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

- Issuing assignments to district personnel to obtain the information necessary for Agency personnel to evaluate the health hazard of the situation;
- Monitoring assignments to assure timely completion;
- Arranging for continuing contact with investigators for flow of information;
- Seeking technical guidance through the EOC relating to the investigation, samples needed, etc.
- 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

- Keeping appropriate District and Regional management informed of investigational and analytical progress;
- Preparing daily status reports;
- Contacting the appropriate state and local authorities already involved with the investigation;
-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 assure 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

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

E. 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.gov or FAX (301-827-3333) 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:

CFSAN Food and Drug Administration
Center for Food Safety and Applied Nutrition
Director, Emergency Coordination and Response
HFS-600
5100 Paint Branch Parkway, Room 3B-069
College Park, MD 20740-3835

CDER Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance (HFD-300)
Montrose Metro II
11919 Rockville Pike
Rockville, Maryland 20852

CBER Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance (HFM-650)
Division of Inspections and Surveillance
1401 Rockville Pike
Rockville, Maryland 20852-1448

CDRH Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance (HFZ-300)
2094 Gaither Road
Rockville, Maryland 20850

CVM Food and Drug Administration
Center for Veterinary Medicine
Office of Compliance and Surveillance
Division of Compliance (HFV-230)
Metro Park North 2, Room E479
7500 Standish Place
Rockville, Maryland 20855

Food and Drug Administration
Emergency Operations Center, ORO/ORA, HFC-160
5600 Fishers Lane, Rm. 12A-55
Rockville, Maryland 20857

(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 ORA/ORO/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

A. 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 8-10-30.

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 activate pagers which are in the possession of key EOC staff members.
FDA Emergency Operations 24-hour telephone number: 301-443-1240

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 8-10-40-A, 8-10-40-D 2(b), 8-10-40 E (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 type 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 8-10-60 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.

B. 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 8-10-60.

Each center has identified the office listed in 8-10-40(D) 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 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 8-10-40 D 2). When the copy of the final report (8-10-40 E 3) 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.

C. 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:

1. Associate Commissioner for Regulatory Affairs
2. Director, Office of Regional Operations
3. Deputy Associate Commissioner for Regulatory Affairs
4. Assistant Commissioner for Regulatory Affairs
5. Director, Office of Enforcement
6. Director, Office of Resource Management

D. 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. Assure 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.
   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 assure 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.

Agencies FDA cooperates with in emergency situations may be grouped under five broad areas of responsibility. These areas are:

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

A checklist of involved federal agencies follows:

A. FEDERAL AGENCY CHECKLIST

1. Overall Emergency Management

Federal Emergency Management Agency (FEMA)/Department of Homeland Security (DHS)
Public Health Service Emergency
Coordinator (PHS)

2. Consumer Products

Food Safety and Inspection Service (USDA)
Consumer Product Safety Commission (CPSC)
National Marine Fisheries Service NOAA/USDC
Defense Logistics Agency
Department of Defense (DOD)
Contract Compliance Service
Veterans Administration (VA)
Environmental Protection Agency

(FIFRA Products) (EPA)
Federal Bureau of Investigation (FBI)

3. The Environment
Environmental Protection Agency (EPA)
National Oceanic and Atmospheric Administration (NOAA)
U.S. Coast Guard (Oil Spills) (USCG)
Nuclear Regulatory Commission (NRC)
Department of Energy (DOE)
Department of Transportation (DOT)

4. Human Health
Department of Health and Human Services – Secretary's Command Center (SCC)
Centers for Disease Control and Prevention (CDC)
National Institute of Environmental Health Sciences
Occupational Safety & Health Administration (OSHA)
U.S. Department of Defense (DOD)

5. Animal Health
Animal and Plant Health Inspection Service (USDA)
National Animal Disease Laboratory (USDA)
U.S. Fish & Wildlife Service (USDI)
Centers for Disease Control and Prevention (CDC)

B. STATE AND LOCAL AGENCY CHECKLIST

1. Overall Emergency Management
   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.

Also, OPA will provide all Associated Press and United Press International wire copy about emergencies to EOC.

A. 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

FMD NO. 17 - Assignments from Headquarter Offices
FMD NO. 141 - Infant Toddler Products
IOM CHAPTER 3 - Federal and State Cooperation
Subchapter 310 - Federal Agency Interaction
IOM CHAPTER 9 - Investigations
Subchapter 910 - Investigation of Foodborne Outbreaks
Subchapter 920 - Investigation - Injury and Adverse Reactions - Drugs, Devices, Cosmetics
Bovine Spongiform Encephalopathy (BSE) Response Plan, version 2.1, September 2002

STANDARD OPERATING PROCEDURES

Field Management Directive (FMD) No.64, "Epidemiological Investigations Alert Reporting Procedures," June 1, 1995, revision.
Field Management Directive (FMD) No.119, "Consumer Products Complaint System," January 12, 1994, revision.
Field Management Directive (FMD) No.141, "Infant and Toddler Products," May 16, 1995, revision.
Compliance Policy Guide (CPG) No.7155e.07, Chapter 55e. Memorandum of Understanding between the Centers for Disease Control and the Food and Drug Administration, April 1, 1982.
Bovine Spongiform Encephalopathy (BSE) Response Plan, version 2.1, September 2002
Multistate Foodborne Outbreak Investigations: Guidelines for Improving Coordination and Communication.
National Food Safety System Project, Outbreak Coordination and Investigation Workgroup, February 2001.
Guide to Traceback of Fresh Fruits and Vegetables Implicated In Epidemiological Investigations, April 2001.
MOU between the Centers for Disease Control and the Food and Drug Administration, dated 6/26/00

8-10 ATTACHMENT AND EXHIBIT

ATTACHMENT:
A - Guidelines for Follow-up of "Tampering" Incidents

EXHIBIT:
8-1 FDA/CDC Memorandum of Understanding: FDA Liaison with CDC for Radiation Emergency Response Planning

Attachment A - Guidelines for Follow-up of Tampering

I. 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:

(a) Tampering, or attempted tampering, with a consumer product with reckless disregard for the risk of death or bodily injury.
(b) Tainting a consumer product with intent to cause serious injury to the business of any person.
(c) Knowingly communicating false information that a consumer product has been tainted.
(d) Knowingly threatening to tamper with a consumer product.
(e) 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).

II. Guidelines

1. The FDA Emergency Operations Center (EOC), 301-443-1240 (HFC-160), 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 8-10.
2. District offices should immediately notify the appropriate Office of Criminal Investigations (OCI) Field office upon receiving information concerning a tampering/threat incident. This notification will enable the OCI Field office and the District office to coordinate operations.
3. OCI Field 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 the District 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).

   (a) 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 Field office. In some situations the District office may be asked by OCI to notify the FBI.
   (b) All requests for assistance from other law-enforcement agencies, including status briefings and notifications, regarding criminal investigations must be coordinated through OCI Field office.
   (c) Complaints/reports concerning products subject to USDA regulations should be immediately referred to their local contact of USDA for their follow-up. The District office should promptly notify the OCI Field office and EOC of all such referrals.

4. 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.)

5. The OCI Field 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 District offices must continue the investigation. District offices must closely coordinate their efforts with OCI Field offices. In these special situations the District office must keep the EOC and OCI Field office advised of their progress. Any referrals to law-enforcement agencies, other than OCI, may be made only after obtaining the concurrence of OCI Field office. The OCI Headquarters will provide details on tampering cases investigated by the OCI Field office to EOC for forwarding to the proper centers for their information and any action they may have to take.
6. 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:
   (a) Where there is a conspiracy.
   (b) When an FDA regulated entity is included as a defendant.
   (c) 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.

Exhibit 8-1
FDA/CDC MOU: FDA LIAISONS WITH CDC FOR RADIATION EMERGENCY RESPONSE PLANNING

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
CENTERS FOR DISEASE CONTROL
AND THE
FOOD AND DRUG ADMINISTRATION
FOR
RADIATION EMERGENCY RESPONSE PLANNING
AND
RADIATION EMERGENCY RESPONSE ACTION

PREAMBLE

Over the past decade, the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) have taken cooperative action to implement the Assistant Secretary for Health's (ASH) May 30, 1979, directive designating CDC as the lead agency within the Public Health Service (PHSA) for health management of toxic environmental emergencies. This directive facilitates intramural communications and liaison with outside groups and ensures a prompt coordinated Federal response to environmental emergencies that endanger public health and safety. CDC's lead responsibility encompasses emergencies involving potential exposure to radiation, e.g., the accident at Three Mile Island. In a September 5, 1979, memorandum to the then Acting Commissioner of Food and Drugs, the Assistant Secretary for Health endorsed an active role for (what was then) the Bureau of Radiological Health of FDA in radiation emergencies because of its specialized expertise for radiation emergency response planning. (In 1984 the Bureau was merged with the Bureau of Medical Devices of FDA and renamed the Center for Devices and Radiological Health.) The CDC and the FDA, in 1980, developed a memorandum of understanding (MOU) to describe the respective responsibilities of each agency with regard to peacetime radiological emergencies and how emergency planning and action will be coordinated.

PURPOSE AND SCOPE

The purpose of the present memorandum of understanding is to revise and extend the previous MOU to reflect current activities and responsibilities of each agency. This document is concerned with radiological accidents which might have an impact on public health and safety. It does not include non-emergency environmental radiation problems (e.g., the dose reconstruction at the Hanford site).

AUTHORITY

FDA and CDC shall continue to act under existing delegations of authority and no transfer of statutory functions or authority is implied by this MOU.

1. Both CDC and FDA derive authority from the Public Health Service Act, 42 U.S.C., 241, et. seq., which provides authority for the conduct of health studies and the provision of guidance, assistance, and information on both health matters and for health emergencies.

The Secretary of HHS is authorized to provide for cooperative planning to cope with health problems resulting from disasters, for participation in carrying out such planning, and, at the request of state and local authorities, in meeting health emergencies.

2. The FDA is responsible for enforcement of the Federal Food, Drug, and Cosmetic Act (U.S.C. Title 21), the Radiation Control for Health and Safety Act (U.S.C. 263b, et. seq.), the Public Health Service Act as it pertains to Regulation of Biological Products (U.S.C. 262, et seq.), other sections of the PHS Act, and other laws. In fulfilling its responsibility under these laws, FDA protects the public health and safety by, inter alia, preventing the adulteration of or controlling adulterated products such as foods, drugs, cosmetics, medical devices, animal feeds, and human biologicals. It also protects the public from the dangers of electronic product radiation.

3. On December 7, 1979, the President directed the Federal Emergency Management Agency (FEMA) to take the lead in activities associated with the off-site planning and response to all peacetime radiological accidents at nuclear facilities. Because of its leadership role, he further directed FEMA to undertake a series of activities including the development and issuance of updated interagency assignments delineating respective agency capabilities and responsibilities. FEMA outlined such responsibilities in 44 CFR Part 351. Planning and response activities were gradually extended to address sources of potential exposure other than nuclear power facilities, e.g., terrorist nuclear devices, and nuclear powered orbital and space vehicles. In 1988, the Federal Radiological Emergency Response Plan (FRERP) was identified as a component of the President's National Security Emergency Preparedness Policy (E.O. 12656).

FDA RESPONSIBILITIES

1. Response Planning

FDA will be responsive to CDC's request for representation on task forces and coordinating committees relating to the FRERP.

The FDA Regional Offices will each appoint a representative to serve on Regional Advisory Committees, and participate in Federal Radiological Monitoring and Assessment Center activities. (A second representative will be appointed by each PHS Regional Office.)

FDA will coordinate the development of FEMA guidance for HHS responsibilities that clearly fall under FDA's jurisdiction and expertise. Specifically, FDA will maintain the responsibility for the following:

A. Provide guidance to state and local governments on the use of radioprotective substances (e.g., thyroid blocking agents) to include dosage and also projected radiation doses at which such drugs should be used.

B. Provide guidance to state and local governments on protective action guides for foods and animal feeds.

FDA will keep CDC regularly informed, and CDC will be requested to provide, as deemed appropriate, review and comments on the overall PHS perspective on the items mentioned above.

FDA will in cooperation with CDC work with Regional Advisory Committees to provide appropriate technical review and comment in areas of FDA responsibility.

FDA will provide technical assistance to CDC in developing and implementing HHS Radiological Emergency Preparedness Training Programs.

2. Emergency Response Actions

When FDA is alerted to a radiation emergency, it will immediately alert CDC.

In accordance with specific state, regional, or national plans, this MOU, and specific requests by CDC, FDA will:

A. As part of the HHS team, participate in the radiological emergency exercises, tests, and responses.

B. Establish appropriate emergency response liaison with the on-site CDC designated coordinator and keep CDC headquarters advised.

C. Provide technical support to state, local and other Federal agencies.

FDA will implement and coordinate its own Emergency Response Procedures as set forth in Chapter 5-10 of the FDA Regulatory Procedures Manual. Radiological emergency responses include such actions as:

A. Environmental monitoring and sampling of milk, foods, and animal feed following a radiological incident.

B. Analysis and interpretation of food and environmental monitoring data.

C. Taking appropriate compliance actions and implementing protective actions for contaminated food and feed under the statutory authority of the Federal Food, Drug, and Cosmetic Act and other Acts administered by FDA.

FDA will provide technical support to CDC for the preparation of HHS news releases, for coordination with other agencies, and for informing the public media about health significance of a radiological incident.

FDA will give CDC emergency contact telephone numbers for maintaining close liaison in case an emergency response action becomes necessary and for implementing HHS resources.

CDC RESPONSIBILITIES

1. Response Planning

CDC has the lead role within PHS for planning the HHS role in the FEMA national response to radiation emergencies. This includes the following activities:

A. CDC is responsible for arranging HHS representation on the Federal Radiological Preparedness Coordinating Committee (FRPCC) and designating membership on relevant

FRPCC subcommittees (e.g., FDA represents HHS on five task forces).

B. CDC arranges for appropriate PHS representation at meetings of all Regional Advisory Committees (RAC).

C. CDC participates in FEMA activities related to planning for radiation emergencies including coordinating the HHS response to review of FEMA documents relating to radiation emergencies.

D. CDC arranges for consultations between appropriate HHS components and state and local agencies and officials to help them plan for radiation emergencies in their jurisdiction.

E. CDC had the lead role for developing specific PHS response for implementation of the FRERP.

2. Emergency Response Actions

CDC has the PHS lead role to coordinate PHS response to radiological emergencies.

When notified of a radiological emergency, CDC:

A. Obtains sufficient information to allow a determination to be made of whether or not an emergency requiring HHS action exists.

B. Alerts all appropriate HHS agencies.

C. Consults with other HHS agencies to determine availability of resources required under the FRERP.

D. Requests mobilization of resources of PHS agencies.

CDC serves as the focal point for communication and coordination of information within PHS and between PHS and other Federal agencies, including designation of an on-site PHS coordinator at the scene of the emergency.

CDC develops and maintains epidemiological surveillance of populations exposed to radiological accidents and emergencies at local, state, and national levels for purposes of disease prevention.

As coordinator for PHS emergency response and liaison with FEMA, CDC consults with other HHS agencies, state and local authorities to:

A. Identify segments of the population which may be at high risk of harm from exposure (e.g., people with predisposing clinical conditions, children, pregnant women, and the elderly).

B. Arrange for collection and analysis of appropriate biological specimens.

C. Consult on recommendations for decontamination and prophylactic procedures.

NAMES AND ADDRESSES OF PARTICIPATING AGENCIES:

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LIAISON OFFICERS:

CDC: Emergency Response Coordinator
Office of the Director
Center for Environmental Health and Injury Control

FDA: Health Physicist
Office of Health Physics
Center for Devices and Radiological Health

APPROVED AND ACCEPTED FOR THE
CENTERS FOR DISEASE CONTROL:

s/ _____
Title: Associate Director for Policy Coordination
Centers for Disease Control
Date: September 10, 1992

APPROVED FOOD AND ACCEPTED FOR THE FOOD AND DRUG ADMINSITRATION:
s/ Ronald G. Chesemore
Title: Associate Commissioner for Regulatory Affairs

Food and Drug Administration

Date: September 10. 1992